Introduction to Implementation and Assessment of Safety for Risk-Informed and Performance-Based Technical Requirements in Non-Light Water Reactors

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ABSTRACT

This report, “Introduction to Implementation and Assessment of Safety for Risk-Informed and Performance-Based Technical Requirements in Non-Light Water Reactors” represents one element in the development of a framework for improving the efficiency and effectiveness of licensing of advanced non-light water reactors (non-LWRs). It is one of the products of the Licensing Modernization Project (LMP) led by Southern Company and cost-shared by the United States Department of Energy (DOE). The LMP work is expected to enable proposals for establishing licensing technical requirements to facilitate risk-informed and performance-based design and licensing of advanced non-LWRs.

The LMP objective is to assist the NRC to develop regulatory guidance for licensing advanced non-LWR plants. To this end, the LMP has submitted for endorsement a guidance document covering licensing-basis event selection, safety classification of structures, systems and components, and defense-in-depth. These constitute important sources of information regarding what performance objectives should be addressed in a license application. This report presents technical information and application examples to describe how these performance objectives may be structured and acted on to obtain risk-informed and/or performance-based outcomes. The information is primarily based on research published by the U.S. Nuclear Regulatory Commission (USNRC). It is meant to be a part of the information that supports a modern, technology-inclusive, risk-informed, and performance-based (TI-RIPB) guidance for an advanced reactor licensing structure. A key outcome of implementing the guidance would be formal conformance with definitions of risk-informed and/or performance-based activities as provided by the Commission.

EXECUTIVE SUMMARY

Introduction

This report, "Introduction to Implementation and Assessment of Safety for Risk-Informed and Performance-Based Technical Requirements in Non-Light Water Reactors" represents one element in the development of a framework for the efficient licensing of advanced non-light water reactors (non-LWRs). It is the result of a project led by Southern Company and cost-shared by the United States Department of Energy (US DOE). This Licensing Modernization Project (LMP) will result in detailed proposals for establishing appropriate technology-inclusive licensing technical requirements to facilitate efficient design and licensing of advanced non-LWRs. Such a framework enables the enhancements in safety achievable with advanced designs to be more efficiently and confidently realized. It reflects more recent states of knowledge and practices regarding safety and design innovation, creating an opportunity for reduced regulatory complexity with increased levels of safety adequacy and demonstration. The project builds on best practices as well as previous activities through NRC initiatives recorded in Commission correspondence and staff sponsored research reports for advanced reactor initiatives.

This document provides information and example applications that could lead to development and approval of formal guidance for implementing and assessing activities labeled as being risk-informed and performance-based. It is intended for use with a spectrum of advanced non-LWRs including gas-cooled reactors, molten-salt reactors and liquid-metal cooled fast reactors.

Why Use Risk-Informed and/or Performance-Based Approaches?

Risk models have demonstrated their utility for setting plant level performance targets that limit radiological releases and thereby realize reasonable assurance of adequate radiological protection. Performance targets that support realization of radiological release limits can also be set for functional objectives for a reactor such as control of criticality, assurance of heat removal capability, and retention of radioactive materials to meet safety requirements. Implementation and assessment of safety using functional objectives, with optimized allocation of performance capabilities, are essential features of a performance-based approach. Implementation and assessment go together in this endeavor because monitoring and assessing performance is a continual process to obtain the requisite levels of confidence regarding acceptable radiological outcomes. Significant improvements in efficiency and effectiveness of safety design and operation become possible with complementary application of risk-informed and/or performance-based approaches.

What is the Basis for Guidance on Risk-Informed and/or Performance-Based Approaches?

The USNRC staff has recognized that LMP's work provides useful guidance for reactor designers and the staff in the key areas of selecting and evaluating licensing basis events (LBEs), identifying safety functions and classifying structures, systems and components (SSCs), and assessing defense in depth (DID). Taken together, these activities provide essential insights for the reactor design process, define needed SSC capabilities and programmatic controls, and support documenting the safety case supporting applications for licenses, certifications, or approvals. The staff has stated that it is more appropriate to define a technology inclusive methodology for non-LWRs than to develop prescriptive guidance of the type that was developed for existing reactors. This document supports the staff's stated objectives by offering technical information that would complement LMP's White Papers on probabilistic risk assessment (PRA) methods, LBE selection, SSC classification, and DID assessment. A historical review of the developmental work that was done and published by USNRC staff is shown in the Appendix. The main body of this report offers information that complements the LMP White Papers by drawing on the developmental work to support a comprehensive RIPB methodology.

How are Risk-Informed and/or Performance-Based Approaches to be Implemented?

Implementation and assessment are part of an integrated set of activities that constitute risk-informed and/or performance-based approaches. The designer implements such an approach as part of decisions that address necessary functional characteristics of a particular technology type. Within a technology, designers make choices toward multiple objectives that may also reflect considerations such as economics and public acceptance. Maximum flexibility is afforded to the designers by providing methods that draw on the strengths of risk-informed, performance-based and appropriately integrated risk-informed and performance-based processes. The successful outcomes sought by the designer manifest in functional allocations reflected in design choices. Multi-attribute decision analysis has been shown to provide means for addressing such complex considerations. The contents of this document reflect the current state of knowledge in these areas. Collectively, these have been labelled as RIPB methods and approaches.

Technical Basis for RIPB Approaches

USNRC's "White Paper on Risk-Informed and Performance-Based Regulation"

The Commission issued SRM-SECY-98-0144, "White Paper on Risk-informed, Performance-Based Regulation" in March 1999. This White Paper provided definitions for the terms "risk-informed", "performance-based", and "risk-informed and performance-based" as applied generically across nuclear technology applications. The Commission's definitions provide the bases for identifying outcome objectives for risk-informed and performance-based approaches applied toward technology-inclusive reactor design, licensing and operation. A technique akin to formal methods is used to extract logical concepts and relationships from definitions that have standing at the same level as the USNRC's Safety Goal Policy Statement which provides the basis for the radiological risk limiting objectives of PRA applications. This helps reduce ambiguity in realizing outcomes associated with these terms.

Technical Basis for Modernized Safety and Licensing

The LMP's focus of activities on non-LWRs enable it to take advantage of the Commission's support for risk-informed and performance-based approaches and build on licensing reviews conducted previously on gas-cooled and sodium-cooled proposals. Modernization of the regulatory practice for non-LWRs enable the safety and licensing considerations to be outcome oriented. Hence, advantage can be pursued of the following statements from the White Paper:

- *"The NRC has established its regulatory requirements, in both reactor and materials applications, to ensure that "no undue risk to public health and safety" results from licensed uses of Atomic Energy Act (AEA) materials and facilities."*

- *"…the Commission is advocating certain changes to the development and implementation of its regulations through the use of risk-informed, and ultimately performance-based approaches."*

These statements have enabled the LMP to pursue modernized selection of LBEs, safety classification of SSCs and assess DID to be much more directed at answering the question, "When is enough, enough"? Additionally, what was considered as an ultimate objective of employing a performance-based approach is now entirely within the scope of the LMP submittals.

The technical basis for methods to realize the outcomes envisaged in the White Paper was developed by NRC and documented in NUREG/BR-0303, "Guidance for Performance-Based Regulation." This guidance was developed using a formal basis for definitions of key terms in the White Paper. The definition of "Performance-Based Approach" was deconstructed to extract essential and desirable attributes of a performance-based approach.

Implementation of RIPB Approaches

The US regulatory framework has enough flexibility for NRC staff to review safety information from an applicant and reach a finding regarding whether or not provisions have been made for adequate protection of health, safety, security, and the environment. The process has been found to be inefficient, and therefore unattractive to current day applicants of advanced non-LWRs. Improvements in efficiency can be made on an incremental basis such that some applicants may find aspects of the traditional approach to work for them. However, it is also possible to accomplish the desired objectives with the current state of knowledge to propose a modern risk-informed and performance-based approach. This document offers information and guidance for such an approach.

This document references guidance developed by NRC in which a hierarchical structured performance model is used with processes that execute principles and policies toward desired outcomes. Within the current state of knowledge, it is evident that success with such a structure has been achieved in operating reactors' oversight. The elements of the structure are technology inclusive. Within the hierarchy, technology and design specific information becomes pertinent several levels below the outcome where a finding of adequate protection would be considered. This document offers information and guidance on adapting this structure generically for application in a continuum of performance objectives covering design and operations.

This approach is characterized by essential and desirable attributes that could be pursued in steps that enable accomplishment of Commission approved performance objectives. This document offers information and examples of how such objectives could be realized for success within a risk-informed and performance-based approach.

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1. INTRODUCTION

1.1 Purpose

The Licensing Modernization Project (LMP), led by Southern Company and cost-shared by the US Department of Energy (DOE) and other industry participants, is proposing changes to specific elements of the current licensing framework and a set of processes for implementation of the proposals. These proposals are described in a series of papers (including this paper), which will collectively lead to modernization and adaptation of the current licensing framework to support licensing of advanced non-light-water reactors (non-LWRs). These proposals are intended to show reasonable assurance of adequate protection of nuclear safety in a more efficient and effective manner.

These proposals are also technology-inclusive, risk-informed, and performance-based (TI-RIPB). The modernized framework is technology-inclusive to accommodate the variety of technologies expected to be developed. They are risk-informed because they employ an appropriate blend of deterministic and probabilistic inputs to each decision. By maximizing the use of risk-informed, performance-based practices, these proposals are intended to create stable performance criteria and enable design and licensing efforts to be made commensurate with safety benefits. The goal is efficient and effective development, licensing, and deployment of non-LWRs on aggressive timelines with even greater margins of safety than prior generations of technology. These goals fully support and reflect DOE and USNRC visions for licensing and deploying advanced non-LWR plants.

The new framework consists of elements including establishment of TI-RIPB licensing-basis event selection; classification of structures, systems, and components (SSC); and establishment of predictable means to determine and preserve adequate defense-in-depth. These process steps are facilitated and informed by papers describing approaches and methods for: risk-informed decision-making; the conduct and application of PRA as part of the early and continuing lifecycle of new designs; and establishment of performance-based licensing criteria in lieu of LWR-centric prescriptive requirements. These elements are supported by reviews of past regulatory precedents and policies to make maximum use of existing approaches and NRC decisions, as well as assessments of current state of the art analytical tools. A gap analysis is used to determine where new or revised requirements are needed for a TI-RIPB framework and to propose changes in language or approach to allow the framework changes to be used effectively.

This report, “Introduction to Implementation and Assessment of Safety for Risk-Informed and Performance-Based Technical Requirements in Non-Light Water Reactors”, represents an element in development of a framework for the efficient licensing of advanced non-LWRs and will result in detailed proposals for establishing licensing technical requirements to facilitate efficient design and licensing of advanced non-LWRs. Such a framework acknowledges enhancements in safety achievable with advanced designs and reflects more recent states of knowledge regarding safety and design innovation, creating an opportunity for reduced regulatory complexity without diminishing levels of safety. The project builds on best practices as well as previous activities through DOE and industry-sponsored advanced reactor licensing initiatives.

This report summarizes guidance that was originally developed with regulatory activities in mind. The guidance was developed by NRC staff, subjected to public review, reviewed by the Advisory Committee for Reactor Safeguards (ACRS), provided to the Commission for information, and incorporated into rulemaking guidance. Although oriented toward regulatory functional purposes, the guidance has equal salience for design and licensing activities. The introductory aspect of the paper highlights the importance of the user having to adapt the guidance to meet a wide range of application scenarios. The introductory guidance could be applied for a spectrum of advanced non-LWRs including gas-cooled reactors, molten salt reactors, and liquid metal cooled reactors.

1.2 Objective of this Paper

The objective of this document is to provide a technology-inclusive, risk-informed and performance-based (TI-RIPB) approach for the identification and implementation of specific activities and methods that support the preparation of license applications for advanced non-LWR plants.

The paper answers the following questions:

- Why Use Risk-Informed, Performance-Based Approaches?
- What is the Basis for Guidance on Risk-Informed, Performance-Based Approaches?
- How is the Guidance on Risk-Informed, Performance-Based Approaches to be Implemented?

For reactors, risk information from a sound PRA provides the foundation for developing and implementing a performance-based approach or giving due consideration to prescriptive approaches when appropriate. Experience shows that making optimal choices between various approaches requires a sound understanding of the design and the context of particular safety issues. Structured methodology and processes have been developed and documented by NRC that can be applied in regulatory as well as safety analysis settings. This paper offers guidance that enables regulators as well as industry applicants to consider the pros and cons of strategies to set performance requirements and criteria to optimize the effectiveness benefits of risk-informed and/or performance-based approaches.

1.3 Scope

The approach described in this guidance applies to a spectrum of advanced non-LWR designs, including gas-cooled reactors, molten salt reactors, and liquid metal cooled reactors and is intended to be reactor technology inclusive. This document discusses implementation of activities and methods that result in safety criteria which focus on acceptable risks and consequences to the public, while enabling design for safe operations and providing for appropriate regulatory oversight. Risks and consequences to the worker are also important but are not within the scope of this report.

Section 2 describes the technical basis for developing and implementing the guidance offered in this document. The first part of Section 2 describes how a formal approach is taken to use the Commission's definition of risk-informed, and/or performance-based approaches to identify essential and desirable attributes. The second part of Section 2 deals with integrated decision making and the factors that are considered for informing design and operations. These include postulated events to be considered in licensing submittals, performance decisions affecting the

plant, and validating the confidence that can be ascribed to performance observations. Section 3 provides the guidance for implementing risk-informed and performance-based approaches including a stepwise process that involves putting into practice the detailed understanding of the analysts of a particular technology and design involved. It summarizes how the proposed approach for implementing and assessing the approach adopted meets the existing regulatory expectations. Section 4 works through specific examples of implementation and assessment.
The Appendix for this document provides an overview of the foundations for regulatory practice and guidance that enables NRC staff to reach a finding of conformity with appropriate regulatory requirements. Some aspects of such requirements, especially as applicable for non-LWRs, have received NRC review and assessment of DOE submittals. The NRC and ACRS reviews of that project offer lessons to be learned relative to considering application of safety analysis in a reactor technology inclusive manner.

1.4 Summary of Outcome Objectives

The LMP is seeking: (1) NRC's concurrence on the adequacy of the planned use of methods for implementing and assessing a risk-informed, performance-based approach within the context of Commission provided guidance on a results oriented framework for licensing; and (2) feedback from the NRC on any issues that have the potential to significantly impact the schedule to prepare a license application for an advanced non-LWR plant under the LMP. The proposed set of methods covers license applications for a single reactor and multi-reactor module plant.

The LMP is seeking NRC concurrence on the adequacy for licensing purposes of the following content within this introductory guidance document:

- Answer the questions: Why use risk-informed, performance-based approaches? What is the basis for guidance on risk-informed, performance-based approaches? How is the guidance on risk-informed, performance-based approaches to be implemented?
- Clarify safety implementation and analysis carried out with one or a combination of using risk-informed and/or performance-based approaches.
- Gain concurrence that Commission direction on risk-informed and/or performance-based activities have provided a sufficient basis for industry to propose and pursue combinations of appropriate approaches in specific design, operational or licensing issues related to modernization of an application under 10 CFR Part 52 so as to build and operate a non-LWR.
- Gain concurrence that a set of formal methods that currently exist in NRC documents are a sufficient basis to proceed with implementing Commission direction flowing from Direction Setting Iissue-12 (Risk-Informed, Performance-Based Regulation) of the Strategic Assessment and Rebaselining activity carried out during the late 1990s.
- Gain concurrence that the relationship between outcomes and performance is inherently hierarchical as explained in Section 2. Hence, with a focus on outcomes, for the domain of reactor safety, the structure developed for the Reactor Oversight Process (ROP) has the necessary characteristics to support the goal of reaching a finding of adequate safety.

This document supports these outcome objectives with a focus on the activities that will inevitably involve combinations and permutations of risk-informed and/or performance-based approaches. There is no intent to diminish the relevance or significance of any of the approaches. However, there is an aspiration to advance the cause of achieving a coherent, holistic, risk-informed, and performance-based reactor licensing structure by noting the completeness of existing guidance relative to such approaches. This effort should support the stated goal of the NRC to develop such a regulatory structure for design, licensing, and oversight of advanced non-LWRs. This document also offers specific examples of implementation and assessment of the approaches where features of the methodology finds greater elaboration.

1.5 Relationship to Other LMP Pre-Licensing Topics/Papers

This document is one of several papers covering key regulatory issues that are being prepared and submitted for NRC review and comment as part of the LMP licensing strategy. Some of these other papers have bearing on the development of the methodology for selecting specific performance factors or may rely on the principles, structure, process or methods outlined in this document. The papers that have the most direct relationship with this paper include:

- LMP LBE Selection Approach
- LMP SSC Safety Classification Approach
- LMP Defense-in-Depth Approach
- LMP Risk-Informed Performance-Based Guidance for Non-LWR Licensing Basis Development (NEI 18-04)

2. TECHNICAL BASIS FOR RISK-INFORMED AND PERFORMANCE-BASED APPROACHES

2.1 Technical Basis for Risk-Informed and Performance-Based Outcomes

The Commission issued the "White Paper on Risk-Informed and Performance-Based Regulation" in March 1999 as SRM to SECY-1998-0144. It defined the terms and Commission expectations for RIPB regulations. It addressed separately the generic meanings of and expectations for the terms "risk-informed", "performance-based" and "risk-informed and performance-based." Given the role that the Commission plays in setting the safety agenda for nuclear technology, Commission expectations sometimes become outcome objectives for the processes implemented by industry for licensing purposes. Hence, industry's efforts in non-LWR designs can also take different approaches with different combinations of "risk-informed", or "performance-based". The optimal approach is an integrated one and "risk-informed and performance-based" best characterizes it.

The LMP's guidance to potential applicants for non-LWRs becomes a vehicle to communicate Commission expectations in the development and presentation of a safety case so as to increase the confidence that it passes regulatory muster. The Commission's expectations articulated in the White Paper have been pursued by NRC staff in a multitude of settings most notably in the Reactor Oversight Process (ROP). The Appendix of this document records much of the historical background and also summarizes significant research work sponsored by the NRC to support Commission expectations. The overall result points to a conclusion that, depending on the context, "risk-informed", "performance-based" and "risk-informed and performance-based" objectives can be pursued separately or in an integrated manner.

The desired outcome objectives of risk-informed and performance-based methods as formally articulated in the White Paper states that such methods

"…enable risk insights, engineering analysis and judgment including the principle of defense-in-depth and the incorporation of safety margins, and performance history to be used to:

1. *focus attention on the most important activities,*
2. *establish objective criteria for evaluating performance,*
3. *develop measurable or calculable parameters for monitoring system and licensee performance,*
4. *provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and*
5. *focus on the results as the primary basis for regulatory decision making."*

The LMP's guidance to potential applicants demonstrates how these outcomes can be realized in a technology-inclusive manner. The risk insights from a PRA form the basis for identifying and setting up design decisions regarding anticipated operational occurrences, design basis events and beyond-design basis events. Judgements regarding where the most conservative safety margins are to be applied (for safety related SSCs) are developed from a systematically implemented process rather than with ad hoc methods. It becomes possible to actually confirm on an ongoing basis a system's capability, reliability and availability in a more direct fashion. This enables evidence-based decision-making regarding fulfillment of design objectives. When requirements are imposed for special treatments, testing, inspection or limiting conditions of operation, results of observations would be available to justify effectiveness of safety decisions. In this manner there is convergence between the interests of regulatory decision-making with those of the designer and operator.

The LMP guidance on defense in depth addresses how evaluations and assessments of this important safety consideration can focus on greater effectiveness of RIPB outcomes. Achievement of adequate defense-in-depth occurs when designers, license applicants, regulators, etc. make clear and consistent decisions as an integral part of the overall design process. Adequacy is evaluated by using information regarding design, plant risk assessment, selection and evaluation of licensing basis events, safety classification of SSCs, specification of performance requirements for SSCs, and programs to ensure these performance requirements are maintained throughout the life of the plant. Completeness is reached when the recurring evaluation of plant capability and programmatic capability associated with design and PRA update cycles no longer identifies risk-significant vulnerabilities where potential compensatory actions can make a practical, significant improvement to the risk profiles or risk significant reductions in the level of uncertainty in characterizing the event frequencies and consequences.

All these factors can be considered when evaluating whether observed outcomes show evidence for the following attributes associated with RIPB outcomes:

1. Whether attention is focused on the most important activities;
2. Whether objective criteria have been established for evaluating performance;
3. Whether parameters have been developed to monitor system and organizational performance;
4. Whether flexibility exists to meet established criteria in a way to encourage and reward improved outcomes (appropriate incentivization);
5. Whether safety decisions are based on results.

These factors are amenable to application of risk insights, engineering analysis and judgements. Conclusions reached through examination of such factors constitute successful achievement of the Commission's expectations. The most direct indication of the expectations regarding defense-in-depth states:

"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."

LMP's guidance to applicants describe processes that result in information that is foundational to the construction of a safety case that addresses a particular technology and within it a specific design. The presentation of this information to the regulator would be based on the appropriate format and content guidance. Hence, the adequacy of the elements of defense can be addressed specifically and more objectively to support a safety case that asserts that the defense-in-depth capabilities and programs have achieved sufficiency.

2.2 Technical Basis for Performance-Based Outcomes

The Commission's expectation for modernization of safety as articulated in the White Paper envisions stages of development with achievement of performance-based methodology being the successful end state. This is evident from the following statements in the White Paper:

- *"The NRC has established its regulatory requirements, in both reactor and materials applications, to ensure that "no undue risk to public health and safety" results from licensed uses of Atomic Energy Act (AEA) materials and facilities."*
- *"…the Commission is advocating certain changes to the development and implementation of its regulations through the use of risk-informed, and ultimately performance-based approaches."*

The changes that the Commission advocated have been evolving over the time since the above statements were published. The ultimate objective of a performance-based design and regulatory review is now possible using the guidance in this document.

Application of a performance-based approach to the implementation of existing regulations can provide significant benefits as recognized by the Commission. An example of how the LMP's guidance document takes advantage of this policy provision is shown by the manner in which LMP addresses the single-failure criterion. In LWR regulatory practice, lack of compliance with the single-failure criterion (SFC) has often required a regulatory exemption or a license amendment, both of which could be expensive. The possibility of an alternative approach toward SFC has been studied and documented in SECY-05-0138, "Risk-Informed and Performance-Based Alternatives to the Single-Failure Criterion."

The alternative approaches to SFC is an example of choices that a designer could face regarding implementation of safety employing either a prescriptive or performance-based approach. NRC developed NUREG/BR-0303, "Guidance for Performance-Based Regulation" to systematically explore the merits of both approaches for the range of regulatory applications that are within the NRC's responsibility. The complexity of issues raised in reactor design are addressed in NUREG/BR-0303 using a structured performance model called an objectives hierarchy. The example objectives hierarchy described in NUREG/BR-0303 is based on the NRC's Reactor Oversight Process. Since then an alternative structured performance model has been proposed in NRC's work on functional containment (SECY-18-0096).

Commission expectations regarding implementation of a performance-based approach have taken account of the tension that can sometimes occur between compliance with prescriptive factors and accomplishment of performance objectives. The Commission directly addressed this issue in "Staff Requirements **-** COMSAJ-97-008 – Discussion on Safety and Compliance." The following statements occur in this document:

- *In the context of risk-informed regulation, compliance plays a very important role in ensuring that key assumptions used in underlying risk and engineering analyses remain valid."*
- *When non-compliances occur, the NRC must evaluate the degree of risk posed by that non-compliance to determine if specific immediate action is required.*
- *…in determining the appropriate action to be taken, the NRC must evaluate the non-compliance both in terms of its direct safety and regulatory significance and by assessing whether it is part of a pattern of non-compliance (i.e. the degree of pervasiveness) that can lead to the determination that licensee control processes are no longer adequate to ensure protection of the public health and safety.*

The importance assigned to ensuring the validity of key assumptions used in the underlying risk and engineering analyses, as well as the risk significance of non-compliances requiring specific immediate action are important to the processes described in the LMP guidance document. Additionally, the importance of programmatic controls for defense-in-depth adequacy has been pointed out in the LMP guidance. These factors identified in COMSAJ-97-008 need to be implemented in a performance-based fashion if the imposition of prescriptive requirements and a compliance-based enforcement approach is to be avoided. However, it should be noted that a performance-based approach does not proscribe prescriptive criteria. Within a performance-based approach, prescriptive criteria to ensure validity of assumptions would be entirely appropriate. Experience has shown that such a necessity often arises at the component levels rather than at the functional level.

The technical basis for methods to realize the outcomes envisaged in the White Paper is documented in NUREG/BR-0303, "Guidance for Performance-Based Regulation." This guidance was developed using a formal basis for definitions of key terms in the White Paper. The definition of "Performance-Based Approach" was deconstructed to extract essential and desirable attributes of a performance-based approach. The definition provided by the Commission is as follows:

"A regulation can be either prescriptive or performance-based. A prescriptive requirement specifies particular features, actions, or programmatic elements to be included in the design or process, as the means for achieving a desired objective. A performance-based requirement relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, but provides more flexibility to the licensee as to the means of meeting those outcomes. A performance-based regulatory approach is one that establishes performance and results as the primary basis for regulatory decision-making, and incorporates the following attributes:

(1) measurable (or calculable) parameters (i.e., direct measurement of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) exist to monitor system, including facility and licensee performance,

(2) objective criteria to assess performance are established based on risk insights, deterministic analyses and/or performance history,

(3) licensees have flexibility to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes; and

(4) a framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern.

….

….

As applied to inspection, a performance-based approach tends to emphasize results (e.g., can the pump perform its intended function?) over process and method (e.g., was the maintenance technician trained?). Note that a performance-based approach to inspection does not supplant or displace the need for compliance with NRC requirements, nor does it displace the need for enforcement action, as appropriate, when non- compliance occurs.

As applied to licensee assessment, a performance-based approach focuses on a licensee's actual performance results (i.e., desired outcomes), rather than on products (i.e., outputs). In the broadest sense, the desired outcome of a performance-based approach to regulatory oversight will be to focus more attention and NRC resources on those licensees whose performance is declining or less than satisfactory."

The LMP is proposing implementation of performance-based approaches in certain contexts as part of an integrated approach to risk-informed and performance-based methods in the manner envisioned by the White Paper. Key concepts focusing on the performance-based approach are summarized below in Table 1.

Table 1. Essential and Desirable Attributes of a Performance-Based Approach

Item #	Verbatim Extract from White Paper Definition	Interpretation for Application	Comments
1	*A regulation can be either prescriptive or performance-based.*	Any element of a safety specification can be chosen with characteristics that are prescriptive or performance-based or blended suitably.	NRC's guidance for rulemaking, NUREG/BR-0058, "Regulatory Analysis Guidelines" provides explanation
2	*A prescriptive requirement specifies features, actions, or programmatic elements to be included in the design or process, as the means for achieving a desired objective.*	Prescriptive requirements specify means to achieve objectives. They now exist pervasively in design and operations. Also, they may occur at any level in a hierarchy that may include features of a design to those that address programmatic elements in operations.	See Section 2, "Licensing Basis Development Process" of LMP Guidance Document.
3	*A performance-based requirement relies upon measurable (or calculable) outcomes (i.e., performance results) to be met,*	An essential goal of a performance-based requirement is that it relies on outcomes as defining success or failure of an activity. The outcome is met through performance results that are measurable, calculable or observable.	Application of deconstruction.
4	*…but provides more flexibility to the licensee as to the means of meeting those outcomes.*	Another essential goal is flexibility to licensees regarding means to achieve outcomes.	

5	*A performance-based regulatory approach is one that establishes performance and results as the primary basis for regulatory decision-making,…*	A regulatory approach is associated with NRC staff practice. A designer's safety implementation approach frequently emulates the regulatory approach. The performance-based part of it focuses on decision-making. The staff's decision making process, that it is performance-based, should be based on performance and results.	This is an example of where outside stakeholders can act to ensure that staff practice is consistent with Commission direction.
6	*…and incorporates the following attributes:*	What follows define the essential attributes of a performance-based safety approach.	
7	*…(1) measurable (or calculable) parameters (i.e., direct measurement of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) exist to monitor system, including facility and licensee, performance,*	<u>Essential Attribute #1:</u> Parameters exist, or are identified and developed, that serve the function of providing a direct measure of performance. Taking the measure of performance includes parameters that assess facility (SSCs, etc.) as well as the licensee (organizational, human factors, etc.) performance.	On the basis of NUREG/BR-0303, parameters may include those that are qualitative. It is still required that they be a direct measure of performance at the hierarchical level.
8	*…(2) objective criteria to assess performance are established based on risk insights, deterministic analyses and/or performance history,…*	<u>Essential Attribute #2:</u> The parameters that are identified and/or developed are considered in the context of risk insights from a PRA or within a deterministic framework to come up with criteria for what constitutes acceptable or unacceptable performance. Good engineering practice dictates that performance history would be used as appropriate.	
9	*…(3) licensees have flexibility to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes;…*	<u>Essential Attribute #3:</u> Licensees (plant operators) must have flexibility regarding how performance criteria are met. This provides a feedback loop into whether the appropriate performance parameters were chosen because of the direct relationship to outcomes. <u>Desirable Attribute #1:</u> Performance parameters and criteria are chosen to incentivize improved outcomes.	

10	*…and (4) a framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern.*	<u>Essential Attribute #4:</u> Violation of a lower level performance criterion, in and of itself, must not result in nonconformance with a designer's higher level safety criterion. This condition requires a margin between performance and the safety criteria. <u>Desirable Attribute #2:</u> Persistent violation of the performance criterion could reduce the margin to zero. The time for this to occur is the temporal margin within a performance-based system.	NUREG/BR-0303 defines safety margin formally as the difference between a capacity function and a challenge function so that EA#4 can be rigorously applied.
11	*As applied to inspection, a performance-based approach tends to emphasize results (e.g., can the pump perform its intended function?) over process and method (e.g., was the maintenance technician trained?).*	<u>Desirable Attribute #3</u> In a performance-based approach the inspection and enforcement processes should focus more on fitness-for-purpose and fitness-for-service rather than compliance alone. Observations of performance should be used to identify and correct licensee organizational performance weaknesses.	The Commission issued a directive to the staff on "Safety and Compliance". (see Attachment COMSAJ-97-008) that is part of the White Paper's background.
12	*As applied to licensee assessment, a performance-based approach focuses on a licensee's actual performance results (i.e., desired outcomes), rather than on products (i.e., outputs). In the broadest sense, the desired outcome of a performance-based approach to regulatory oversight will be to focus more attention and NRC resources on those licensees whose performance is declining or less than satisfactory.*	<u>Desirable Attribute #4:</u> Assessment of performance within a performance-based system makes a distinction between production of a product (i.e. output) and the higher-level success parameters related more directly to the desired outcomes. The safety focus should be on the trending of observations related to outcomes as contrasted with outputs. The significance of this attribute is that it integrates design and operational performance. Design tends to emphasize products of deterministic calculations. Operational observations are more amenable to risk-informed interpretation. Hence, this performance-based attribute is of more significance to new technologies.	Parameters associated with performance of components tend to support conclusions regarding basic elements of a system. Observations of these would generally be classified as outputs. Outcomes tend to be associated with higher level observations at the system, functional or train level which tend to include qualitative aspects.

Technical Basis as Logical Elaboration of Essential and Desirable Attributes

<u>Essential Attribute #1:</u> *Parameters exist, or are identified and developed, that serve the function of providing a direct measure of performance. Taking the measure of performance includes parameters that assess facility (SSCs, etc.) as well as the licensee (organizational, human factors, etc.) performance.*

Establishing performance assessment parameters is a significant challenge. The notion of performance, when applied to elements beyond components such as pumps and valves, can have considerable subjectivity associated with it. Unless the subjectivity is recognized from the outset, proposals for performance assessment parameters can become controversial and become distractions. A current example of such challenges is identification of appropriate parameters for passive systems. The most suitable parameters are likely to be combinations of quantitative and qualitative parameters that are most appropriate for particular applications. As the purpose of identifying parameters is to take the measure of performance, it is equally important to consider how gradations of performance will be recorded as part of performance monitoring.

In general, parameters may be quantitative or qualitative, with quantitative parameters being usually preferred. Among quantitative parameters are those that can be observed directly, such as pressure, temperature, incurred cost, and radiation exposure. These are called natural measures. Some quantitative measures require a simple calculation, such as reliability, percentage, and concentration. Other quantitative measures may require more complex calculations, such as subcooling margin, which requires combining temperature and pressure parameters. Event sequence frequency is also an example of a calculable measure.

Qualitative parameters are of value because they could be more efficient, are readily available, and are widely used as measures of performance. Their use could promote efficient communication to non-technical people. An example of a qualitative parameter that could have safety significance is the quality of the housekeeping in a facility, which affects the likelihood of fire initiation. Such an observable characteristic may be extremely difficult to quantify yet may be quite amenable to objective assessment through observation within a linguistically defined measure that expresses the level of impact or significance. These are termed constructed measures, and the actual categories created linguistically are a constructed scale. For example, the fire potential from housekeeping factors can be categorized as high, medium, or low. Hence, a performance-based approach insists on observable parameters.

The parameters identified or developed for Essential Attribute #1 can be formulated using the following measures:

- Natural measures that have a direct and quantifiable relationship to a performance objective.
- Constructed measures that are associated with performance objectives at higher levels of an objectives' hierarchy. The scales of performance may need to be developed through application of value judgements. Constructed measures are generally characterized by descriptive statements of specific attributes that are presented in a graded manner. A special case of a constructed measure is a binary measure that represents a "true" or "false" judgment on a hypothesis;
- Proxy measures, which support certain higher-level performance objectives, but typically in some partial or indirect way. They may correspond directly to lower level objectives through natural measures, and thereby reflect some, but typically not all, of the considerations associated with the desired outcome. The metric of CDF for LWRs is an example of a proxy measure.

Natural measures (ones that directly quantify performance with respect to an objective) are desirable but, in general, can be difficult to find for safety performance with respect to severe or catastrophic events that fall in the category of residual risk. As a practical matter, metrics are frequently constructed. In general, this is an area where expert judgement is employed. The application of constructed and/or proxy measures will need to be done by qualified persons to be reasonably unambiguous.

Essential Attribute #2: The parameters that are identified and/or developed are considered in the context of risk insights from a PRA or within a deterministic framework to come up with criteria for what constitutes acceptable or unacceptable performance. Good engineering practice dictates that performance history would be used as appropriate.

The prime example of this Essential Attribute for non-LWRs are the risk significance metrics proposed by LMP. They constitute a combination of natural, constructed and proxy measures. The proxy measures are useful in dealing with incorporating defense-in-depth into a performance-based safety system. For example, an objective measure for risk significance relative to beyond-design-basis events would be important for establishing a performance-based criterion for "When is enough, enough?" This type of consideration is an example of integrated decision-making addressed in NRC regulatory practice where flexibility is offered with respect to licensing basis changes.

Essential Attribute #3: Licensees (plant operators) must have flexibility regarding how performance criteria are met. This provides a feedback loop into whether the appropriate performance parameters were chosen because of the direct relationship to outcomes.

The general principle that governs decision making relative to this attribute is that the degree of flexibility is directly proportional to the magnitude and confidence in the safety margin. Related to this is the consideration of uncertainty and variability in the region of the acceptance criterion. The term "robustness" is usually associated with reaching conclusions around the region where acceptability becomes an issue.

The structure of an objectives hierarchy generally offers considerable flexibility toward achieving desired outcomes. In the ROP structure, to monitor and measure plant performance, the oversight process focuses on seven "cornerstones" that support the safety of plant operations in the three key areas of reactor safety, radiation safety and safeguards. The elements of this structure are technology inclusive. The "cornerstones" directly account for success in the outcome of "Public Health and Safety as a Result of Civilian Nuclear Reactor Operations". A non-LWR license application would have as its goal achieving this outcome.

Associated with reactor safety are the following four "cornerstones":

1. **Initiating Events:** Any potential occurrence that could disrupt plant operations and challenge safety functions is an initiating event. This cornerstone focuses on limiting the occurrence of these type of events. The LMP's consideration of licensing-basis events is analogous to this cornerstone. However, in the LMP each sequence is considered in its entirety. A performance metric in LMP is that, for high-frequency, low-consequence events, the total frequency of exceeding a site boundary dose of 100 mrem from all sequences not exceed 1/plant-year. The

value of 100 millirem is selected from the annual exposure limits in 10 CFR Part 20.

2. **Mitigating Systems:** These are safety systems designed into each plant that alleviate the effects of event sequences. Mitigating systems can prevent an accident or reduce the consequences of a possible accident. This cornerstone monitors the function of these safety systems through periodic testing and actual performance. In LMP, these are related to the mitigating functions associated with component level performance as modeled in the PRA.
3. **Barrier Integrity:** In the LMP, this cornerstone is part of the consideration of the layers of defense. The designer includes within the consideration of layers of defense physical barriers to show that radioactive materials are retained within the facility with a high degree of confidence. Such an approach requires information provided by a PRA to identify challenges to the physical barriers and evaluate dependencies among the physical barriers. The structured performance model, such as that described SECY-18-0096, "Functional Containment Performance Criteria for Non-Light-Water-Reactors", should reflect the systems, inherent characteristics, and the designed limitations to public health hazard expected of some non-LWR designs.
4. **Emergency Preparedness:** Each nuclear plant is required to have comprehensive emergency plans to effectively respond to a possible accident. The LMP considerations of this performance factor are described under evaluation of defense-in-depth. This cornerstone measures the effectiveness of the plant staff in carrying out emergency plans. Such emergency plans are tested involving plant staff as well as local, State, and, in some cases, Federal agencies.

In the LMP guidance, the performance criteria associated with event sequences are based on a combination of natural, calculable, constructed and proxy measures. The criteria associated with 10 CFR Part 20 are natural measures involving data collected during normal operations and can be subjected to the Commissions performance-based outcome attributes analysis. The average individual risk of early fatality within 1 mile of the Exclusion Area Boundary is a calculable measure using the Commission's quantitative health objective as a proxy.

<u>*Essential Attribute #4:*</u> *Violation of a lower level performance criterion, in and of itself, must not result in nonconformance with a designer's higher-level safety criterion. This condition requires a margin between performance and the safety criteria.*

The term "margin" is employed in NUREG/BR-0303 to enable integrating the results of implementing Essential Requirements # 1, 2, 3 to assure flexibility as a defining characteristic of performance-based safety. The significance of "margin" is closely associated with the factor performance parameters, objective criteria, and flexibility. If the magnitude of the safety margin is sufficient to support a performance-based approach, it can, in concept, be subdivided and apportioned in such a way as to consider the objectives of different stakeholders. On matters of design, the applicant and the NRC are the principal stakeholders. The allocation of margins may be apportioned to support compliance-based safety (which may be of interest to the regulator) or operational efficiency and stability (which may be of interest to applicants and operators). Hence, as a qualitative and conservative interpretation, and for ease of practical application, the term "concern" has been associated with high-level safety criteria.

In terms of relative importance, the guideline concerned with performance failure leading to an immediate safety concern is pre-eminent. Because regulatory criteria are generally set conservatively, defining performance criteria relative to regulatory criteria assures favorable regulatory consideration. Generally, adequate safety is associated with criteria within the design basis range. However, it must be recognized that some regulatory criteria occur outside of the design basis. A performance-based requirement is justified only if assurance exists that adequate safety margins can be preserved to meet regulatory needs. A safety margin is adequate for this purpose when, if there is a failure to meet the performance objective, sufficient time will be available to take corrective action to avoid a more serious condition associated with a safety concern. The importance of safety margin considerations justifies placing this attribute at a high priority.

A framework that incorporates a performance criterion which enables avoiding a safety concern implies that performance is directed at maintaining a safety margin. This is a key concept of a performance-based approach to safety. Hence, a performance-based framework contains the concept of "margin," which in this construct is a quantity that expresses the difference between performance within the limits of a "criterion" and performance that is representative of a "concern." The word "immediate" requires that a time element be considered in the development of a performance-based approach. The guidelines in NUREG/BR-0303 incorporate this understanding. They are also consistent with a responsibility to monitor potential erosion of margin, as well as responsibility for prompt corrective actions. In developing NUREG/BR-0303, these interpretations were discussed with the public and later presented to the Commission which assures that the guidance in this document would offer confidence regarding regulatory review.

The above analysis of the term "margin" leads to a further, more precise identification of its characteristics. Safety margin can be divided into two parts, physical and temporal. Physical margin is the difference between two physical conditions, the first of which represents expected conditions and the second of which represents a performance-limiting condition. An example of a performance-limiting condition is the peak pressure capability of a pressure vessel. Physical margin in a pressure boundary is the difference between the pressure retaining capability of the vessel and the expected maximum pressure during an accident condition. Here, distinctions can be made between a margin that is evaluated deterministically using allowable stress levels within the vessel wall, and a probabilistic evaluation that considers actual vessel breach. This perspective on "margin" can be generalized to define it as the difference between two system states. The analytical prediction of the conditions under design basis challenge defines the predicted system state during a design basis accident. The verified and validated response state of the system under design-basis conditions represents the conditions from which a margin is estimated.

A temporal margin represents the time available to identify a concern (exceedance of allowable pressure, for example) and the time to take actions, such as restoring a failed safety function, implementing a corrective action program, or initiating a regulatory response that mitigates the concern. A temporal margin in a spent-fuel pool, for example, could be the difference in time between when the temperature of the pool water is detected to be at some elevated level (caused by loss of cooling) and the time needed to reach the boiling point of the water. Again, a temporal margin could be expressed probabilistically as the time to evaporate the amount of water to expose the heat source to air, which would provide a larger estimate of margin compared to observation of the elevated temperature condition and the boiling point of water.

<u>Desirable Attribute #1:</u> Performance parameters and criteria are chosen to incentivize improved outcomes.

The safety basis for providing flexibility in a regulatory framework is that licensees would be empowered to improve safety. There is considerable evidence for this expectation from the operating history of the existing fleet of reactors in the US. Additionally, there has been a perception for some time that a prescription-based regulatory system generates perverse incentives. An example offered in NUREG/BR-0303 is when licensees, faced with the approach of the end of an allowable outage time for a safety system maintenance feel forced into actions that may meet compliance standards but are not fully supportive of safety. Such an approach can result in such an emphasis on compliance that safety may be adversely affected. This is sometimes expressed as a trade-off between availability and reliability. In general, it could happen when a rigid focus on compliance with a low-level criterion causes a decrease in safety margin at a higher level. The Commission's issuance of COMSAJ-97-008 offers a basis for alleviating such concerns.

<u>Desirable Attribute #2:</u> Persistent violation of the performance criterion could reduce the margin to zero. The time for this to occur is the temporal margin within a performance-based system.

Performance monitoring is a key aspect of a performance-based system. Adoption of this approach through the ROP structure is considered as a major step toward regulatory modernization. In the LMP guidance, existence of a temporal margin for performance factors under programmatic defense-in-depth allows the designer, operator and regulator to address cross-cutting issues as follows:

- **Human Performance:** This area monitors the licensee's decision making process, availability and adequacy of resources to ensure nuclear safety, coordination of work activities, and personnel work practices.
- **Problem Identification and Resolution:** This area monitors the licensee's corrective action and operating experience programs, and the licensee's self- and independent-assessments.
- **Safety-Conscious Work Environment:** This area monitors an environment in which workers feel free to raise nuclear safety concerns without fear of harassment, intimidation, retaliation, or discrimination.

The proper estimation and use of temporal margins also enable formulation of strategies to deal with beyond design basis events. Such strategies could be considered a part of implementing programmatic defense-in-depth to deploy plant capabilities that may not have been incorporated formally into plant procedures. Examples of such considerations relative to operating reactors can be found among the performance factors instituted as post-Fukushima strategies.

<u>Desirable Attribute #3:</u> In a performance-based approach the inspection and enforcement processes should focus more on fitness-for-purpose and fitness-for-service rather than compliance alone. Observations of performance should be used to identify and correct licensee organizational performance weaknesses.

As described earlier, COMSAJ-97-008 offers a basis for focusing on the desired outcomes of accomplishing functional success in safety systems. Hence, in a RIPB approach, a focus on fitness-for-purpose and fitness-for-service would ensure that key assumptions used in the PRA model are valid when it is being employed in a risk-informed decision making effort. The same principle applies even if the engineering analysis is of a deterministic nature.

Regulatory practice that focuses on safe outcomes rather than compliance have often been portrayed with pejorative connotations. In a performance-based system, the licensee would have the ability to present arguments as part of a safety case that recognizes the magnitude of available margins (if they exist and can be proven) with no negative connotations.

<u>*Desirable Attribute #4:*</u> *Assessment of performance within a performance-based system makes a distinction between production of a product (i.e. output) and the higher-level success parameters related more directly to the desired outcomes. The safety focus should be on the trending of observations related to outcomes as contrasted with outputs.*

The significance of this attribute is associated with data generated as part of the monitoring aspect of a performance-based system. Often the quality of a monitoring activity is gaged by the number of data points collected or the frequency of data collection. However, unless a constant effort is made to understand the significance of the collected data relative to the desired outcome, the value of the data collection effort may be suspect. Frequently, significance becomes evident only when data streams are put together in an integrated decision making framework such that information is revealed that would be otherwise lost. Thus, a monitoring activity can be effective only if proper observation techniques and trending are incorporated into an integrated safety decision making system.

A Proposed Performance-Based Score

The need to find alternatives to regulatory prescriptiveness is long-standing and currently finds expression in “performance-based” approaches used as a term of art. As discussed in the Appendix, the Government Performance and Results Act of 1993 (P.L. 103-62), was intended to bring about a fundamental transformation in the way government programs and operations are managed and administered. Mission statements covering major functions and operations of an agency were to be articulated that would be the basis for developing general goals and objectives, including outcome-related goals and objectives, for the major functions and operations. It called for a hierarchical structure to address challenges in performance goals to be included in performance plans which were required to relate to the general goals and objectives in the higher-level strategic plan.

NRC’s efforts at regulatory improvement using an outcome-oriented approach with the Maintenance Rule predated GPRA and indicated a need for establishing a common understanding of key terms. The Commission tackled this issue head on with the White Paper on “Risk-Informed and Performance-Based Regulation” (SRM to SECY-1998-0144). Given the importance that the regulatory function plays in standardizing the use of terminology, this action was a key landmark in modernizing the assessment and implementation of safety. As a Commission level document, it had the authority to be useful to the whole nuclear technology technical community.

The long-term usefulness of the Commission's White Paper depends on the technical community implementing nuclear technology employing the definitions so that it gains currency within the industrial culture. The term "performance-based" is used quite often without anchoring it to a definition. This can become a disservice to the aspirations of federal initiatives such as the implementation of OMB Circular A-119 as described in the Appendix.

To address this issue, and stay consistent with the spirit of modernization, a process is proposed to employ constructed measures to serve as numerical figures of merit as indicators of how well a performance-based initiative reflects the Commission's White Paper. This is shown in Table 2.

Table 2. Performance-Based Scoring

Attribute	Considerations	Score
<u>*Essential Attribute #1:*</u> *Parameters exist, or are identified and developed, that serve the function of providing a direct measure of performance. Taking the measure of performance includes parameters that assess facility (SSCs, etc.) as well as the licensee (organizational, human factors, etc.) performance*	• Examine the monitoring of performance at each of the hierarchical levels. • Examine the nature of how observations are recorded • Identify what type of measures (natural, constructed, proxy) works best at each level	Maximum Score=20 points
<u>*Essential Attribute #2:*</u> *The parameters that are identified and/or developed are considered in the context of risk insights from a PRA or within a deterministic framework to come up with criteria for what constitutes acceptable or unacceptable performance. Good engineering practice dictates that performance history would be used as appropriate.*	• Examine the performance history for the parameters within and outside nuclear technology • Examine whether the observed parameter has a reasonably smooth variation around the acceptance criterion • Examine temporal aspects such as leading or lagging indication	Maximum Score=20 points
<u>*Essential Attribute #3:*</u> *Licensees (plant operators) must have flexibility regarding how performance criteria are met. This provides a feedback loop into whether the appropriate performance parameters were chosen because of the direct relationship to outcomes.*	• Can proportionality between safety margin and flexibility be established? • What are the consequences of a wrong flexibility decision at each level? • At each level, what is the safety significance of error in safety margin assessment?	Maximum Score=20 points
<u>*Essential Attribute #4:*</u> *Violation of a lower level performance criterion, in and of itself, must not result in nonconformance with a designer's higher level safety criterion. This condition requires a margin between the performance and the safety criteria.*	• A key consideration that may or may not be related to safety significance relates to applicable regulatory criteria and compliance therewith. • What are the safety considerations related to physical and temporal margins and flexibility?	Maximum Score=20 points
<u>*Desirable Attribute #1:*</u> *Performance parameters and criteria are chosen to incentivize improved outcomes.*	• At each level are there, and if so, how significant are perverse incentives? • If errors occur in incentives, what are the impacts on Essential Attributes # 3 and 4?	Maximum Score=5 points

<u>Desirable Attribute #2:</u> Persistent violation of the performance criterion could reduce the margin to zero. The time for this to occur is the temporal margin within a performance-based system.	• How does the performance monitoring system react to persistent misuse of flexibility? • What is the safety significance of persistent violation of acceptance criteria?	Maximum Score=5 points
<u>Desirable Attribute #3</u> In a performance-based approach the inspection and enforcement processes should focus more on fitness-for-purpose and fitness-for-service rather than compliance alone. Observations of performance should be used to identify and correct licensee organizational performance weaknesses.	• What are the consequences of strict compliance with criteria, or lack thereof? • At what level in the hierarchy does non-compliance make it impossible to meet outcome objectives? • Are organizational factors geared for correcting non-compliance in a timely fashion?	Maximum Score=5 points
<u>Desirable Attribute #4:</u> Assessment of performance within a performance-based system makes a distinction between production of a product (i.e. output) and the higher-level success parameters related more directly to the desired outcomes. The safety focus should be on the trending of observations related to outcomes as contrasted with outputs.	• Is the performance monitoring system designed for and capable of reacting appropriately to trends in observations? • What is the relationship between the incentive structure and observation trends? • At what level in the hierarchy does adverse relationship between safety, compliance and trending data jeopardize outcome objectives?	Maximum Score=5 points

The proposed Performance-Based Score system provides a 100-point scale to make judgements on how well a system designed for implementing a performance-based approach does or could work. Such a system could be helpful to managers and key stakeholders to make decisions regarding merits of resource allocation and organizational behavior.

2.3 Technical Basis for Integrated Outcomes

The relationship between outcomes and performance is inherently hierarchical because outcomes have complex characteristics that reflect performance over a wide range, and performance reflects activities directed at purposes that mediate over different levels. For example, designers of advanced non-LWRs might seek to achieve outcomes that optimize safety, economics, and public acceptance. A common framework does not currently exist to rationalize safety, licensing, economic, and product delivery objectives to organize a project reflecting such complexity. Experience with nuclear technology shows that a generic framework constructed to address such outcomes necessarily needs to be risk-informed and performance-based.

NURG/BR-0303 envisions a hierarchical structure with processes that execute principles and policies toward an outcome that could be characterized as a performance-based approach. A hierarchy is an abstract organizational model of inter-level relationships among entities. Hierarchies are useful for organizing and manipulating domain knowledge. A hierarchy is not a natural object but a conceptual construct. As a general matter, decomposing an outcome into supporting performance objectives arranged in a hierarchical structure can be done in multiple ways. A hierarchy can be made as rigorous and exhaustive as required by the contribution of the knowledge domain to the outcome. For example, separate hierarchies may be proposed for safety, licensing and economics related to a particular technology.

For the domain of reactor safety, the structure developed for the Reactor Oversight Process has all the necessary characteristics to support the goal of reaching a finding of adequate safety, if the appropriate information is provided. The top level mission objective for the ROP framework is "Protect Public Health and Safety in the Use of Nuclear Power". Experience with the structure shows that the process derived from it has been a success with operating reactors even though the structural elements are technology inclusive.

The framework for the ROP was set up showing the relationship between the NRC's overall safety mission, strategic performance areas, and cornerstones of safety. The cornerstones of safety were chosen to: (1) limit the frequency of initiating events; (2) ensure the availability, reliability, and capability of mitigating systems; (3) ensure the integrity of barriers to radiological exposure; (4) ensure the adequacy of the emergency preparedness functions; (5) protect the public from exposure to radioactive material releases; (6) protect nuclear plant workers from exposure to radiation; and (7) provide assurance that the physical protection system can protect against the design basis threat of radiological sabotage.

The above descriptions of the cornerstones suggest a high degree of technology inclusiveness. For example, limiting the frequency of initiating events is functionally equal to establishing limits on Anticipated Operational Occurrences that challenge SSCs under normal operation. A normal design objective is that such perturbations will not cause any SSC to experience conditions outside of normal operational limits. This is part of the margin that is a normal design objective as well as the margin called for within a performance-based approach for AOOs. Ensuring the availability, reliability, and capability of mitigating systems is quite technology inclusive and would apply to any non-LWR design. Considering the range of technologies that are under consideration for advanced reactors, a characteristic that is valued significantly is inherent safety. In the context of AOOs and mitigating systems, an example of employing inherent safety features could be that a performance objective is for AOOs to result in parameter deviations through inherent feedback mechanisms only, without invoking any mitigating systems.

The NRC's safety framework requires providing emergency preparedness regardless of whatever inherent features may exist in a design. This is considered as an aspect of implementing the defense-in-depth philosophy. Even if the exclusion area is shown to be much smaller than for currently operating reactors, an exclusion area boundary is likely to be a performance feature of any advanced non-LWR.

The cornerstones regarding public and worker radiation protection and provisions for security of radiological materials are clearly technology inclusive. NUREG/BR-0303 does not include consideration of these for RIPB methods. With a focus on reactor design and operation, the areas covered involve just the first four cornerstones.

The NRC sought to identify performance indicators where ever possible as a means of measuring the performance of key attributes in each of the cornerstone areas. Where such a performance indicator could not be identified, supplementary inspection activities were instituted. Additional types of inspections were included to verify the accuracy and completeness of the reported performance indicator data.

Hence, a hierarchical structure for performance elements in the design of an advanced non-LWR can adopt and adapt aspects of the ROP model. The requirements for effective performance of monitoring can also be adapted in a technology inclusive manner. Figure 1 depicts the arrangements of lower level performance objectives for the mitigating system cornerstone.

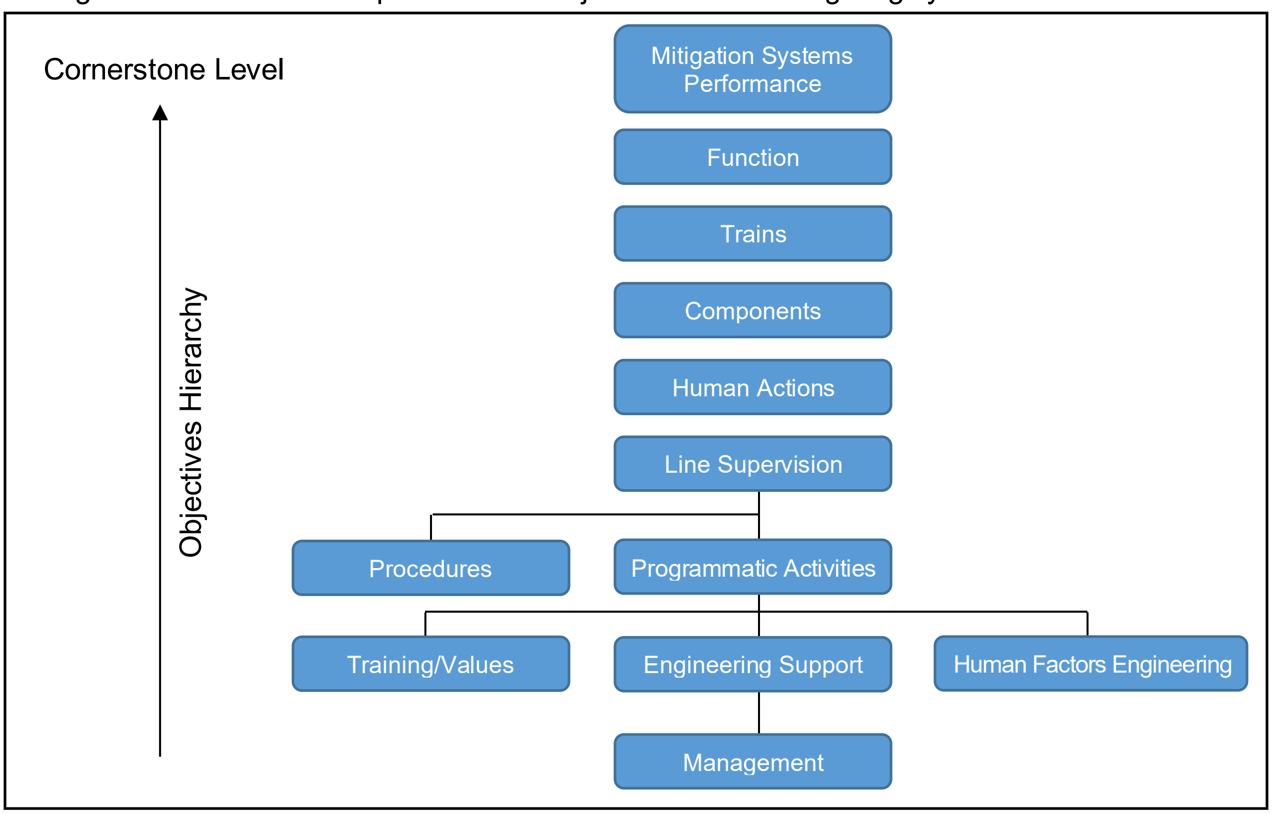

Figure 1. Decomposition of Mitigating Systems Cornerstone

Performance objectives can be sought to be accomplished either prescriptively or with RIPB methods. NUREG/BR-0303 offers a systematic approach to explore the options available to the analyst or designer to examine the options to proceed. The process is intended to determine whether a given issue or performance objective is suited for an approach that most strongly reflects performance-based attributes. In addition, other competing objectives may be included such as setting the measures at as high a level as feasible or using multiple parameters to satisfy defense-in-depth considerations. These considerations suggest an iterative process, with each iteration resulting in more detailed and focused information to be used for improving the RIPB alternative.

NUREG/BR-0303 also offers a systematic approach to explore the viability of considering risk and performance information to achieve the Commission's White Paper outcomes. The high-level guidelines were intended for a wide range of applications using as a key attribute that, *"...a framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern."* Such a framework contains the concept of "margin." In this construct, "margin" is a quantity that expresses the difference between performance within the limits of a "criterion" and performance that is representative of a "concern." The word "immediate" requires that a time element be considered in the development of a performance-based approach. The high-level guidelines incorporate this understanding. They are also consistent with the designer's responsibility to provide for a monitoring system to incorporate surveillance and testing requirements to detect potential erosion of margin, as well as an operator's responsibility for prompt corrective actions.

The High-Level Guidelines in NUREG/BR-0303 have been adapted for LMP as follows:

I. Viability Guidelines
   a. Verify that the objectives hierarchy offers a framework to show that performance by identified elements will serve to accomplish desired goals and objectives. Margins of performance exist such that if performance criteria are not met, an immediate safety concern or jeopardy to outcome will not result.
      i. An adequate safety margin exists.
      ii. Time is available for taking corrective action to avoid safety concerns or jeopardy to outcome.
      iii. The operator can detect and correct performance degradation.
   b. Measurable, calculable, or constructible parameters to monitor acceptable plant and operator performance can be inferred from the objectives' hierarchy.
      i. Directly measured parameters related to the safety objective or outcome objectives are preferred and will typically satisfy this guideline.
      ii. Calculated or constructed parameters based on objective observation may also be acceptable if there is a clear relationship to the safety or outcome objective.
      iii. Parameters that the operator can readily observe or access, or are currently accessing, in real time are preferred and will typically satisfy this guideline. Parameters monitored periodically to address postulated, design basis, or other conditions of regulatory significance may also be acceptable.
      iv. Acceptable parameters will be consistent with defense-in-depth and uncertainty considerations.

c. Objective observation-based criteria to assess performance exist or can be developed.
    i. Objective criteria consistent with the desired outcome are established based on risk insights, deterministic analyses, and/or performance history.
d. Operator flexibility in meeting the established performance criteria exists or can be developed.
    i. Programs and processes used to achieve the established performance criteria will be at the designer's or operator's discretion.
    ii. A consideration in incorporating flexibility to meet established performance criteria will be to encourage and reward improved outcomes, provided inappropriate incentives can be avoided.

II. Assessment Guidelines
a. Maintain fidelity to outcome objectives as well as safety, environmental protection, and the common defense and security.
    i. Safety considerations play a primary role in assessing any change arising from the use of RIPB approaches.
    ii. Adequate safety margins are maintained using realistic safety analyses, including explicit consideration of uncertainties.
b. Increase public confidence and acceptance of a project.
    i. An emphasis on results and objective criteria (characteristics of a performance-based approach) can help the design and operations activities to be viewed as being executed by competent, transparent, efficient, effective, and reliable performers.
    ii. A performance-based approach helps provide the public clear and accurate information about, and a meaningful role, in the design and operations enterprises.
    iii. A performance-based approach helps explain participant's and stakeholders' roles and responsibilities and how public concerns are considered.
c. Increase effectiveness, efficiency, and realism of enterprise activities and decision making.
    i. The level of conservatism existing to show fitness for purpose or fitness for service would be assessed, considering analysis methodology and the applicable assumptions. Any proposal to use realistic analysis would consider uncertainty factors and defense-in-depth relative to the scenario under consideration.
    ii. The performance criteria and the level in the performance hierarchy at which they have been set would be assessed. In general, performance criteria would be set at a level commensurate with the function being performed. In most cases, performance criteria would be expected to be set at the system level or higher.
d. Reduce unnecessary constraints on design and operations.
    i. A performance-based approach enables the designer or operator to impose the burdens of limits and constraints that are commensurate with the safety or operational benefit and that effectively focus resources on outcome objectives.

    ii. A performance-based approach will enable the costs associated with activities expected to be performed by stakeholders to be focused on areas of highest priority and avoid burdens imposed by overly prescriptive requirements.

e. The expected result of using a performance-based approach is an overall net benefit.
    i. A reasonable net benefit test begins with a qualitative approach to evaluate whether there is merit in changing the existing performance framework. When the net benefit test is approached from the perspective of existing practices, stakeholder input would be sought.
    ii. In contemplating a change in existing practices of design and operations personnel toward a formal performance-based approach, expending resources would be justified only if the positive outcomes pass a net benefit test. Designers and operators themselves will be the primary source of initial information and feedback regarding potential benefits.
    iii. For the limited purpose of screening potential performance-based changes, consideration of a specific high-value results (such as net reduction in worker radiation exposure, or prospects for return on investment) may be sufficient for weighing the immediate implications of a proposed change.

f. The performance-based approach can be incorporated into the decision-making framework.
    i. The decision-making framework may include areas of technical regulation (Code of Federal Regulations, the associated regulatory guides, NUREGs, standard review plans, technical specifications, and inspection guidance) as well as broader areas representing investment and other stakeholders.
    ii. A feasible performance-based approach would be directed specifically at changing one, some, or all of the elements in the objectives' hierarchies involved.
    iii. The proponent of the change to the elements of the decision-making framework would be responsible for providing sufficient justification for the proposed change; all stakeholders would have the opportunity to provide feedback on the proposal, typically in open meetings.
    iv. Performance monitoring considerations would be addressed during the formulation of proposals for changes rather than afterwards. Such considerations could include reduced constraints or audit scrutiny if performance so warrants.

g. The risk-informed and performance-based approach would accommodate innovation and new technology.
    i. The incentive to consider a performance-based approach may arise from the development of new technologies, as well as difficulty in finding spare components and parts for existing technologies.
    ii. Advanced proven technologies may provide more economical solutions to support outcome objectives without compromising safety, economics or public acceptance. Such factors may also justify consideration of the more complex decision framework of a performance-based approach.

III. Guidelines for Consistency with Societal Principles and Policies

a. A proposed change to a more performance-based approach is consistent and coherent with other overriding goals, principles, policies and approaches in the enterprise's functional ecosystem.

i. The regulatory system has such factors within institutional policy guidelines such as NRC's Principles of Good Regulation and the Strategic Plan. Consistent with the high level at which the guidelines have been articulated, specific factors that need to be addressed in each case (such as defense in depth and treatment of uncertainties) would depend on the performance objectives involved.

Integrated Risk-Informed Decision Making

It was mentioned earlier that a hierarchical structure with processes that execute principles and policies toward an outcome is required for a safety approach that is based on combining risk and performance information. The basic elements of the structure, processes and principles have been developed at the NRC and are being used by the agency in most cases implicitly. The applications focus on LWRs because that is where the bulk of the agency's work happens. However, the nature of the structures, processes and principles are technology inclusive and can be applied by LMP for non-LWR issues.

The sources and the content of the guidance used by the NRC staff are widely dispersed but a few of them are much more prominent in their contribution to regulatory practice. The guidance for applicants developed by LMP has also used the same sources that providing confidence that the guidance will receive favorable regulatory review. Among the most important documents is RG-1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to The Licensing Basis". A more recent work, NUREG-2150, "A Proposed Risk Management Regulatory Framework" is also an important source of guidance because it captures existing policies and practices while proposing improvements toward an improved risk management framework. The main elements of a structured integrated decision-making approach is shown in the following Figures.

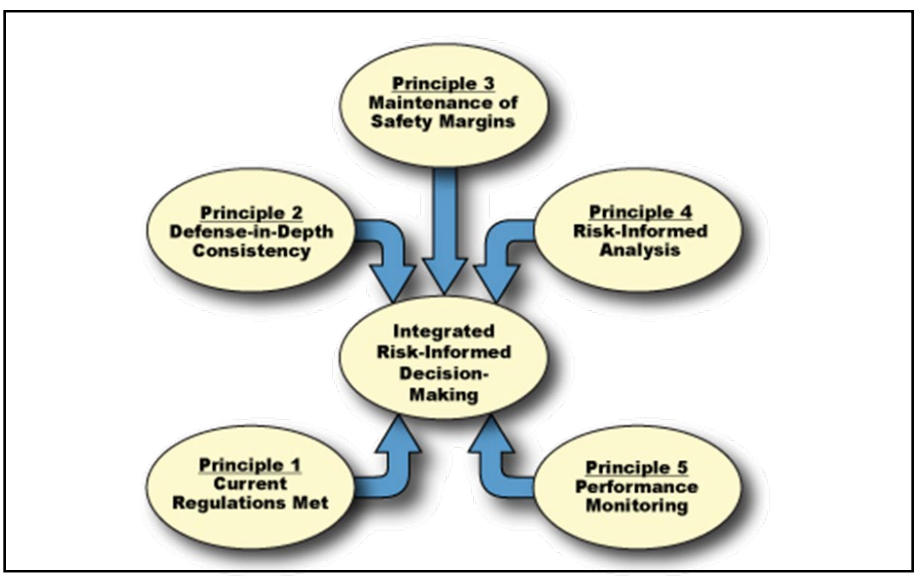

Figure 2. Integrated Risk-Informed Decision Making from RG 1.174

It is expected that the Integrated Risk-Informed Decision-Making model described above will be executed within a framework that was recommended by a Commission-level Task Force in NUREG-2150, “A Proposed Risk Management Regulatory Framework”. The components of this framework are shown below. The objective is stated to be to manage radiological risk through appropriate performance-based controls and oversight. Although the framework was developed with regulatory applications in mind, there is no reason that the structure and processes cannot be adopted for use in design and operation.

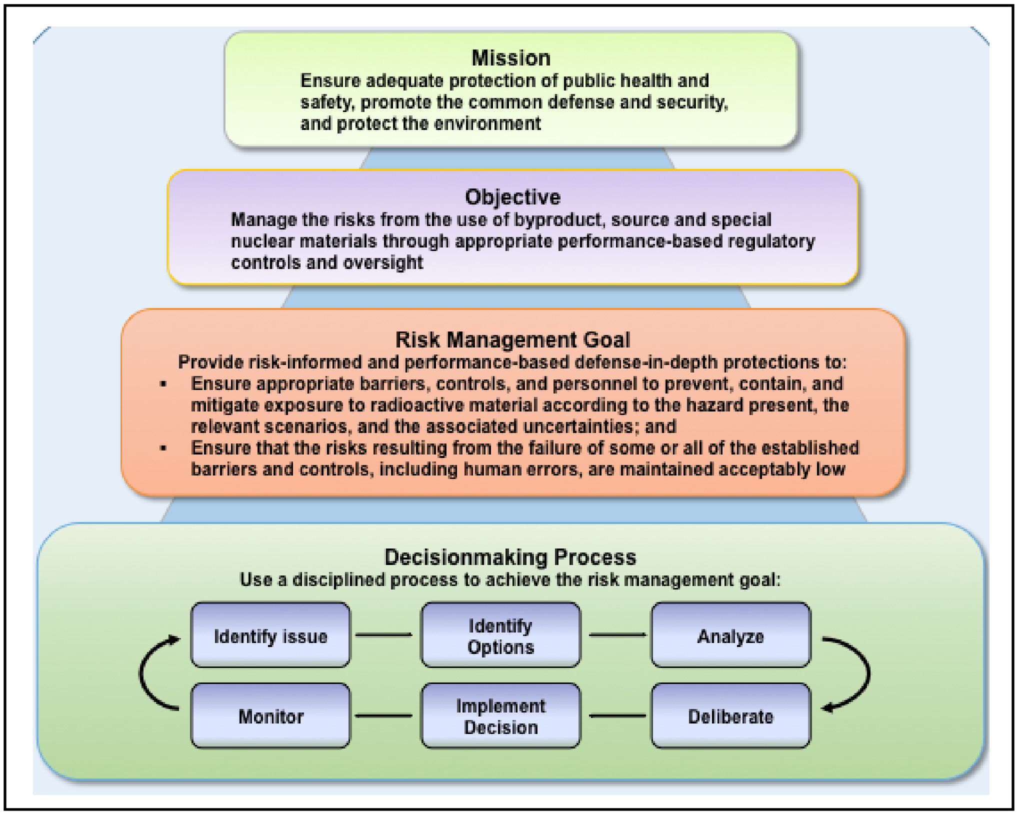

Figure 3. Risk Management Regulatory Framework

The following addresses the five principles related to integrated risk-informed decision making:

1. **Current Regulations Met:** This takes account of the flexibility in the regulatory framework. Many aspects of the current regulatory framework do not apply to non-LWRs and so do not count to fulfill this principle. In some cases, the situation may call for exemption from regulations or deviations from guidance. Such instances still count as current regulations being met.
2. **Defense-in-Depth Consistency:** Being consistent with the philosophy of defense-in-depth is a key requirement for reaching an adequate safety finding by the NRC staff. At present, the best definition of the functional attributes for implementation of the philosophy has been endorsed by NRC within DG-1353. This definition is contained within the LMP guidance document NEI-18-04. The guidance takes account of Commission-directed modifications to Regulatory Guide 1.174.

3. **Maintenance of Safety Margins:** Implementation of the performance-based approach would be a key basis for obtaining information about the most important safety margins relevant to a given decision. The functional analysis that clarifies the purposes to be served by performance objectives determines which safety margins should be focused on to meet this principle.
4. **Risk-Informed Analysis:** An important consideration in exercising this principle may be the distinction that should be made with a risk-based perspective. As pointed out in the White Paper on Risk-Informed and Performance-Based Regulation the insights from risk analysis should be given greater importance than the numerical result. The risk-informed analysis will be the best source of information for priority setting and resource allocation.
5. **Performance Monitoring:** This is another key aspect of implementing a performance-based approach. The parameters monitored should be associated with outcome and performance objectives as closely as practicable. Sound technical judgement from appropriate subject matter experts is likely to be the most important source of information for exercising this principle.

3. GUIDANCE ON FORMULATING A SUITABLY PERFORMANCE-BASED APPROACH

The methods associated with "risk-informed" and "performance-based" can be brought together in a multitude of permutations and combinations optimized toward context and application. The LMP guidance for defense-in-depth offers a model that integrates plant capability factors, programmatic factors and evaluation factors that serve as the basis for judgements regarding adequacy. In this context it is appropriate to invoke the following definition from the Commission's White Paper:

> "*Risk-Informed Approach and Defense-in-Depth Approach: 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.*"

From the perspective of design applications, the key question is, "How much defense makes safety sense"? The thrust of the Commission's statement is that decisions on the adequacy of or the necessity for elements of defense are essentially the results of a performance-based approach.

An applicant's safety case will be based on arguments that address the adequacy of defense-in-depth along with other topic areas that also serve to meet regulatory expectations. Three questions are key to making a sufficiently complete safety case:

1. What are the factors for which credit is taken for the defense-in-depth elements of the safety case?
2. How much credit is allocated for these factors to fulfill expectations?
3. How is confidence obtained that assigned level of credit to these defense-in-depth elements will be available during the stages of design and construction, and confirmed during operation?

A suitable performance-based approach will be the most efficient and effective way for developing the answers to these questions. A structured performance model, most likely in the form of an objectives' hierarchy, would enable a technically sound response to the questions. Such a model, described in NUREG/BR-0303, explicitly depicts the relationships and dependencies among the performance objectives. NUREG/BR-0303's high-level guidelines can also be applied to specific performance objectives. The guidelines to assess viability are emphasized because they represent what is distinctive regarding identifying and assessing performance-based activities. The high-level guidelines to assess viability center on selection or formulation of performance parameters and associated performance criteria. Application of these guidelines depends on certain definitions, which are developed below.

Kinds of "Performance"

In formulating a concept for performance, this guidance has drawn on ideas used in the Reactor Oversight Process, in which "performance" refers to those activities in design, procurement, construction, maintenance, and operation that support achievement of the objectives of the cornerstones of safety. In an analogous manner, other applications would entail identification of key aspects of performance and focus on activities which are important to safety or other outcome objectives.

Risk-significant performance changes generally affect system characteristics such as frequency of events and reliability, availability, or capability of SSCs. Here, "capability" refers to the physical capacity of the system to accomplish a given function, such as "deliver required flow at a given pressure," "successfully bear a given load," or "effectively filter air taken into a breathing apparatus." Availability refers to the fraction of time that the SSC is capable of performing its function. Reliability refers to the probability that a given SSC will function on demand and during the required mission time, given that it was available.

Many kinds of performance affect the system characteristics including such factors as human performance, and the condition in which equipment is left after preventive or corrective maintenance (recognizing that the conduct of testing and maintenance itself affects availability). Ultimately, corrective action programs also affect reliability and availability. Even spare parts management can affect availability.

The important point to stress is that design and operations activities affect the whole range of such performance factors. A framework to consider “performance” must necessarily be able to take account of such factors in a systematic way. A good PRA will be able to account for many, but likely not all, such factors. Risk information will be the most reliable means to bringing the focus of management attention and resource allocation to the most important of these factors. Thereafter, the performance-based approach works to enable the “PRA to come true” by considering many more factors in a structured and systematic way.

Characteristics of Functional Requirements

A complete set of functional requirements should include the following:

1. A definition of the mission to be carried out.

   In the LMP guidance, each of the event sequences and the category of LBE implies a set of mission objectives and the likelihood of success or failure. This entails at least an implicit specification of the physical challenges that need to be met. Meeting the challenge will require a level of performance characterized in terms of one or more physical parameters such as flowrate at a particular pressure, or heat removal rate. The system performance specification may be made implicitly, as when a functional outcome is mandated, conditional on a specific challenge.

2. An indication of the required degree of assurance (functional reliability) that the mission will be carried out successfully.

   Assurance of successful performance has previously been approached prescriptively using concepts such as redundancy (single-failure proof design), special treatment requirements (in procurement, installation, and surveillance), and limiting conditions of operation (so that individual trains or channels of the system cannot be out of service longer than allowed outage times). Surveillance testing or inspection have been mandated at specified intervals so that the probability of undetected faults is limited. System reliability has been promoted by prescribing redundancy, QA, surveillance testing, and allowed outage times. The LMP guidance breaks from such practices in the past by enabling designers to choose performance-based alternatives.

3. An assessment of the degree of confidence that is associated with the decision-making structure and process.

   The degree of confidence takes into account the uncertainties associated with the PRA as well as assessing those aspects not included in PRA models. Included in such considerations is the degree to which the models employed are validated. Validation includes computational models as well as empirical models. In the traditional prescriptive approach employing deterministic decision making, validation of models and data took on an “all or nothing” characteristic. Using a performance-based approach for non-LWRs opens up the possibility of developing the appropriate level of confidence in the desired outcomes and thereby avoid some of the more onerous prescriptive requirements. The economics of some new technologies may be critically dependent on this consideration. Hence, the research and data-gathering that supports the decision-making process could employ research published by the NRC and described in the Appendix to serve optimization of safety and economics. Guidance on these factors is available in NUREG/CR-6833. Ultimately, the assessment reaches a conclusion regarding the fitness for purpose of meeting performance criteria. NUREG/CR-6833 also addresses the issue of considering consequences of concluding erroneously.

Stepwise Implementation

The guidance is implemented in a stepwise manner as depicted in Figure 4. The steps are based on technical explanation contained in the high-level guidelines provided in the appendices of NUREG/BR-0303. The NRC guidance focused on regulatory outcomes as it was directed toward the NRC staff. The premise of this guidance is that a regulatory focus is substantively the same as a safety focus using the NRC guidance for a performance-based approach. Standard engineering practices that use probabilistic methods appropriately will achieve successful project related outcomes with safety being an important component of other desirable outcomes. This could be the case even in the absence of consideration of regulatory requirements in many engineering applications. The focus of this guidance is non-regulatory applications of the framework created by the guidance in NUREG/BR-0303 and subsequent work. However, traditional approaches that often begin and end with a regulatory focus should be part of the mix of options available. The particular steps in the guidance have been adapted for non-regulatory applications by focusing on the viability guidelines used to develop performance-based options. The other guidelines are assessment guidelines and consistency-checking guidelines. For the purposes of this guidance, anything beyond the viability guidelines would be considered to be application specific.

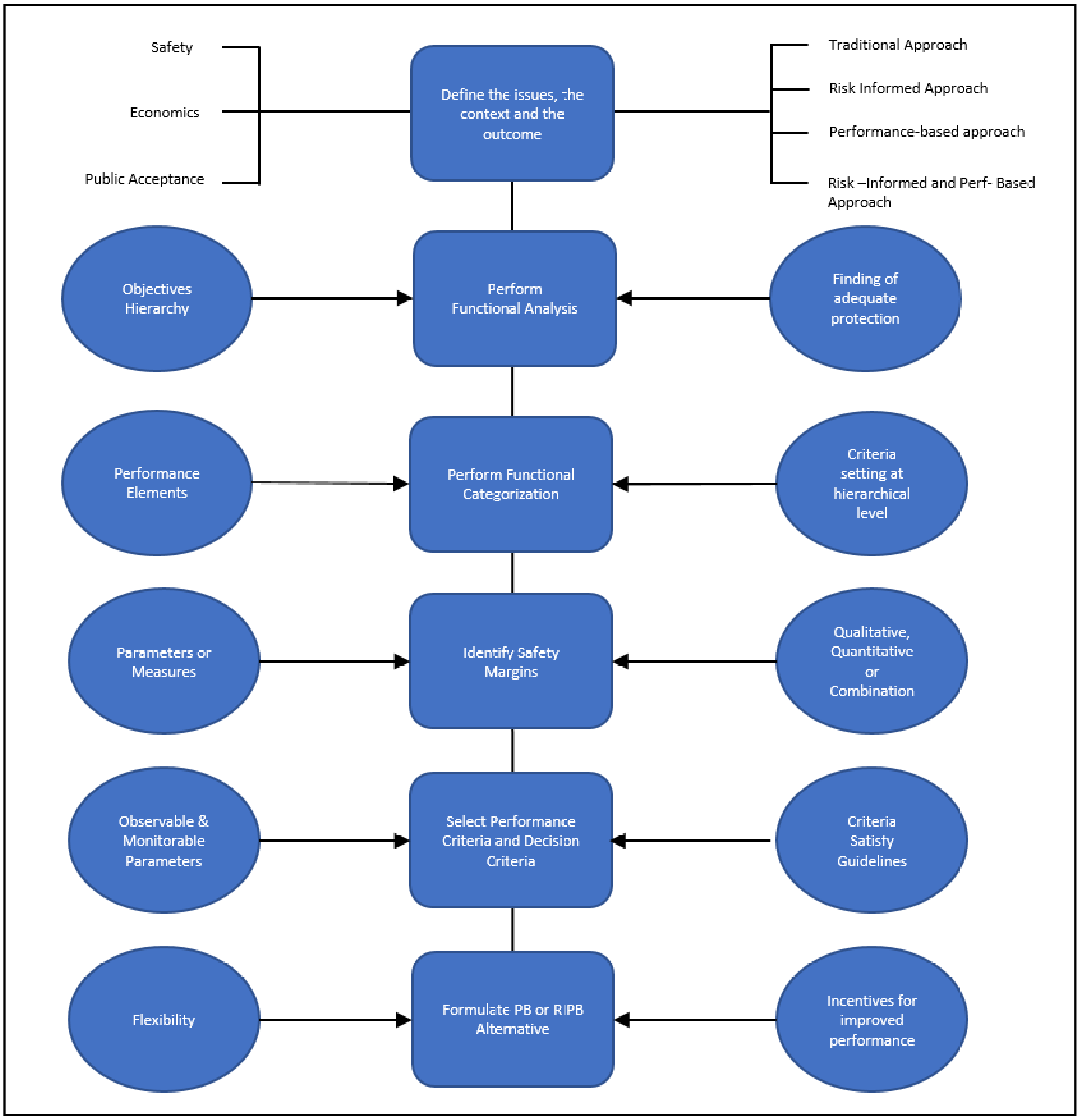

Figure 4. Implementation Steps for Performance-Based Approach

Step 1: Define the Issue, the Context and the Outcome

In the non-regulatory context, the outcome that would generally be sought would be project related. The scope of this guidance will focus on design related issues. A formal performance-based option would be a choice available to the designer to the extent that engineering solutions to specific issues can be shown to meet the Essential Attributes and the Desirable Attributes.

The design aspects of a non-LWR project can be addressed using a variety of strategies. As mentioned earlier, NUREG/BR-0303 identifies four main options as (1) the traditional approach, (2) the risk-informed approach, (3) the performance-based approach and (4) the risk-informed and performance-based approach. A project related outcome could generally be decomposed into outcome objectives that relate, for example, to safety, economics and/or public acceptance considerations. Much regarding a performance-based approach depends on the clarity with which particular activities are defined relative to outcome objectives. Implementation of a suitably performance-based approach can assure that outcomes are consistent with those described in the Commission's White Paper.

Step 2: Perform Functional Analysis

The construct within which the four Essential Attributes could be envisioned requires that performance takes place to fulfill the demands of functions that accomplish specific objectives each of which contributes tangibly to the desired outcomes. Part of the preparatory work toward a performance-based approach is that the functional analysis identifies a complete set of functions. In a risk-informed approach, the functions would be derived from a PRA as described under SSC classification in the LMP guidance. In an integrated risk-informed and performance-based approach, the functions would be defined based on an objectives' hierarchy or a safety case that incorporated defense-in-depth considerations as described in the LMP guidance.

NUREG/BR-0303 is based on the structure of the Reactor Oversight Process which simulates an objectives hierarchy associated with reactor safety. This structure has sufficient generality to be technology independent. The ROP structure explicitly states that the outcome objective is "Public Health and Safety as a Result of Civilian Nuclear Reactor Operations" which is the same as the goal of a designer's safety case.

Hence, from the perspective of fulfilling well defined functional purposes that can reach a conclusion of adequate safety and implement a risk- informed and performance-based approach to preparing a non-LWR license application, the outcome objectives would include (as described in the LMP guidance):

1. A set of design basis events

   From the perspective of an advanced non-LWR applicant, the characteristics of the technology and the proposed design attributes would contribute to a structured performance model in which the proposed DBEs challenge particular design functions. Traditionally, Anticipated Operational Occurrences and Design Basis Accidents have been considered DBEs. The applicant can simulate the challenge and response in the performance model to establish sufficiency and acceptability, or otherwise, of the consequences. In a deterministic formulation, both challenge and response are preset scalar quantities. In a probabilistic formulation, each could be a vector and defined by a probability distribution. A PRA employs a probabilistic formulation.

An additional consideration for the US regulatory framework is that activities supporting conclusions regarding adequate protection cannot take cost factors into considerations. The applicant would be expected to validate results applying sufficiently rigorous methods, tools and data using appropriate QA procedures to submit an analysis that shows acceptable magnitude and confidence in design basis safety margins.

2. A set of beyond-design-basis events

   The BDBEs also represent challenges in simulation models of particular design functions and features. From the perspective of the regulatory framework, the functional purpose of BDBEs is to address cost-justified safety enhancements. Such enhancements may be considered to be a manifestation of the philosophy of defense-in-depth. Another perspective is to consider them as a part of the regulatory structure to assure public acceptance. The supporting analysis for BDBE differs from the DBE type of analysis by the degree of validation that would apply and the cost considerations that may provide significant opportunity for optimization. The PRA for the design would be an essential part of considering BDBEs. BDBEs are selected by the process described in the LMP guidance in a way that is informed by deterministic insights and PRA results. They are not prescribed by ad hoc considerations as sometimes occurred in the past.

3. Implementation of defense-in-depth

   The Commission provided guidance on implementation of defense-in-depth in the SRM to SECY-2015-0168 within a context dealing with decisions regarding NUREG-2150 and the NTTF Recommendation 1 matters (see Appendix). The Commission approved maintaining the existing regulatory framework for the nuclear power reactor safety program area and directed the staff to expeditiously complete revision of Regulatory Guide 1.174 on defense-in-depth to improve the clarity of the guidance. RG 1.174 has been a document that has provided clarifications on many matters related to risk-informed regulatory matters. The LMP guidance on defense-in-depth takes into account the most recent guidance.

The LMP guidance uses the “layers of defense” formulation recommended in IAEA guidance documents (see Appendix). This can be translated into functional performance criteria as follows:

1. Disturbances and transients do not lead to initiating events;
2. Initiating events are detected, controlled and corrected in a timely way;
3. Validated performance of required safety functions is supported by demonstrated adequate assurance of margin to limiting levels of associated parameters;
4. Analysis of plant performance under conditions in which some SSCs are challenged beyond normal acceptance shows that parameters reflective of critical safety functions have sufficient margin to faulted states as to offer acceptable confidence in safety margins to radiological release;

5. Adverse public health and safety impacts are held within acceptable limits through preparedness for emergencies.

The functional performance areas that contribute to the above layers of defense would be expected to be described within the safety case that supports an application. A safety case approach for performing functional analyses employs a narrative form for identifying and describing the functions that accomplish performance objectives. A safety case could be prepared from the modelling within a PRA supported by the structure of an objectives' hierarchy. The functional analysis should produce a hierarchy of functional specifications as a result of decomposition or disaggregation of functions associated with principal design criteria.

The functional performance areas can be examined more closely with respect to employing a performance-based approach by posing the three questions mentioned earlier, namely:

1. What are the factors for which credit is taken for the defense-in-depth elements of the safety case?
2. How much credit is allocated for these factors to fulfill their expectations?
3. How is confidence obtained that assigned level of credit to these defense-in-depth elements will be available during the stages of design, during construction and confirmed during operation?

Such an examination could provide information useful to an applicant toward meeting one of the key aspects of 10 CFR Part 52, which is a risk-informed and performance-based regulation that is applicable to a non-LWR license application. A license application for a non-LWR can take advantage of a distinctively performance-based aspect of Part 52, which in paragraph 10 CFR Part 52.47 (b) (1) states that an application must contain: "The proposed inspections, tests, analyses, and acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, a facility that incorporates the design certification has been constructed and will be operated in conformity with the design certification, the provisions of the Act, and the Commission's rules and regulations." This sets up the outcome of the entire safety review in the form of a necessary and sufficient condition to be met. Hence, 10 CFR Part 52 is amenable to a formal performance-based implementation because each ITAAC could be constructed to serve a functional purpose validated appropriately with inspections, tests and analyses, and can be the subject of an exercise in integrated risk-informed decision making.

NUREG/BR-0303 does not go beyond identifying the need to specify performance elements. From the perspective of a designer, the performance elements could be specified from a PRA, an objectives hierarchy, or both. The performance elements could be presented as a safety case that could even include elements of the regulatory framework such as SRP sections.

Step 3: Perform Functional Categorization

Functional categorization is part of a systematic and reproducible process in which desired goals and objectives can be represented within structures that provide relationships and dependencies among appropriate performance objectives. For the purposes of this guidance, functional categorization within regulatory and safety contexts would be relevant. A functional categorization in a regulatory context may consider the structure of the regulatory framework as the basis for creating categories. NUREG/BR-0303 suggests that the regulatory framework consists of several interrelated aspects. They are (1) the NRC's mandate from Congress in the form of enabling legislation, (2) the NRC's rules in Title 10 of the Code of Federal Regulations, (3) the regulatory guides and review plans that amplify those regulations, (4) the body of technical information, obtained from research performed by NRC or by others and from evaluation of operational experience, that supports the positions in the rules and guides and review plans, (5) the licensing and inspection procedures utilized by the staff, and (6) the enforcement guidance. The Commission's White Paper definition of a performance-based approach includes staff positions within the ambit of the regulatory framework.

The NRC's regulatory practice suggests at least two ways of categorizing safety. Within the ROP area, "Reactor Safety" is decomposed into four cornerstones, "Initiating Events", "Barrier Integrity", "Mitigating Systems" and "Emergency Preparedness". In more recent work on functional containment, the staff has proposed a structure with "Reactivity Control", "Decay Heat Removal", and "Radioisotope Retention". The foundational material for a safety case includes a comprehensive set of plant level and system level functional requirements that are identified through processes described in the LMP guidance document. The information includes the identification of systems and components and their functions, including energy production functions, maintenance functions, auxiliary functions, and safety functions and an identification of hazards associated with these SSCs. All this information is embedded within the construct of the objectives' hierarchy.

The integrated decision-making process of a performance-based approach includes consideration of where in the hierarchy criteria are to be specified. According to NUREG/BR-0303, an ACRS recommendation was that performance levels and reliability parameters should be set at the highest level possible. Functional categorization enables use of a formal systematic and reproducible approach for performance-based criteria at the highest levels while resorting to prescriptive approaches at lower levels. In the LMP guidance, functional categorization in the regulatory context could enable more appropriate use of guidance from NUREG-0800 or use of consensus standards that are endorsed by NUREG-0800. Combining the regulatory framework with the ROP based or other objectives hierarchy could produce product proposals that match functional accomplishments in an internally consistent and coherent way. This supports a safety case narrative approach that could be more efficient in generating a way to justify fitness-for-purpose licensing positions.

Another ACRS recommendation was that guidance should be given on the extent to which multiple performance parameters that provide redundant information should be used to satisfy the defense-in-depth philosophy. The activities of functional analysis and functional categorization should enable consideration of specific elements of defense-in-depth that would be addressed in a licensing proposal. Provision of redundancy, independence and diversity are key attributes of defense-in-depth.

Another type of functional categorization could be based on the expected frequency of demand for specific functions. The categorization of licensing basis events produces event categories. Within each could be created functional scenarios that would be considered by the designer appropriately for performance objectives beyond consideration of radiological releases. Recent developments attempting to address public acceptance appear to require that a category of events be considered to address residual risks. This is when high-consequence, but very low likelihood events or scenarios are part of the regulatory framework. The use of a PRA would greatly facilitate consideration of such factors.

The results of the functional characterization are needed to check for completeness. Some analyses have characterized adequate safety as composed of adequate safety margins and adequate defense-in-depth. The adequacy of each from a structuralist perspective would be gaged by how a structured decomposition covers the entire safety landscape.

Step 4: Identify Safety Margins

The Commission's White Paper states that a performance-based approach requires that

"a framework exist(s) in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern."

NUREG/BR-0303 used this statement to create Essential Attribute #4, which interprets the Commission's statement to imply the existence of a margin between performance and acceptance criteria. This interpretation is fully consistent with standard engineering design practice in which normal and challenged operating conditions are considered in relation to a system state that represents an acceptance limit. Most design practices, however, do not explicitly incorporate a hierarchical structure. If they did, they would take into consideration that this type of margin could occur at every level of decision making. For example, power uprates are authorized because the required margins were present at those facilities at levels where some reduction in margin can still assure acceptable performance. The activity in Step 4 is meant to bring attention to a deliberative process that considers in a formal way whether there is sufficient confidence in the existence of such margin at the various levels. The evaluation at the outcome level is likely to involve quantitative as well as qualitative factors using expert judgement. Quantitative considerations can become more prominent as means objectives and other performance elements are considered.

Essential Attribute #4 and Desirable Attribute #2 address the need to identify and define safety margins more specifically relative to functional objectives. In this construct, "margin" is a quantity that expresses the difference between performance within the limits of a "criterion" and performance that could be representative of a "concern." The word "immediate" requires that a time element be considered in the development of a performance-based approach. The high-level guidelines incorporate this understanding using the argument that design practice normally incorporates a safety margin between system capacity and the expected challenges against which the system is designed. When public safety is involved, it is to be expected that such margins are verified and validated by appropriate research and testing protocols. There is also an element of confidence associated with the estimates of the margin depending upon whether the estimates apply to design basis considerations or those beyond the design basis. The consideration of the margin and the level of confidence involved are also consistent with supporting the regulatory function to monitor potential erosion of margin, as well as licensee responsibility for prompt corrective actions.

For certain performance elements, a formal definition of a safety margin may offer benefits. The following may be considered as an example of such a definition in the context of a system state perspective:

"***Safety Margin*:** Safety margin is represented as the difference, expressed in consistent terms, between a capacity function (a representation of a system state in a mathematical sense) and a challenge function within the context of a particular scenario. The capacity function is associated with a structure, system or component (or a set of such elements) to represent its time-dependent capability to perform a safety function successfully in a conservatively or a realistically evaluated analysis. The capacity function could be expressed probabilistically in terms of likelihood of successful performance when challenged as specified. The challenge function is defined within the context of the design basis or licensing basis scenario as the limiting or time dependent conditions imposed on a structure, system or component (or a set of such elements) due to challenging events. The challenge function could incorporate time-dependent physical parameters expressed in natural or calculated measures (see NUREG/BR-0303) or qualitatively with constructed or proxy measures. A probabilistic representation of the challenge function could be employed provided a suitable basis for comparison with the capacity function is defined in context and in consistent terms."

Step 5: Select Performance Parameters and Decision Criteria

The first four steps provide the knowledge and information that offers the basis for selecting proper performance parameters and thresholds of performance that would achieve functional objectives. Performance parameters may be dispersed throughout the regulatory framework and thresholds can be set in a prescriptive manner to facilitate compliance verification. In a risk-informed approach, performance parameters are viewed in terms of contribution to a risk metric. Risk could be considered in different ways as described by NRC staff (see Appendix):

1. A Basis for Establishing Appropriate Level of Performance
2. To Provide Metrics, Thresholds and/or Monitoring Response
3. Conditions of Unavailability of Quantitative Risk Evaluation Models

The approach recommended by the ACRS is to apply the performance criteria at as high a level in the hierarchical structure as practicable. Setting the criteria at a higher level can allow more flexibility to apply principles associated with fitness-for-purpose and fitness-for-service. However, the need to assure opportunity to take appropriate corrective action requires that criteria be set in context appropriately for the issue, in a way that depends on available margin. In general, this tradeoff between flexibility and the need for prompt corrective action will require an iterative approach.

Strong linkages can exist between observable characteristics chosen as the performance parameters to be used in a performance-based approach and the assessment of margin based on criteria applied to these parameters. For example, the quality of emergency backup power provided by a diesel generator would not necessarily be well-reflected by prescriptive criteria that are applied to each component part of the diesel generator. Hence, a prescriptive approach at the component level can become unnecessarily onerous. This is because even if very strict quality criteria are applied to each of the component parts, the overall diesel generator performance may not meet regulatory standards. On the other hand, a diesel generator taken as a whole system may adequately meet performance standards even if the component parts are of only commercial grade quality.

Step 6: Formulating Suitably RIPB Design Options

Provisions in the LMP guidance offer instances where a designer may benefit from being able to compare “risk-informed”, “performance-based” and “risk-informed and performance-based” approaches. The LMP guidance considers categories of “plant functional capability” and “plant physical capability”. Performance attributes such as “reserve capacity to perform in severe events” and “robustness” of SSCs are considered important. Protective strategies are identified so that reasonable assurance is provided that the predicted performance of SSCs incorporate special treatment while designing, manufacturing, constructing, operating, maintaining, testing, and inspecting the plant and the associated processes.

The structure of the guidance offered in this document is to lead an applicant through a step-by-step process that produces an outcome that is (1) consistent with the outcomes defined by the Commission’s White Paper; and (2) formally meets performance objectives that have been structured as elements within hierarchies. Suitable performance parameters and criteria are likely to be prescriptive at the lowest levels of the hierarchy, with other options becoming available at higher levels. The steps are not formulaic and involve deliberations that are referenced in NUREG-2150 to consider all aspects of desired outcomes. For example, the ACRS recommended that defense-in-depth could be addressed by having multiple performance parameters provide redundant information to satisfy the defense-in-depth philosophy. The LMP guidance implements this principle by avoiding reliance on any single design or operational feature.

The LMP guidance identifies design sensitive programs with activities developed during design and licensing phases such as:

- Plant technical specifications
- Inspections, tests, analyses and acceptance criteria
- Operating procedures for licensing-basis events
- Maintenance programs
- In-service inspection and in-service testing programs.

The license application would be expected to address such activities by placing them in a location within the hierarchy associated with the regulatory context as described in Step 3. Technical specifications would be placed in the category of compliance requirements specified in Chapter 16 of NUREG-0800 review guidance. In relation to a structured performance model, technical specifications would likely occur at the lowest levels associated with “Barrier Integrity” or “Mitigating System” cornerstones. Similarly, ITAACs have been described in Step 2 and would likely occur at higher level functional objectives. ITAACs would be addressed in Chapter 14 of NUREG-0800 and various inspection procedures. Operating procedures can cover a wide range of possibilities from highly prescriptive to formally performance-based to cover symptom-based beyond-design-basis events. Maintenance programs subject to 10 CFR Part 50.65 can be formally performance-based to provide flexibility to licensees. ISI and IST programs could be prescriptive to the extent required by the ASME codes.

The construct of a performance-based approach enables treatment of design and operation as a continuum within which operating data and information can be used as part of monitoring performance parameters as well as confirming key design assumptions. Hence, new technologies need not become hostage to the same type of research and development as has been the case with traditional regulatory practices. Operational flexibility can be incorporated as part of monitoring and oversight to ensure maintenance of adequate margins. Operational flexibility can be coupled with positive and negative incentives. Examples of positive incentives occur when licensees may be able to reduce costs of operation if they meet specified levels of safety or trends in safety of operation. Negative or perverse incentives can occur if performance in one important area is set up to be in competition with another, with the possibility of a net adverse outcome. As a hypothetical example, measures that sought only to minimize the unavailability of components might create an incentive to reduce maintenance to a level at which reliability of performance would be adversely affected.

An integrated risk-informed and performance-based approach to safety holds promise for reducing costs by eliminating many unnecessary requirements. The framework promotes a transparent and more objective examination of quantitative and qualitative factors that enables decision making which offers optimization of safety, economics, and public acceptance.

4. IMPLEMENTATION EXAMPLES FOR RISK-INFORMED AND/OR PERFORMANCE-BASED OUTCOMES

An early example of NRC employing risk-informed and/or performance-based methods was promulgation of 10 CFR Part 50.65, the Maintenance Rule. The engagement on behalf of these methods intensified as a result of the Strategic Assessment and Rebaselining Project. The Commission's "White Paper on Risk-Informed, Performance-Based Regulation" enabled NRC staff and other stakeholders in nuclear technology to coalesce around formally defined terminology. Thereafter, the staff developed the Reactor Oversight Process and issued NUREG/BR-0303, "Guidance for Performance-Based Regulation". This document describes adaptation of that guidance to activities associated with reactor design, licensing, and operation.

This section describes three examples in which the various aspects of the technical bases for risk-informed and/or performance-based outcomes are exercised using six sets of activities as follows:

1. Define outcomes
2. Structure objectives
3. Identify margins
4. Identify performance measures and criteria
5. Assess effectiveness
6. Monitor performance

These activities are functionally the same as the steps described earlier. They are presented to highlight functional purposes in a way to better support the iterative nature of the processes. The examples described illustrate how the main components of the technical bases work together to fulfill each of the six functions that support a risk-informed and/or performance-based approach.

4.1 Example Implementation: Safety Classification of Structures, Systems and Components

Some of the key activities described in the LMP guidance relate to establishing the specific design requirements for SSCs which include design criteria for safety-related SSCs, regulatory design and special treatment requirements for each of the safety significant SSCs classified as safety-related or those that are non-safety-related but with special treatment, and design requirements for those SSCs that serve a wide range of performance objectives but do not merit any special treatment. The specific requirements are tied to the SSC functions reflected in event scenarios and are determined utilizing the same integrated decision-making process used for evaluating the adequacy of defense-in-depth.

A reactor designer would consider a successful outcome to be one in which safety and economics are simultaneously accomplished optimally. Such aspirations are complex and may need to be represented by multiple hierarchical performance objectives structures. Safety classification of a plant's structures, systems and components becomes important because both safety and economics are affected. Safety classification of SSCs offers a challenging, but realistic example, for application of a performance-based approach with the following attributes:

- Characterized by outcomes
    - Lived experience (e.g. Public Health and Safety, economic design)
    - Realization of intentions (efficiency, effectiveness, transparency)
    - Complex needs (e.g. Reactor Safety, Radiation Safety, Safeguards, environment)
- Fitness for purpose
    - Flexibility to seek multiple preferences
    - Safety, economics, environmental benefits
- Characterized by multiple hierarchies
    - Safety framework, Regulatory framework, resource allocation
- Fault tolerant
    - Failure at one level does not preclude success at a different level
- Evidence based
    - Objective observation, data gathering, objectivity of decisions
- Non-dependence on prescription from authority
    - Conformance with high-level objectives versus compliance at all levels

The traditional methods applied in this area were prescriptive in terms of postulating the design basis and specifying acceptance criteria. With the advent of 10 CFR Part 52, the acceptance criteria can be evidence based relying on inspections, tests and analyses that prioritize performance based on risk considerations and achieve safety margins that can be monitored to show continued acceptability in operations. This is the mechanism for risk-informed and performance-based ITAACs.

The example will be worked through using the stepwise implementation process described and discussed previously in Section 3 above.

Step 1: Define the Issue, the Context and the Outcome

The prescriptive approach of nuclear reactor design was based on postulated design basis accidents that represented maximal (but not necessarily the maximum) challenge conditions. The difference between the maximum and the actual challenge considered was accounted for by using qualitative risk considerations. A modern approach, like that proposed by LMP, would more formally employ a sound PRA to provide a defensible technical basis for postulating challenges from which would be derived suitable performance capabilities for SSCs.

The process to define requirements for design, operation, and other features of SSCs with safety functions requires a logic or system to classify equipment according to its role in ensuring plant safety. The traditional system developed around the notion that there only needed to be two types of SSCs: Safety Related (synonymous with Safety Grade) and Non-Safety Related. "Safety Related" SSCs were subjected to "special treatment" that qualified them through a quality assurance program (10 CFR Part 50, Appendix B), code requirements for pressure and temperature thermal/hydraulic conditions, accident related environmental conditions, and seismic challenges. These “special treatments” were assumed to be required to develop requisite confidence in estimated safety margins. In a performance-based approach, only those “special treatments” would be proposed that substantively add to the magnitude and confidence in the safety margins.

The label of “safety related” is applied based upon the selected licensing-basis events and considering defense-in-depth attributes. The plant’s SSCs are evaluated for the safety significant role they may play in preventing or mitigating the radiological consequence of such events. This example uses an approach that is similar to that described in 10 CFR 50.69. The classes are described as follows:

1. Safety-Related
    a) SSCs relied on to perform required safety functions to prevent or mitigate the consequences of design-basis events (DBE);
    b) SSCs relied on to perform required safety functions to prevent the frequency of beyond-design-basis events (BDBE) from increasing into the DBE region of the frequency-consequence curve.
2. Non-Safety-Related with Special Treatment:
    a) SSCs relied on to perform functions to mitigate the consequences of anticipated operational occurrences (AOO);
    b) SSCs relied on to perform functions to prevent the frequency of DBEs from increasing into the AOO region of the frequency-and-consequence curve.
3. Non-Safety-Related:
    a) All other SSCs (with no special treatment required).

Step 2: Perform Functional Analysis

The outcome objective for the functional analysis is to develop a logic and a system for assigning every SSC to a safety classification of “Safety Related” (SR), “Non-Safety-Related with Special Treatment” (NSRST), and “Non-Safety-Related” (NSR). In a performance-based approach, the default classification is NSR. Any special treatment administered to an SSC should be based on the need to increase the magnitude and/or confidence level in the safety margin. An SSC that is NSRST would likely be so classified because its functional role may be in a specialized application such as in an accident environment.

The safety functions to prevent or mitigate the consequences of events would be performed by elements specifically identified in the appropriate structured performance model. In the ROP structure, these would be under the three safety cornerstones of “Initiating Events”, “Mitigating Systems”, and “Barrier Integrity.” These would represent fundamental outcome objectives as described in Appendix B of NUREG/BR-0303. The particulars of the technology and the design would need to be considered to reach any conclusions regarding performance factors and the measures to be employed within a performance-based framework. These would be best dealt with using the integrated risk-informed and performance-based decision-making process described above in Section 2.3.

There are two distinct kinds of activities involved in implementation of functional requirements associated with performance parameters. The first kind of activity is associated with design and construction (includes design, procurement, installation and gaining assurance that system design is capable of achieving the desired reliability). The second kind of activity is operational and aimed at maintaining the required reliability and availability. It includes such things as surveillance testing, preventive maintenance, corrective maintenance, and corrective action programs. In the regulatory sphere the first kind of activity is generally associated with licensing. Later, plant modifications may also be included. The first kind of activity includes formulation, initial achievement, and subsequent modification of a safety case (which could be seen as a narrative form of a set of ITAACs); the second kind of activity is aimed at keeping the current safety case valid (these could be seen as the operational ITAACs).

The safety function performance could be analyzed within the objectives' hierarchy of the ROP structure if that is the chosen performance model. The performance requirements within the regulatory framework are also important and would be based on a different hierarchy based on whether requirements are enforced through regulation, guidance, or inspection procedures. The license application for a non-LWR offers an opportunity to avoid many parts of the existing regulatory framework that evolved primarily for LWRs.

The designer has an opportunity to take advantage of the flexibility that exists within the regulatory framework by making choices in constructing the safety case. Regulatory requirements are formulated at several distinct levels which have a hierarchical structure in which rules state high-level requirements while lower-level guidance documents provide more specific guidance, including examples of acceptable ways to meet requirements. Technical Specifications and other license conditions play a role in imposing requirements that are more prescriptive.

Rules generally state the mission to be accomplished, including the challenges to be addressed and the definition of successful performance. Many existing rules are performance-based in the sense that the rule language does not prescribe how the challenge is to be addressed. Such rules may be adopted for non-LWRs as part of the safety case.

Regulatory guides and standard review plans may be considered guidance level documents. Guidance at this level does not have the standing of rules, but it may articulate standards (including consensus standards) that are a way to satisfy the intent of rules.

At the operational level, requirements are aimed at assuring that assumptions related to safety are upheld. Requirements may be imposed on surveillance test interval and/or test protocols. Technical Specifications may limit the amount of time that the plant is allowed to operate with known deficiencies because risk has been evaluated and found to be acceptable. Consensus standards cited by rules are also effectively operational level guidance.

Ultimately, a successful application for a non-LWR license is likely to conclude in a rulemaking within the framework of 10 CFR Part 52. This would be the mechanism by which the process for SSC classification would be documented within the regulatory framework. The integration of the design, construction and operational requirements within a licensing framework can work to increase flexibility and effectiveness.

Step 3: Perform Functional Categorization

Functional categorization addresses the outcome objectives of the regulatory framework so that a finding of adequacy of safety can be addressed. The classification of SSCs is an important part of enabling such a finding. The functional categorization of SSCs, or groups of SSCs, that provide for specific functional purposes can take advantage of an objectives hierarchy to produce proposals for functional accomplishments in an internally consistent and coherent way. This could be used to implement the ACRS recommendation that performance levels and reliability parameters should be set at the highest level possible. Functional categorization enables formal use of a performance-based approach at higher levels while employing prescriptive approaches, such as ASME Section III or Section XI requirements, at lower levels.

The functional performance objectives of SSCs are determined in the context of the following:

1. A set of design basis events
2. A set of beyond-design-basis events
3. Implementation of defense-in-depth

As discussed previously, design basis events are anticipated operational occurrences and postulated design basis accidents. The beyond-design basis events to be considered would depend on the particulars of the technology and the design to be implemented within an application. Examples of the nature of the challenges within each category of events are shown in Table 3 below:

Table 3. Performance Factors for Events

Event Sequence Designation	Treatment of Sequence in Regulatory Practice	Performance Characteristics that Represent Acceptable Outcomes
Anticipated Operational Occurrences (AOO)	• Considered part of normal operations • Includes consideration of multiple independent failure sequences • Should include all higher-frequency Postulated Initiating Events (PIEs) • Consider all perturbations to critical safety functions	• Strict compliance with normal operational limits • Compliance demonstrated by prescriptive criteria validated with conservative models • No consideration of cost • Predicted consequences well within normal operational limits (ample and high-confidence safety margins)

Design Basis Events (DBE)	• Significant departure from normal operations due to one or more anomalies
	• Breach of one or more AOO conditions leads to challenge of safety function such as
	  o Criticality
	  o Barrier integrity
	  o Heat removal
	  o Geometric stability
	  o Chemical reactions
	• Estimated frequency of scenarios under DBE significantly lower than AOO
		• Design incorporates engineered systems that include multiple barriers and mitigating systems
		• Anomalies create challenges to SSCs that formally represent the design basis meaning
		  o Magnitude and confidence in safety margins at maximal levels
		  o Predictive models use conservative deterministic criteria enforced prescriptively
		  o SSCs responding to challenges subject to App B, EQ rules, code material limits, avoids human intervention, etc.
		  o No consideration of costs
		• Regulatory practice has not permitted any measurable radiation at the EAB

Beyond Design Basis Events (BDBEs)	• Deterministic framework of DBE is breached resulting in major increase in uncertainty and ability to validate outcomes • Integrity of barriers is not assured • Mechanistic and probabilistic estimation of system behavior is reasonably robust • Scenario complications may include factors such as geometric instability and unfavorable chemical reactions • Temporal margins may be considered • Estimated frequencies of BDBEs significantly lower than DBEs	• Operator actions are permitted for analytical predictions • Responding SSCs may be commercial grade • Cost-benefit analysis permitted for design purposes • Limited validation of simulation models • Major increase in uncertainty relative to capabilities of SSCs • Consideration of EP measures may be in order • Consideration of probabilistic safety margins including Seismic Margin Analysis, High Confidence of Low Probability of Failure, hypothesis testing, is permitted • Best Estimate with uncertainty predictions of end states (including operator actions) would be permissible • Invoking engineered safety features to meet EAB radiological limits would be permitted

An important aspect of regulatory practice that has significant relevance with advanced non-LWRs relates to passive safety features. The classification of such items has been addressed as part of defense-in-depth in the LMP guidance. It may not be necessary to assume that special treatment of SSCs is necessary to assure the required magnitude and confidence in the estimated safety margins. However, it may be necessary to include appropriate monitoring of performance capabilities of specific SSCs to confirm that the safety case is upheld at all times.

Step 4: Identify Safety Margins

As mentioned earlier, in this example, the default classification of SSCs is taken to be NSR. In a performance-based implementation, the desired outcome is to show that sufficient safety margin exists to be consistent with Essential Attribute #4 and Desirable Attribute #2 relative to functional objectives. Given that the assessment of a safety margin takes place with a formality that provides for such qualities as accountability and auditability, achieving functional objectives should not depend on the label attached to an SSC unless some aspect of the margin would be lacking unless the label is called out. It would be expected of a designer to be sufficiently familiar with details of the expected quality of an NSR item, the expected variability of the item's critical attributes, and the predicted impacts on installing, commissioning, operating, and maintaining the item in the setting where its performance contributes to safety. As has been addressed in NUREG/CR-6833, the proposition that an NSR item may not fulfill its expected role can be subjected to hypothesis testing and the consequence of an erroneous conclusion assessed in a formal way.

For the purposes of this example, NSR and "Commercial Grade" as labels applied to SSCs are considered synonymous. For reactors, "commercial grade item" means:

> *"…a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified)."*

As provided under US regulations under 10 CFR Part 21, a Commercial Grade Item can be converted to a safety grade item through a process of "dedication", which for reactors is defined as:

> *"…dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hold-points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a basic component."*

In a prescriptive framework, acceptability is determined by specific actions (commercial grade surveys, product inspections or witness at hold-points at the manufacturer's facility, and analysis of historical records for acceptable performance) taken subject to applicable provisions of 10 CFR Part 50, Appendix B. In a performance-based framework, where the focus is on the outcome of the process (hence can employ whatever means are effective and appropriate for supporting essential and desirable attributes of a performance-based approach) equivalent inspections, tests, or analyses could be proposed to establish acceptability. In the performance-based approach, acceptability is determined by validation of the magnitude and confidence in the safety margin for decisions regarding functional success in operation of the SSC. Hence, in a performance-based approach, some or all steps associated with dedication is the process to provide reasonable assurance that a commercial grade item can be used as a basic component to perform its intended safety function.

Step 5: Select Performance Parameters and Decision Criteria

The performance parameters would need to be proposed for each SSC or groups of SSCs that support a performance objective. The particulars of a technology and the design features proposed for the license application would determine what parameters or measures merit consideration. As described earlier, qualitative and quantitative measures should be considered. The LMP guidance under defense-in-depth identifies and describes many such measures. Natural measures (which may be qualitative or quantitative) would be preferred if practicable. Prescriptive requirements at lower levels in the objectives' hierarchy will likely come with specified parameters to determine compliance.

Historical evidence may be helpful in finding or avoiding certain parameters and criteria. The experience with emergency diesel generators (EDGs) may offer lessons. As part of implementing 10 CFR Part 50.63, the Station Blackout Rule, EDGs were classified according to their performance objectives set based on PRA insights. Compliance with the regulation was based on achieving target reliability values of 0.95 or 0.975. Some years later, the NRC assessed the effectiveness of the implementation of 10 CFR 50.63 in NUREG-1776. The staff studied the areas of coping capability, risk reduction, EDG reliability and value-impact. The study results appeared to show that testing and inspection prescribed by NRC did not focus on the dominant contributors to unreliability during actual demands. A lesson drawn suggested that imposing more stringent requirements may not be effective toward improved performance.

Constructed measures based on qualitative, but objective, observations should not be ignored. Among initiating events, fire initiators are quite significant. Experience has shown that organizational effectiveness regarding housekeeping impacts the likelihood of fire initiation. A constructed measure related to housekeeping may be a more effective performance measure regarding combustibles than some other quantitative parameters. It is also likely to be higher up in the objectives' hierarchy, and therefore a better performance criterion.

In the LMP guidance risk metrics address event sequences that may involve one or more reactor modules or non-reactor radionuclide sources. The guidance offers more details on how useful calculable, proxy or constructed measures may be proposed for non-LWRs. Each technology may have unique properties that require consideration for proposing appropriate performance measures that serve functional roles for operational and oversight purposes.

Step 6: Formulating Suitably RIPB Design Options

Clarity in defining the outcome is a key aspect of implementing a risk-informed and/or performance-based approach. On the issue of safety classification of SSCs for advanced non-LWRs where modern practices become part of the NRC's regulatory framework, an outcome different from the past can be envisaged. The proposed outcome is:

- Prepare a safety case supporting a regulatory finding of adequate safety in which no SSC is required to receive special treatment unless such treatment is needed to enhance safety margins related to performance requirements identified within the safety case.

Thus, SSCs classified as safety-related (SR) or non-safety-related with special treatment (NSRST) should have a formal basis for validating the effectiveness of a special treatment or not require it. In the hierarchy of the regulatory framework, activities that support such an outcome would target rulemaking that is part of the process in 10 CFR Part 52 for certification pertaining to a particular technology and design. Such a rulemaking requires that risk-informed and performance-based ITAACs be prepared geared for assuring that safety considerations associated with design basis events, beyond-design-basis events, and defense-in-depth are satisfactorily addressed.

The biggest challenge could be expected regarding monitoring performance to verify and validate continued confidence in the safety margins. It may not be sufficient to look for actual failures, but to diligently follow up on precursors to actual failure events. Useful information on leading indicators may be found in NUREG/CR-5392 (see Appendix). Although the as-built PRA would be extremely valuable, other techniques involving treatment of uncertainty in decision making as described in NUREG/CR-6833 (see Appendix) may also be helpful. Proper consideration of organizational factors in assuring functional success programmatic defense-in-depth as described in the LMP guidance should be emphasized.

4.2 Example Assessment: Performance-Based Scoring for the Reactor Oversight Process

The regulatory framework for the Reactor Oversight Process (ROP) is a risk-informed, performance-based, tiered approach to assessing plant safety. Although the ROP was developed to provide tools for inspecting and assessing operating licensee performance in a more risk informed, objective, predictable, and understandable way, the structure at the higher levels is technology inclusive and applicable for design, installation, commissioning, operation and maintenance phases also.

The ROP provides a means of collecting information about performance, assessing the information for its safety significance, taking appropriate action, and verifying that corrective actions are taken appropriately. Inspections may be done on a risk-informed sampling basis to obtain representative information. The most essential elements of performance areas which form the foundation for meeting the overall NRC mission were identified from a risk-informed perspective. These elements were identified as the cornerstones of the framework structure. These cornerstones serve as the fundamental building blocks for the oversight process, and acceptable performance in these cornerstones provides reasonable assurance that the overall mission of adequate protection of public health and safety is met. Also, these cornerstones are technology inclusive and applicable to any reactor design.

The purpose of this example is to show how the elements of a performance-based approach could be used to assess the effectiveness of a set of regulatory actions relative to implementing that approach. The concept of a performance-based score, described earlier, will be demonstrated on a trial basis. This exercise may be useful as part of the certification process in which an appendix is incorporated into 10 CFR Part 52 as a response to an advanced non-LWR application. This appendix would be expected to be risk-informed and performance-based.

In the area of reactor safety, the cornerstones of safety are defined as follows:

> **Initiating Events:** The objective of this cornerstone is to limit the frequency of those events that upset plant stability and challenge critical safety functions. The likelihood of a reactor accident is reduced by maintaining a low frequency of such initiating events. Such events include unplanned transients of all types, including reactor trips, loss of key heat removal capabilities, loss of off-site power, and other unexpected events.
>
> **Mitigating System:** The objective of this cornerstone is to ensure the availability, reliability, and capability of systems that mitigate plant transients and reactor accidents. The possibility and consequences of reactor accidents are reduced by enhancing the availability and reliability of mitigating systems. Mitigating systems include those systems associated with heat removal, and associated support systems, including such functions as emergency AC power. This cornerstone includes mitigating systems that respond to events in all reactor states and modes.
>
> **Barrier Integrity:** The objective of this cornerstone is to ensure that physical or functional barriers protect the public from radionuclide releases caused by accidents. The effects of reactor accidents or events are reduced, if they do occur, by maintaining the integrity of, and confidence in, the barriers.
>
> **Emergency Preparedness:** The objective of this cornerstone is to ensure that actions required by the emergency plan provide protection of the public health and safety during a radiological emergency.

In addition to identifying the cornerstones of safety, certain elements of performance were also identified considered as "cross-cutting" and potentially impacting more than one cornerstone. Elements of performance such as human performance, the establishment of a safety-conscious work environment, and the effectiveness of licensee problem identification and resolution programs, although not identified as specific cornerstones, were considered important to meeting the safety mission. These items could manifest themselves as root causes of performance problems. Adequate performance in cross-cutting areas are assessed for each cornerstone area.

For the reactor safety area to fail to meet the goal of adequate protection of public health and safety, an initiating event would have to occur, followed by failures in one or more mitigating systems, and ultimately failure of multiple barriers (physical or functional). If not properly mitigated, and multiple barriers are breached, a reactor accident could result, which would compromise the public health and safety. At that stage, the emergency plan is implemented as the last defense-in-depth measure for public protection.

In the ROP, licensee performance within each cornerstone is measured by a combination of performance indicators (PIs) and inspection results. PIs could be developed for each of the cornerstones to provide an objective indication of design and licensee performance. For the ROP, a risk-informed baseline inspection program was developed to both independently verify the PIs and to inspect those aspects of licensee performance not adequately covered by a PI.

Risk-informed thresholds were developed for both PIs and inspection findings to establish performance bands. These performance bands provide for increased attention if performance degrades, as indicated by crossing risk significant thresholds. A key aspect of using performance thresholds is that it establishes a level of performance that represents success of design and operation. This is the desired outcome that a performance-based approach incentivizes.

The ROP developed a risk-informed scale to establish thresholds for PIs and corresponding thresholds for inspection findings. The attributes of the concept were:

- The scheme should include multiple levels with clearly defined thresholds to allow unambiguous observation and assessment of declining (or improving) performance,
- The thresholds should be risk informed to the extent practical, but should accommodate defense-in-depth and indications based on existing requirements and safety analyses,
- The risk implications and regulatory actions associated with each performance band and associated threshold should be consistent with other risk applications, and based on existing criteria where possible (e.g., Regulatory Guide 1.174),
- The scheme should provide for consistency of risk-informed indications of performance which are based on existing requirements and safety analyses to the extent practical,
- The scheme should be capable of accounting for performance indicated by risk-informed inspection findings,
- Thresholds that cannot be risk-informed should be set at levels that will result in the level of response necessary to address the finding,
- Thresholds should provide sufficient differential to allow meaningful differentiation in performance and limit false positives (e.g., allow an order of magnitude in the risk differential between thresholds),
- Sufficient margin should exist between nominal performance bands to allow for initiatives to correct performance problems before reaching an escalated response threshold; and sufficient margin should exist between thresholds that signify initial declining performance to allow for diagnostic and corrective actions to be effective before performance becomes unacceptable,
- Each individual PI should have its own performance thresholds,
- Where appropriate, the process should take account of specific design or other differences that should be technically accommodated.

The philosophy behind the establishment of the thresholds on PIs and inspection findings was essentially to assume that an increase in PI values or conditions indicated by a performance finding, would, if their root causes were uncorrected, be equivalent to accepting a de facto increase in risk metrics or reduction in safety margins. This is clearer for the PIs than it is for the inspection findings. These factors are entirely consistent with the five principles of integrated risk-informed decision making discussed earlier.

Extensive work was done as part of the ROP activity to develop performance measures and criteria. Although many of these may be specific to operating LWRs, it should be possible to find conceptual analogs for application in a non-LWR at the design stage.

It should be noted that the NRC is implementing an oversight program for plants under construction based on principles like those for operating plants. Hence, NRC practice demonstrates the transference of the ROP structure to reactor projects other than in operations phase.

The emphasis of the NRC approach to focus on performance, as contrasted with compliance, is highlighted by the way the results of the ROP program are reported to the public. The structure of the objectives' hierarchy is reproduced and a display is provided for the performance under the cornerstones of safety for every operating plant. In the interests of transparency, a color code reveals the summaries of the observations associated with each cornerstone, trended over time.

The evaluation of performance is summarized as follows:

Table 4. ROP Model for Evaluating Performance

Performance Description	Response to Observations	Color Code	Comments
Cornerstone objectives met. Nominal risk with deviation from expected performance	Licensee response band	Green	Non-compliances, if any, have no safety significance
Cornerstone objectives met with minimal reduction in safety margin. Slight increase in risk.	Increased regulatory response	White	Safety margins have been assessed and reductions, if any, are minimal. May elicit NRC response
Cornerstone objectives met, but with significantly reduced safety margins	Required regulatory response band	Yellow	Reductions in safety margins deserve heightened NRC scrutiny
Performance represents unacceptable loss of safety margins. Sufficient safety margin still exists to prevent undue public risk.	Extensive regulatory response band	Red	Permission to operate is withdrawn

It is to be noted that the conclusions regarding the risk-informed decision-making process is expressed as the effect on safety margins. Such an approach is entirely consistent with the guidance in NUREG/BR-0303 and the application of the high-level guidelines for performance-based approaches.

It is also worth noting that at the stage where a licensee loses the permission to operate (a decision made by NRC) the level of performance is such that sufficient safety margins still exist to prevent undue risk to the health and safety of the public. This is the reason for the emphasis on regulatory criteria in Essential Attribute #4.

As discussed previously relative to NUREG/BR-0303, performance objectives could become prescriptive at lower levels of the objectives' hierarchy. The lower level structure of the ROP exemplifies how this can happen. Clearly, a performance-based approach was not envisioned two levels below the cornerstone level. This is understandable because the structure represents a merger and transition of the traditional prescriptive approach with a modern approach.

The following pages show the ROP structure below the cornerstones:

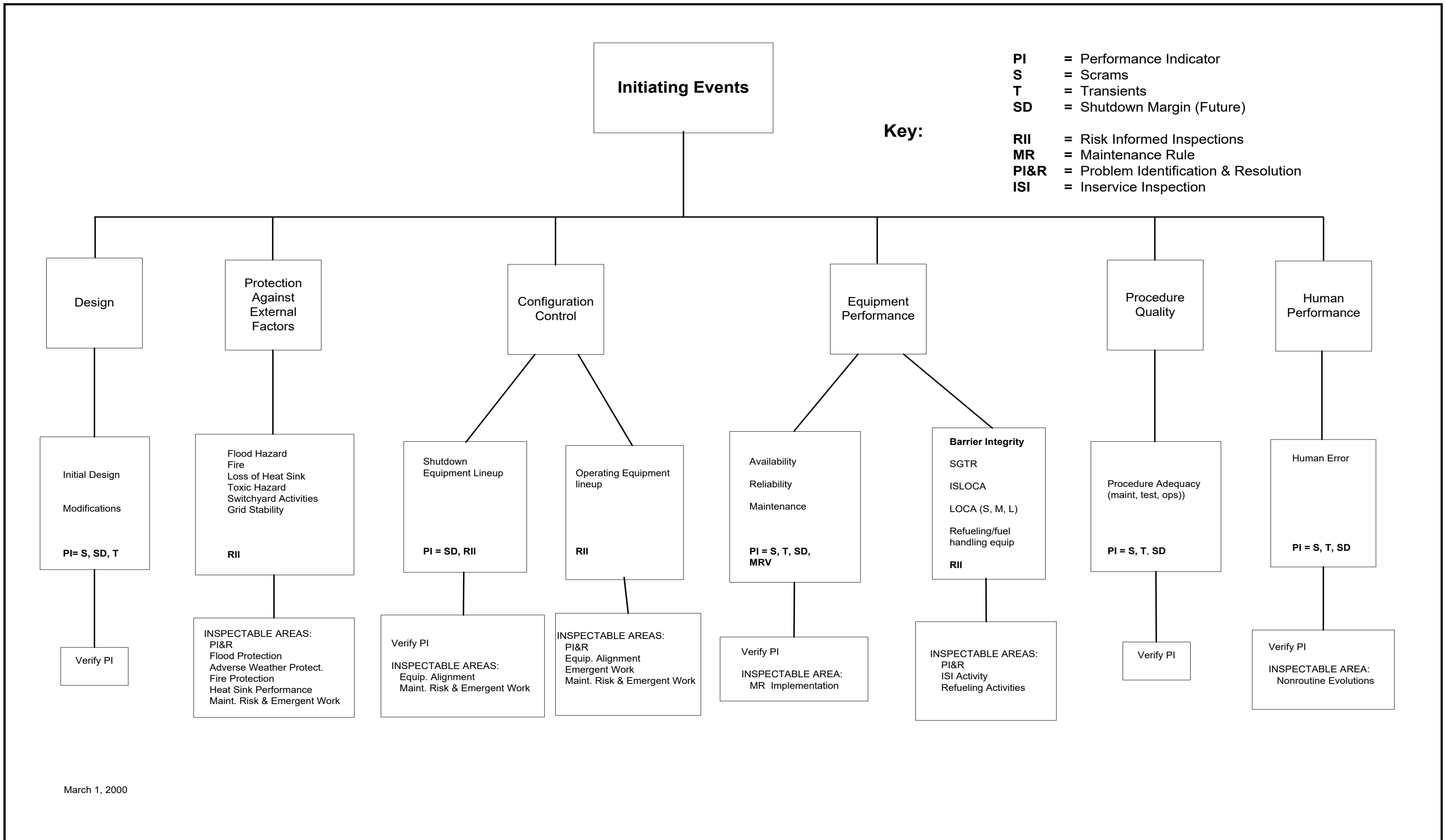

Figure 5. Performance Factors for Initiating Events Cornerstone

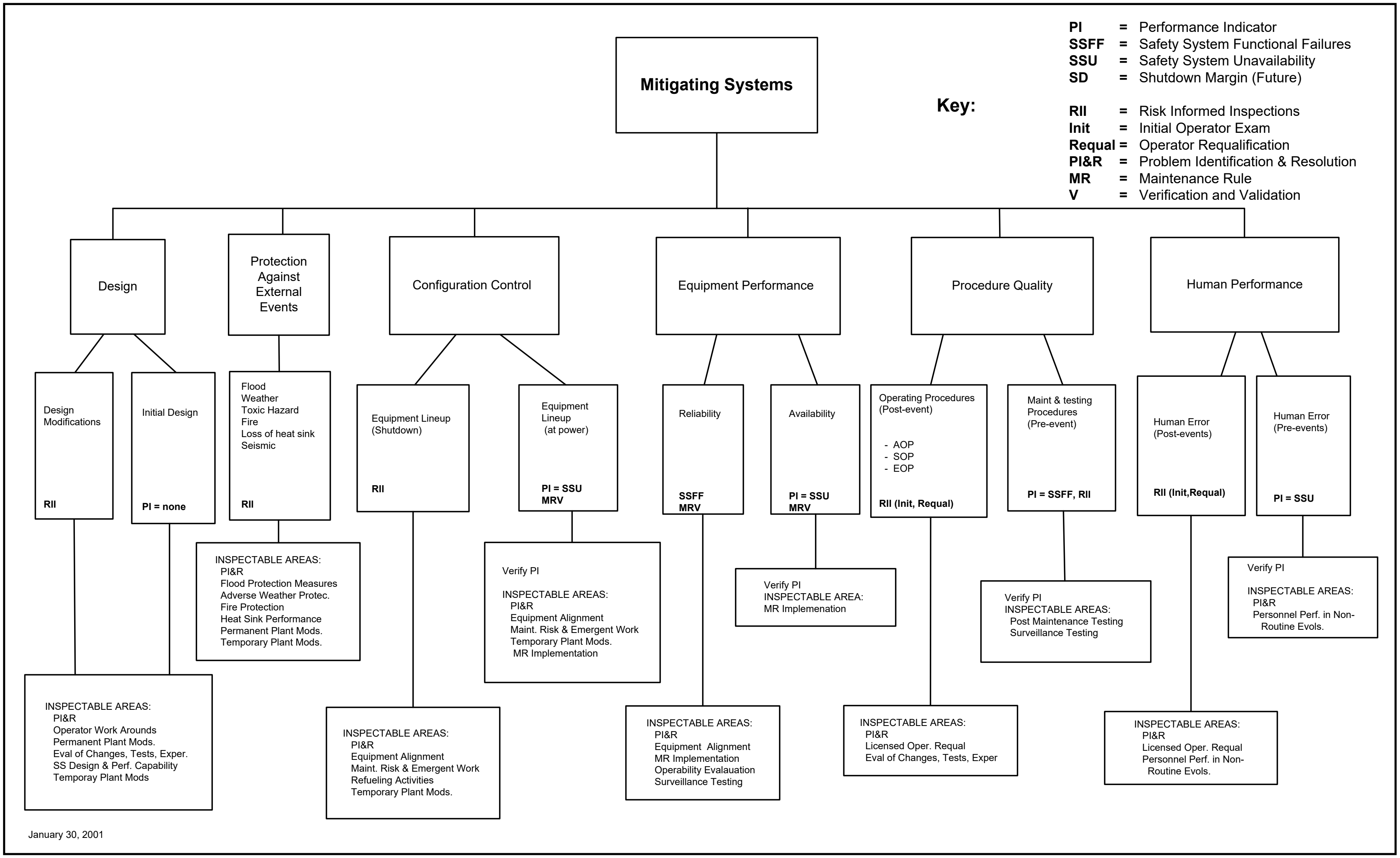

Figure 6. Performance Factors for Mitigating Systems Cornerstone

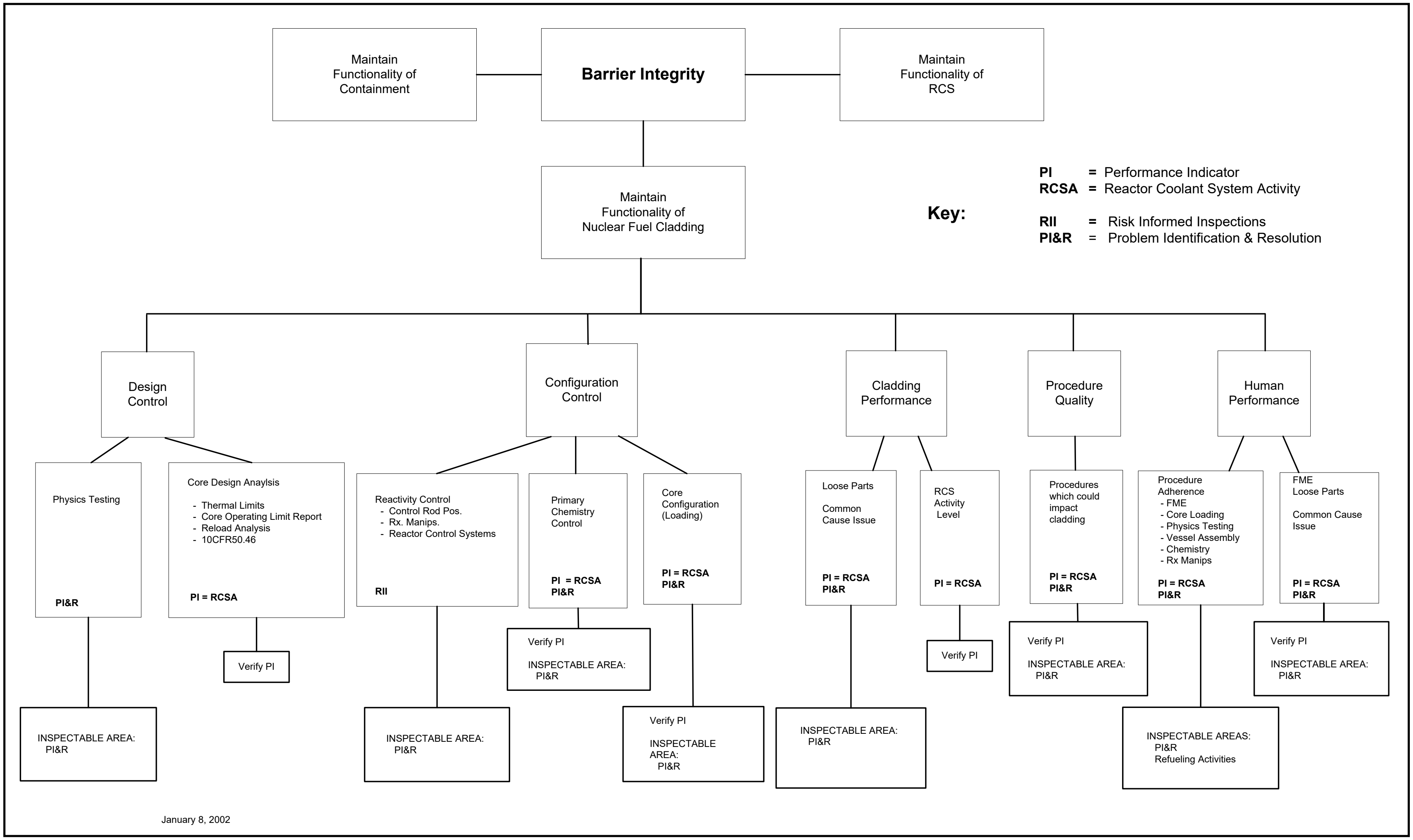

Figure 7. Performance Factors for Fuel Cladding (Barrier Integrity Cornerstone)

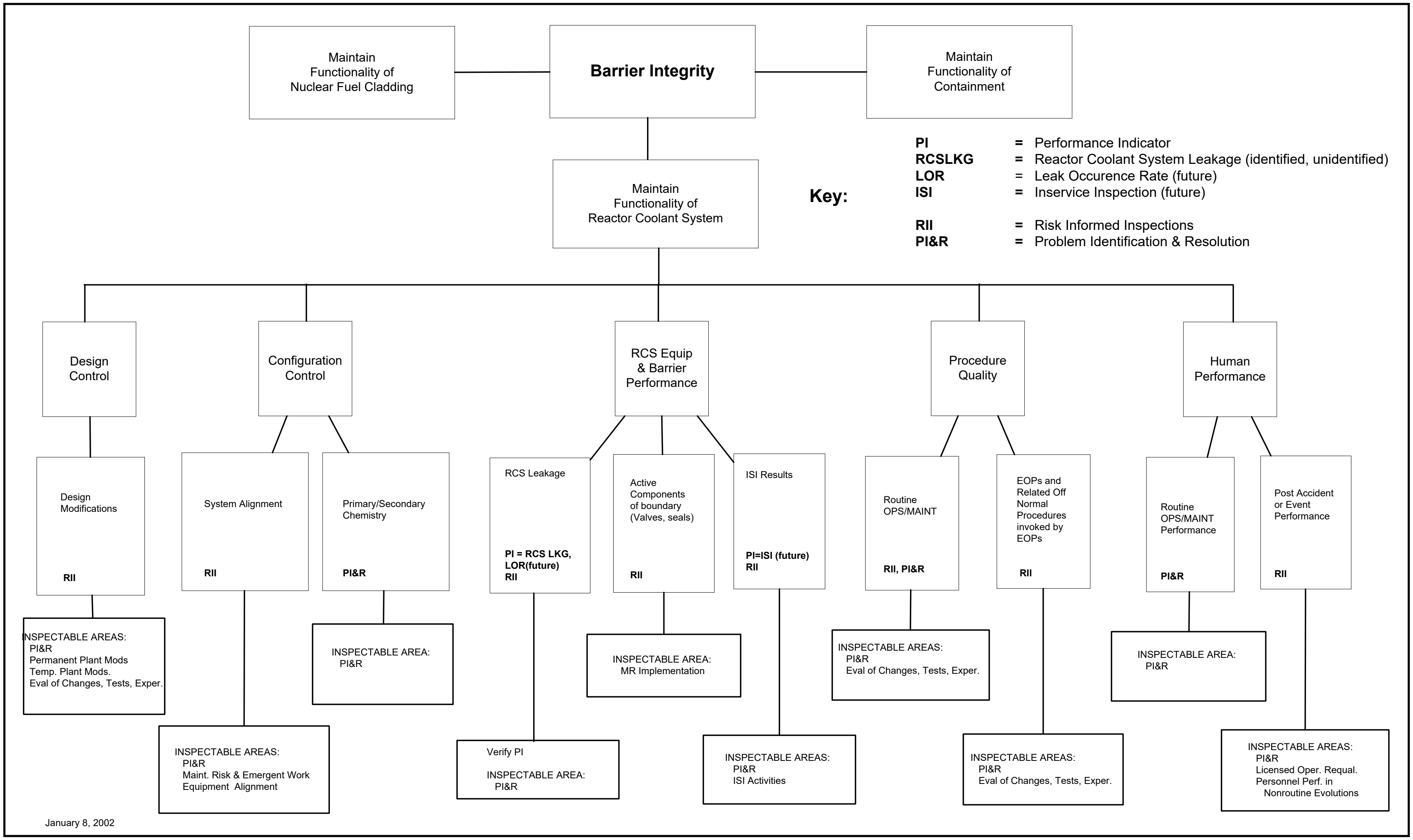

Figure 8. Performance Factors for Reactor Coolant Pressure Boundary (Barrier Integrity Cornerstone)

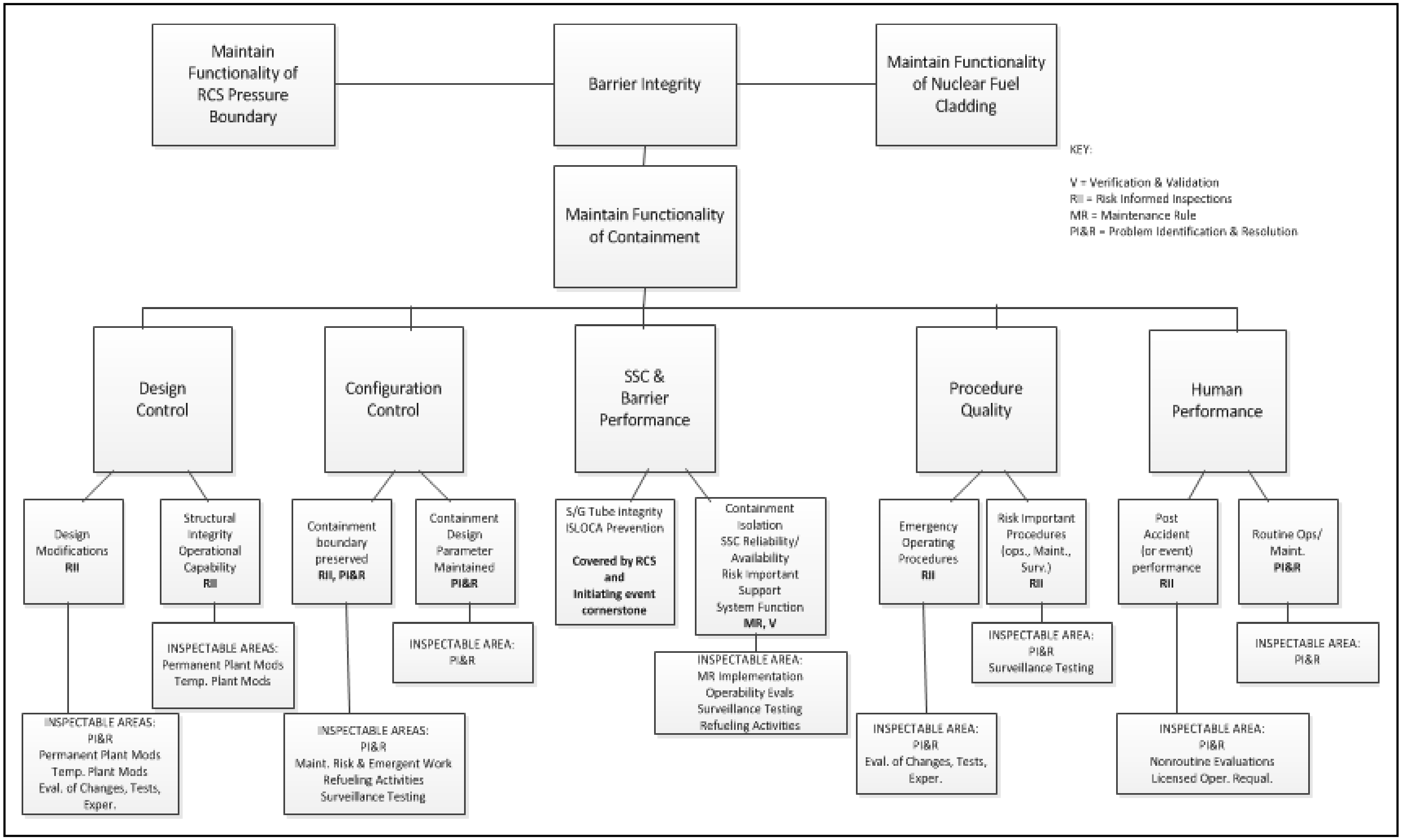

Figure 9. Performance Factors for Containment Function (Barrier Integrity Cornerstone)

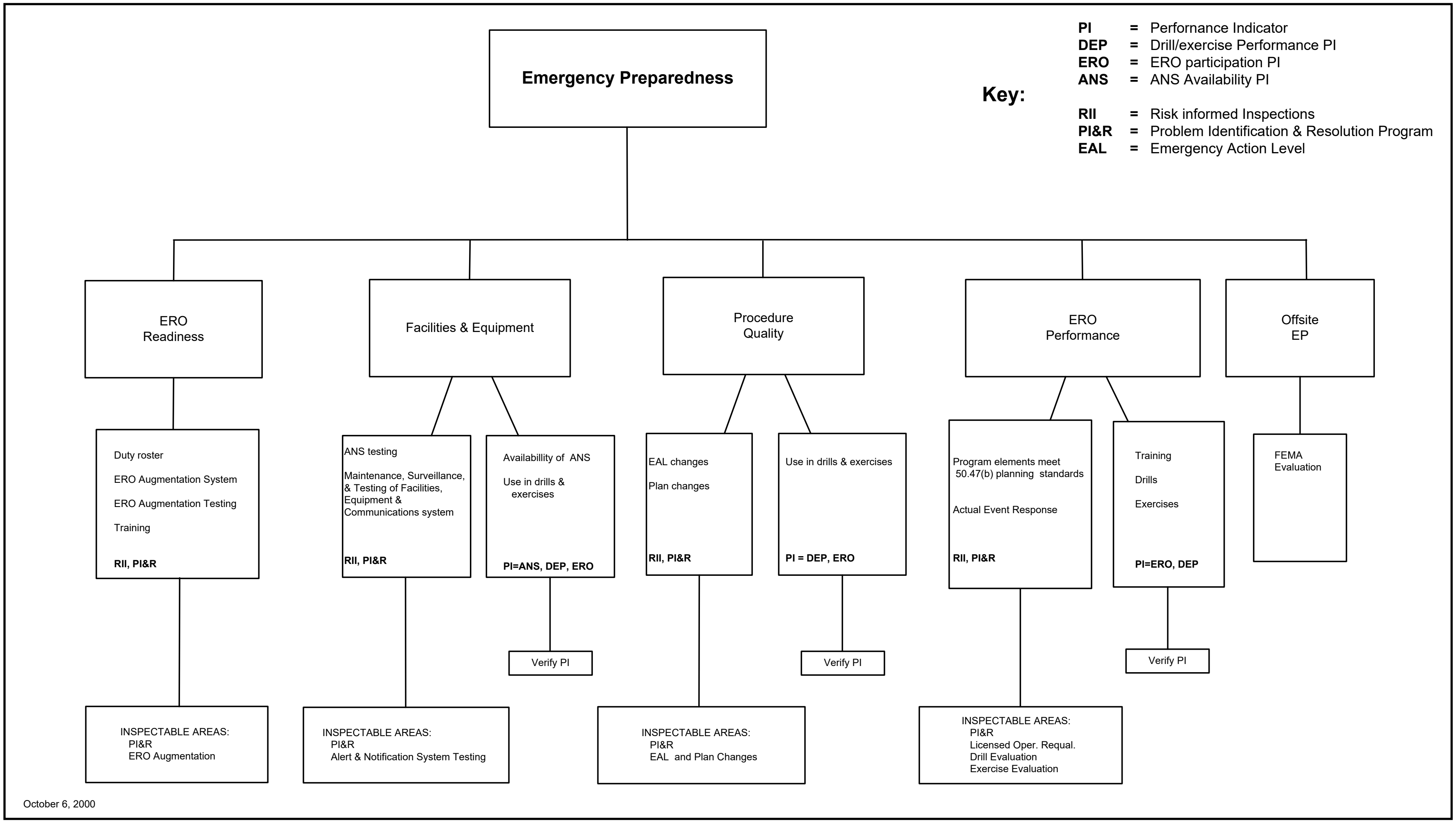

Figure 10. Performance Factors for Emergency Preparedness Cornerstone

The following are noteworthy from the structure of the cornerstones:

- Each cornerstone is decomposed into performance areas that are design related, operations related, and cross-cutting. Similar characteristics would be expected from an objectives' hierarchy for a non-LWR design.
- Many of the observations are not focused on the outcome objectives, but on compliance related factors. This is to be expected from a structure that was overlaid on the existing prescriptive system.
- There was apparently no attempt to apply the high-level guidelines for a performance-based approach.

The following exercises the proposed performance-based scoring system relative to the way that the ROP is currently implemented:

Table 5. Performance-Based Scoring

Attributes and Considerations	Observations from Current ROP Implementation	Proposed Score
Essential Attribute #1: Parameters • Examine the monitoring of performance at each of the hierarchical levels. • Examine the nature of how observations are recorded • Identify what type of measures (natural, constructed, proxy) works best at each level	• The monitoring of performance at levels below the cornerstones are based on complex methods that sometimes consider the plant specific PRA. • Observations are recorded using IMC • Type of measures to optimize PB approach at each level does not seem to exist	15 points
Essential Attribute #2: Criteria • Examine the performance history for the parameters within and outside nuclear technology • Examine whether the observed parameter has a reasonably smooth variation around the acceptance criterion • Examine temporal aspects such as leading or lagging indication	• The performance history for the parameters at each plant is trended • Observed parameters have long standing practice to rely on, so should have smooth variation around the acceptance criterion • Temporal aspects for inspections could have leading or lagging indication	15 points
Essential Attribute #3: Flexibility • Can proportionality between safety margin and flexibility be established? • What are the consequences of a wrong flexibility decision at each level? • At each level, what is the safety significance of error in safety margin assessment?	• Proportionality between safety margin and flexibility has been established. • The consequences of errors at each level get reflected in the cornerstone assessment • The safety significance of error in safety margin assessment is low (Red still has sufficient margin)	20 points

<u>Essential Attribute #4:</u> Margins • A key consideration that may or may not be related to safety significance relates to applicable regulatory criteria and compliance therewith. • What are the safety considerations related to physical and temporal margins and flexibility?	• The margins for safety significance in the ROP relate to PRA-based regulatory criteria and the significance determination process. • The safety considerations related to physical and temporal margins and flexibility have not been considered.	15 points
<u>Desirable Attribute #1:</u> Incentives • At each level are there, and if so how significant, are perverse incentives? • If errors occur in incentives, what are the impacts on Essential Attributes # 3 and 4?	• Perverse incentives have essentially been eliminated by the ROP. • If errors occur in incentives, the impacts on Essential Attributes # 3 and 4 manifest as regulatory impacts and not safety.	5 points
<u>Desirable Attribute #2:</u> Temporal Margins • How does the performance monitoring system react to persistent misuse of flexibility? • What is the safety significance of persistent violation of acceptance criteria?	• The performance monitoring system uses the temporal margins in the design to reduce flexibility if misuse occurs. • The safety significance of persistent violation of acceptance criteria is minimal because of the regulatory response.	5 points
<u>Desirable Attribute #3:</u> Fitness-for-purpose • What are the consequences of strict compliance with criteria, or lack thereof? • At what level in the hierarchy does non-compliance make it impossible to meet outcome objectives? • Are organizational factors geared for correcting non-compliance in a timely fashion?	• The consequences of strict compliance were experienced by the earlier SALP process. • It would be impossible to meet outcome objectives loss of operating permit. • Organizational factors are geared for correcting non-compliance in a timely fashion.	5 points
<u>Desirable Attribute #4:</u> Outcome focus • Is the performance monitoring system designed for and capable of reacting appropriately to trends in observations? • What is the relationship between the incentive structure and observation trends? • At what level in the hierarchy does adverse relationship between safety, compliance and trending data jeopardize outcome objectives?	• The performance monitoring system is designed for and capable of reacting to trends in observations. • The relationship between the incentive structure and observed trends promotes safety. • Adverse relationship between safety, compliance and trending data would be revealed at the cornerstone level.	5 points

Hence, the proposed overall Performance-Based Score is 85. This likely constitutes a quite satisfactory score.

4.3 Example Assessment: Respiratory Protection Rulemaking

This example was a case study included in SECY-2000-0191. It applies all three groups of high-level guidelines to examine and assess changes to 10 CFR Part 20, Subpart H, Respiratory Protection and Controls to Restrict Internal Exposures that were made in 2002. The revised rule is consistent with 1992 American National Standards Institute (ANSI) guidance for respiratory protection and respiratory protection regulations published by Occupational Safety and Health Administration (OSHA). The stated goals of the revision were to reflect existing guidance and to make the requirements for radiological protection less prescriptive while reducing unnecessary regulatory burden without reducing worker protection. A review of the changes made to the requirements indicates three generic types of changes:

1. Administrative changes that clarify the requirements,
2. Regulatory framework changes to the structure of the requirements resulting in a more logical order (e.g., moving Appendix A footnotes to the regulatory text), and
3. Regulatory changes that change the requirements explicitly identified in the rule and thus may impact the licensees' regulatory burden.

The purpose of this case study is to apply the three groups of guidelines to specific regulatory requirements and determine whether the revised rule can be judged to be more performance-based than the prior version of the rule. Hence, the guidelines are being applied as an assessment tool to the changes made to the rule by a revision, and not to the rule. The assessment was performed using a sampling approach. To assess the impact of the change to Subpart H, three of the changes to the rule were analyzed. The three changes selected were of the third type above. One change reflected an increased regulatory burden, one a reduction in regulatory burden, and one an overall neutral impact on the regulatory burden.

Application of the Viability Guidelines

The sample of three rule changes are examined below:

1. A provision to reduce regulatory burden was contained in §20.1702(b), which added text to permit licensees to consider safety factors other than radiological factors when performing an ALARA analysis to determine whether respirators should be used. Applying the viability guidelines to assess this change results in the following:

   Guideline 1a: By definition, the ALARA program operates in a dose regime that does not correspond to an immediate safety concern. Generally, the airborne concentrations of radioactive material are such that failure of performance criteria will not result in an immediate safety concern. By including non-radiological safety factors, the revised requirement should result in lower total risk. Thus, the revised requirement should generally increase the safety margin. On occasion, hazards may be such that a failure of equipment might result in a relatively small safety margin. These rare cases may result in more prescriptive requirements for equipment.

Guideline 1b: The parameters should reflect licensee performance of the ALARA program as well as consider non-radiological factors that affect worker safety. Under the original rule requirements, the non-radiological factors had to be considered, but were divorced from the radiological ALARA determination. This could have resulted in reduced worker protection from non-radiological factors while licensees sought to meet ALARA requirements. Measurable or calculable parameters would be available from performance history associated with the non-radiological and ALARA factors. When compared to the prior version of the Subpart H requirements, the revised requirement would only require identification of parameters associated with non-radiological safety factors, such as trending of occupational health and safety incidents, in addition to parameters associated with radiological factors.

Guideline 1c: Objective criteria to assess performance of a licensee's ALARA program exist in the form of past performance. Objective criteria on performance of a licensee's ALARA program could be based on trending of worker doses.

Guideline 1d: The prior version of the requirement allowed licensee flexibility by the definition of ALARA. The revised requirement provides another degree of freedom for the ALARA analysis by including non-radiological safety factors. Under the revised requirement, it is possible for the ALARA analysis to result in higher doses to workers but lower overall risk to the workers once non-radiological safety factors are included. By allowing slightly higher worker doses in this scenario, the NRC has provided the licensee increased flexibility. Thus, flexibility is increased with the revised requirement.

Summary: This change expands the scope of the ALARA analysis by including non-radiological safety factors. This introduces greater flexibility by not requiring respirator use in some circumstances in which it would previously have been required. The licensee may, however, expend some extra effort in justification. The net effect may be to decrease overall licensee burden. In summary, this change satisfies the viability guidelines, making the revised rule more performance based than the prior version.

2. A provision that increased regulatory burden was contained in §20.1703(c)(6) which added text to require fit testing before first field use of tight-fitting, face sealing respirators and at least annual testing thereafter. The quantitative criteria for successful fit testing are also codified. The prior version of the rule only included a requirement that the licensee's respiratory protection program include written procedures for fitting. The revised rule does not alter these requirements but includes specific requirements for fit testing frequency and quantitative criteria for test fit factors that must be achieved during testing in order to use the Appendix A APFs. These new specific requirements explicitly provide lower-level (less outcome-oriented) objective criteria for assessing fit testing. Both the prior version of the rule and the revised rule included a requirement that the licensee include surveys and bioassays, as necessary, to evaluate actual intakes in the respiratory protection program.

   Applying the viability guidelines to assess this change results in the following:

Guideline 1a: For performance in the area of respirator equipment fitting, sufficient safety margin may not exist when performance criteria are not met. As discussed above in the analysis of the ALARA program, hazards may be such that a failure of the respirator fitting properly may result in a relatively small safety margin. In addition, time is not available for taking corrective action due to the nature of the hazards, such as internally deposited radioactive material or non-radioactive airborne materials, and the typical frequency of surveys and bioassays.

Guideline 1b: The parameters that measure desired outcomes associated with this requirement, dose due to internal exposure, are not affected by this change. The revised requirement explicitly mentions lower-level parameters for monitoring performance, but these parameters do not measure outcomes and were implicit in the prior version of the rule.

Guideline 1c: Objective criteria to assess performance of a licensee's fit testing exist. The revision simply explicitly stated some of the objective criteria for fit testing.

Guideline 1d: The prior version of the rule allowed licensee flexibility by only specifying that a written procedure for fitting be included in the respiratory protection program. The revision adds requirements at a lower level: it increases the specificity of requirements imposed by the rule. Thus, application of the third viability guideline would indicate that the revised rule may be less performance-based.

These scenarios require prescriptive requirements for fit testing. In addition, since proper fit is assumed when making dose calculations for legal records, prescriptive requirements are necessary to provide the proper assurance of accuracy. This guideline therefore corresponds to the motivation for the rule change.

Summary: This revision to the rule does not make the rule more performance-based. However, the reason for this is that sufficient safety margin and time for taking corrective action do not exist in the event the performance criteria are not met.

The viability guidelines indicate that this area of the rule is not suitable for performance-based activities and support the motivation for the rule change.

3. A provision considered neutral relative to regulatory burden was included in the rulemaking relative to §20.1703(a)(6) [which becomes §20.1703(e) in the revised rule] such that text was added to require consideration of low temperature freezing of exhaust valves on negative pressure respirators and removed text that specified protection against skin contamination. The only difference between the prior version of the rule and the revised rule for this particular change is the list of requirements explicitly mentioned by the rule that need to be considered when selecting respiratory protection equipment. Adding the requirement for consideration of low temperature work environments increases the analysis effort explicitly required. Removing the requirement for consideration of skin contamination requires the licensee to address skin contamination using means other than respiratory equipment. Applying the viability guidelines to assess this change results in the following:

Guideline 1a: Failure to meet the performance criteria of either the prior version of the rule or the revised rule could lead to situations that do not provide sufficient safety margin or time for taking corrective actions. For example, failure to consider low temperature work environments could result in exhalation valves on negative pressure respirators to freeze in the open position due to moisture from exhaled air when temperatures are below freezing. This situation would provide a pathway for airborne hazards, such as radioactive material, to bypass the respirator filter without the users' knowledge. Thus, requirements are necessary to provide worker protection while in radioactive areas. This guideline therefore corresponds to the motivation for the rule change.

Guideline 1b: The parameters would be equivalent for the prior version of the rule and the revised rule.

Guideline 1c: The objective criteria may be based on performance history.

Guideline 1d: Although the list of requirements explicitly mentioned changes, the net effect on licensee flexibility is negligible. The level of specificity of the explicit requirements does not change. Since the objective criteria remain equivalent, the flexibility is unchanged by the change to the Subpart H requirements.

Summary: The revised rule is not more performance-based than the prior version of the rule. The specific requirements changed in this example are prescriptive due to the fact that sufficient safety margin and time for taking corrective action do not exist in the event the performance criteria are not met. This example does demonstrate the validity of using the viability guidelines to assess performance-based activities and support the motivation for the rule change.

Conclusion: Application of the guidelines to the three selected changes to the rule indicates that the changes appear to comport with the guidelines. A premise in the testing of the guidelines was that the process of testing may indicate a need to change one or more of the guidelines. The guidelines worked well as they are and no changes are proposed as a result of the testing.

Application of Assessment Guidelines

For completeness, the changes to the requirements of Subpart H were evaluated against the remaining performance-based guidelines to verify that the changes resulted in a net regulatory benefit. For this evaluation, the composite of all the changes must be evaluated to provide the integrated consideration required, rather than evaluating each change individually. Thus, the results of the sampling approach above are extrapolated to include all changes to the rule when necessary. However, this evaluation is based primarily on the existing results contained in the staff's Statement of Considerations and the Regulatory Analysis for the amendment of Subpart H requirements.

Guideline 2a: The following factors were noted:

- Allowing the consideration of non-radiological safety factors when performing an ALARA analysis results in an overall reduction in the worker's risk from all hazards;
- Explicitly identifying fit test criteria, intended to ensure that sufficient margin of safety (specifically, proper fit) is maintained under field and work conditions,

increases assurance that respiratory equipment will perform as expected during use;

- Explicitly identifying environmental factors, such as low temperatures, for consideration in determining respiratory protection increases assurance that the proper operation of respiratory equipment will not be adversely affected during use.

Guideline 2b: The following factors were noted:

- Identifying regulatory requirements in the amended rule text and removing guidance from the rule, such as moving some of the Appendix A footnotes to the regulatory text and deleting some that are addressed in the Regulatory Guide, clarifies the requirements and reduces confusion;
- Recognizing new devices and new technologies updates the rule to reflect current practices by licensees;
- Allowing use of single-use disposable masks when ALARA analysis indicates that respiratory protection is not necessary, provides a means for addressing respiratory protection equipment when requested by the worker.

Guideline 2c: The following factors were noted:

- Including decontamination to reduce resuspension of radioactive material in the work place provides an effective and efficient means of controlling internal dose instead of using respirators;
- Adopting the existing guidance of ANSI, such as reduced equipment assigned protection factors (APFs) provides consistency;
- Adopting the existing requirements of OSHA, such as fit testing frequency and fit factors for positive pressure, continuous flow, and positive-demand devices, provides consistency.

Guideline 2d: The following was noted:

- Each amendment to the rule was reviewed by the staff to determine the impact on licensee burden and the conclusion was that 13 amendments reduced burden, 3 amendments increased burden, and 36 amendments had no impact on burden; with the net result being a reduction in licensee burden.

Guidelines 2e, f, and g: The following was noted:

- The backfit analysis performed by the staff for the amendments concluded that the changes constitute not only a burden reduction, but also a substantial increase in the overall protection of public (worker) health and safety. Based on a review of public comments, public confidence is not significantly affected by the rule amendments. However, it is assumed that the substantial increase in the overall protection of worker health and safety would result in an associated increase in public confidence. The Regulatory Analysis estimated a net benefit of $1.5 million per year, including the cost to revise licensee procedures. Finally, since this is an amendment to an existing rule, the regulatory framework can inherently incorporate the approach into the existing regulatory framework. Thus, the existing

Regulatory Analysis adequately addresses the regulatory improvement guidelines, demonstrating that the amendments to the rule result in a net regulatory benefit.

Application of Consistency Principles

The revision is inherently consistent with other regulatory principles. However, use of the guideline will support the assertion that the guideline is valid for evaluating future performance-based activities. The revised rule is consistent with 1992 American National Standards Institute (ANSI) guidance for respiratory protection and respiratory protection regulations published by Occupational Safety and Health Administration (OSHA). The findings of the environmental assessment analysis state that the revised rule is expected to result in a decrease in the use of respiratory protection and an increase in engineering and other controls to reduce airborne contaminants while maintaining total occupational dose as low as reasonably achievable. Thus, subject to the limitations of the sampling approach used, the revision to the rule is consistent with other regulatory principles.

5. REVIEW OF OUTCOME OBJECTIVES

This report emphasizes technical aspects of a risk-informed and/or performance-based approach because standardizing what those terms mean will substantially advance the cause of developing a coherent, holistic, risk-informed, and performance-based reactor licensing structure. While much literature has addressed developing and using risk information, a single document that summarizes the state of knowledge on the integrated view of risk-informed and performance-based approach does not currently exist.

The question, “Why use performance-based approaches?” should be seen in the context of performing an optimization among four approaches: (1) the traditional prescriptive approach; (2) a risk-informed approach; (3) a performance-based approach; and (4) a risk-informed and performance-based approach. This guidance document addresses the following:

- Assuring safety with complex systems such as reactors will require a sound basis for allocating performance among the many competing functional demands of a reactor design, making it necessary that risk information be available as part of integrated decision-making.
- Assuring that the evidence from construction and operation phases of a design is consistent with the desired outcomes of the design phase makes it necessary to employ the formal aspects of a performance-based approach so that effectiveness (as defined by congruence between expectations and outcomes) can be demonstrated.
- Overall, specific prescriptive requirements, such as ASME Code criteria, will always be needed. Hence, although a dichotomy between prescriptive and performance-based criteria may appear as a local choice on some issues, no one approach should be expected to meet all complex needs.

The answer to the question, “What is the basis for guidance on risk-informed and/or performance-based approaches?” is that the Commission’s definitions provide the bases for performance-based as well as risk-informed and performance-based approaches. A technique akin to formal methods is used to extract logical concepts and relationships from definitions that have an authoritative standing to help reduce ambiguity that is inevitable in some of these terms. The increased precision in understanding of the terminology enables more effective conversion of ideas expressed linguistically into actionable statements. This has been implemented in NRC guidance for performance-based regulation, NUREG/BR-0303. In it a connection is made between certain essential and desirable attributes, and physical and temporal margins while executing a performance-based option. The formality and use of margins are key to distinguishing the performance-based approach from the others.

The ideas related to margins and other aspects of the Commission’s definitions are used to answer the question, “How is the guidance on performance-based approaches to be implemented?” The experience with development of the Maintenance Rule (10 CFR 50.65) showed that focusing on outcomes can help simplify the regulatory approach on a complex set of issues. The Reactor Oversight Process does this because it is characterized by a hierarchical structure that enabled accountability at various levels of performance. For example, actions taken at the field level can be related to the highest mission related outcomes in a formally structured approach.

Additionally, to maintain accountability toward outcomes, this document also contains high-level guidelines for implementing and assessing a performance-based option. These were categorized as viability guidelines, assessment guidelines and guidelines to assure consistency with principles and policies that need to be explicitly considered.

This document makes the point that the principles, structure and processes of the Reactor Oversight Process are more generically applicable than merely for operating reactor regulatory oversight. In principle, it is important to maintain continuity between performance factors that influence safety going from design to construction to operation. It would be beneficial to the advancement of non-LWRs if a lesson learned from past experience is that a modernized licensing framework should avoid unnecessary compartments.

The proposed licensing framework is simply stated in functional terms. To achieve the goal of adequate protection of public health and safety, the designer must assure that sufficient and highly reliable safety margins have been provided for in consideration of a suitable set of design basis accidents postulated to challenge safety systems in a way that covers the most significant risk factors. Cost cannot be a consideration in designing these safety systems or providing for the required margins. Additional risk reduction measures should be provided for beyond those included within the design basis. These measures can consider cost as a factor in design decisions. Measures that are too expensive in comparison with the benefits achieved could be rejected. Fire protection is an example of a beyond-design-basis consideration for which costs can be considered but should be functionally provided. Lastly, the design should provide for defense-in-depth adequately. An example of adequately providing for defense-in-depth is to consider formally the attributes for defense-in-depth identified in the functional analysis described in the LMP guidance. These should be considered as outcome objectives for implementation of an integrated risk-informed and performance-based approach.

While Commission direction and guidance provide a sufficient basis for pursuing a modernized licensing framework, there remained a need to include within the framework development of formal processes and practices for decision making. It is essential that the safety of advanced reactors be assessed from the perspective of integrated safety outcomes. Lack of integrated decision making has often led to focus on isolated objectives that may not optimize overall outcomes. Such sub-optimized results inevitably lead to greater costs. The work documented in NUREG-2150 provides the framework for decision making for integrated risk managed outcomes. Such a framework includes functions of assessment and monitoring. This document proposes a scheme for assessing the results of a process that was intended to use a performance-based approach. This scheme uses the same techniques as employed for the high-level guidelines to pose and answer questions that elicit information to perform the assessment. It is proposed that a score be awarded to each of the essential and desirable attributes to come up with an overall score. The score is proposed within a 100-point scale.

This document provides three examples in which various steps associated with implementing or assessing a risk-informed and performance-based approach have been exercised. The first example is a hypothetical safety classification system for non-LWR SSCs. The example works through what results might be possible if the traditional approach is set aside and a different set of premises based on a performance-based approach were adopted. A designer optimizing for cost, but still providing for functional requirements under design-basis and beyond-design-basis conditions, might be able to propose commercial grade items that have the requisite properties related to magnitude and confidence level in the safety margins. The default classification for SSCs would then be commercial grade. The functional reliability needed to show adequacy of response to design basis conditions could be demonstrated by employing redundancy, diversity and independence as additional attributes to support the design. Special treatments would be imposed only if such treatment demonstrably improves particular aspects of the magnitude and confidence level for the safety margins. Such a possibility could be considered as being within the range of existing Commission decisions.

The second example represents a hypothetical assessment of the ROP with a focus on characterizing the attributes from the perspective of a formal risk-informed and performance-based approach. The ROP is currently administered through the inspection function of the NRC. The inspection procedures provide all the information about the program. Although no reference has been given to NUREG/BR-0303, the structure and processes in the program conform quite closely to the performance-based guidance. Where there are significant differences, it appears to be because the ROP was overlaid upon an existing program.

The third example is also a hypothetical assessment, but the subject is not directly reactor related. It involves a rule change to 10 CFR Part 20 dealing with worker respiratory protection. The high-level guidelines were exercised to show how prescriptive requirements play an important role within a performance-based framework.

In summary, this document presents information that shows the availability of existing principles, processes, practices and documents to prepare a license application for a non-LWR using a risk-informed and performance-based approach. Commission level policy guidance can be used to show conformity with required attributes in a formal manner. Such conformity should be necessary and sufficient for a staff review to reach a conclusion regarding adequacy of protection as applied to a new design.

6. REFERENCES

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APPENDIX

APPENDIX A: REGULATORY FOUNDATION

In this Appendix, background is described that has developed over the past several decades which enables an understanding of the policy and practical reasons that have and are continuing to motivate a drive toward risk-informed and/or performance-based approaches. The driving forces arise not only on account of concerns regarding efficiency and effectiveness for implementing safety measures, but also to address major issues related, for example, to procurement activities. More recently, an important driver that has developed is related to international trade. Overly prescriptive specification of characteristics of goods and services have been found to become impediments to free and efficient trade. International disputes have arisen because a country may object to overly detailed requirements as being an unfair trade practice on the part of another country.

Whether related to nuclear power reactor safety or other matters (such as building codes) the difficulties with prescriptive approaches have accumulated over decades. The ease of conducting business and enforcing rules and criteria using a prescriptive approach is a strong attraction when there is schedule and resource pressure. The countervailing arguments in favor of a performance-based approach generally requires that key decision makers be convinced of the ineffectiveness of the prescriptive approach applied in the traditional way.

Performance-based approaches became a significant imperative for change within the practice of safety regulation at the NRC by the enactment of the Government Performance and Results Act (GPRA) in 1993. This section relates GPRA to regulatory thinking that prevailed in the early 1990s when issues related to maintenance preventable functional failures became apparent. Many observers related the poor capacity factors for nuclear power plants during the 1980s to lack of maintenance effectiveness, which in turn, some related to prescriptive requirements that were not producing desired outcomes. This section begins with the two important statutes that are prime drivers for relying more on performance standards rather than prescriptive directives. Initiatives undertaken at the NRC are described, which were always considered in conjunction with availability of risk information to offer objective measures of safety significance.

A.1. US REGULATORY FOUNDATION FOR PURSUING PERFORMANCE-BASED APPROACHES

A.1.1 Federal Mandates

The Government Performance and Results Act

The Government Performance and Results Act of 1993 (P.L. 103-62), known as GPRA or the Results Act is intended to bring about a fundamental transformation in the way government programs and operations are managed and administered. It sought to promote greater efficiency, effectiveness, and accountability in federal spending by establishing a new framework for performance management and budgeting in federal agencies. The act established government wide requirements for agencies to set strategic and annual performance goals and to report annually on their results in achieving goals. It led to federal agencies tracking progress by identifying promising practices in performance measurement and results-based management, as well as by evaluating agencies' strategic and performance plans. All this provides Congress and federal managers with more objective information on the results of federal programs and thus means to improve government performance and accountability.

The gradual transition of federal agencies away from the old-fashioned prescriptive approaches is being facilitated by the structure and processes provided for within GPRA. The Act requires a comprehensive mission statement covering the major functions and operations of an agency. This would be the basis for developing general goals and objectives, including outcome-related goals and objectives, for the major functions and operations. A description is required of how the goals and objectives are to be achieved, including a description of the operational processes, skills and technology, and the human capital, information, and other resources required to meet these goals and objectives. In recognition of the need for a hierarchical structure to address such challenges, the performance goals to be included in the performance plan are also required to relate to the general goals and objectives in the higher-level strategic plan.

The performance plan covering each program activity is required to:

- Establish performance goals to define the level of performance to be achieved by a program activity;
- Express such goals in an objective, quantifiable, and measurable form;
- Describe operational processes, skills, and technology, and the human, capital, information, or other resources required to meet the performance goals;
- Establish performance indicators to be used in measuring or assessing the relevant outputs, service levels, and outcomes of each program activity;
- Provide a basis for comparing actual program results with the established performance goals; and
- Describe the means to be used to verify and validate measured values.

The far-reaching impacts of GPRA are highlighted by the rigor with which details of a performance-based approach are addressed. For example, the definitions include the following:

- “Outcome Measure” means an assessment of the results of a program activity compared to its intended purpose;
- “Output Measure” means the tabulation, calculation, or recording of activity or effort expressed in a quantitative or qualitative manner;
- “Performance Goal” means a target level of performance expressed as a tangible, measurable objective, against which actual achievement can be compared, including a goal expressed as a quantitative standard, value or rate;
- “Performance Indicator” means a value or characteristic used to measure output or outcome;
- “Program Activity” means a specific activity or project; and
- “Program Evaluation” means an assessment, through objective measurement and systematic analysis, of the manner and extent to which programs achieve intended objectives.

It is notable that GPRA differentiates between “outcomes” and “outputs”. An outcome has far more complex characteristics, having to take account of intended purposes. Outputs are far simpler entities perhaps merely requiring checking a table or recording a quantity. More frequently than not, outputs are associated with prescriptive approaches just as outcomes are associated with performance-based approaches.

OMB Circular A-119

The Federal Office of Management and Budget (OMB) has responsibility toward OMB Circular A-119: “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.” OMB revised this Circular in January 2016 considering developments in regulation, standards, and conformity assessment since the Circular was last revised in 1998. The revisions to the Circular inform agencies of their statutory obligations in standards-setting activities. The term “standards-setting” is a legal term that includes promulgation of agency regulations. The USNRC is an independent agency and is not required to comply with OMB Circulars. However, in the case of OMB Circular A-119, the agency has chosen to comply through its Management Directive 6.5, “NRC Participation in the Development and Use of Consensus Standards.” Relative to consideration of performance-based approaches, the NRC is subject to the provisions of the revised OMB A-119 because it includes a requirement that standards-setting should include:

> *“Developing standards based on performance criteria rather than design criteria when appropriate*”

As mentioned above, OMB Circular A-119 is directed at federal agencies, and one of the specific questions addressed is:

> *“Should my agency give preference to performance standards?”*

The revised Circular A-119 provides the following answer:

> *“Yes. Pursuant to Section 1(b)(8) of Executive Order 12866 and 19 U.S.C.§ 2532(3), your agency should give preference to performance standards where feasible and appropriate. The term “performance standard” refers to a standard that states requirements in terms of required results, but without stating the methods for achieving the required results. A performance standard may define the functional requirements for an item, operational requirements, and/or interface and interchangeability characteristics. A prescriptive standard, by contrast, may specify design requirements, such as materials to be used, how a requirement is to be achieved, or how an item is to be fabricated or constructed. It is important to recognize that, in many instances, a standard may contain both performance and prescriptive elements. In such cases, agencies should select standards that provide the most flexibility for achieving the desired results. In most instances, these will be standards that rely more heavily on performance-based criteria.”*

The Circular explicitly clarifies that agencies should consider the extent to which a standard establishes performance rather than design criteria, where feasible. This can have implications relative to licensing and certification of advanced reactor designs because each license or certificate is a separate rulemaking process. An applicant has the option of presenting information for NRC staff review that employs a performance-based approach, and the staff may be obliged to review such information using the guidance that is currently in place.

Certain provisions of OMB Circular A-119 can have implications for US reactor vendors that wish to participate in the globalization of nuclear technology. Among international trade obligations that US agencies must pay attention to are treaty obligations with the World Trade Organization (WTO). Such obligations arise for all sides of the trading arrangement, but the significance for US companies is that asserting violation that may occur with any other side may require that the US side is able to show scrupulous observance of such provisions. For example, the Circular states:

> *"The United States also has procurement obligations under the WTO Agreement on Government Procurement (GPA) and several Free Trade Agreements (see FAR Subpart 25.4) to base the technical specifications on international standards, where available. Article X.2 of the WTO GPA provides:*
>
> *In prescribing the technical specifications for the goods or services being procured, a procuring entity shall, where appropriate:*
>
> *(i) set out the technical specification in terms of performance and functional requirements, rather than design or descriptive characteristics; and*
>
> *(ii) base the technical specification on international standards, where such exist; otherwise, on national technical regulations, recognized national standards or building codes."*

Hence, if a US company's advanced reactor design certification meets performance-based standards, it is highly likely that it may have significant competitive advantage in relation to other countries that belong to the WTO but use prescriptive standards. To some extent, performance standards may also help with protecting intellectual property assets by the way a structural performance model can differentiate higher-level functional criteria from lower-level prescriptive requirements.

A.1.2 NRC Regulations

Outcome Objective of NRC Regulations and Practice

A summary of the NRC's overall regulatory approach ("Enhancing Reactor Safety in the 21st Century", Report of the Near-Term Task Force, July 2011: Ref. 1) for ensuring safety has articulated the essential elements of the review that NRC conducts with respect to information submitted by an applicant or licensee. This summary in the NTTF report was directed at providing the background information on the goals of the NRC's regulatory framework and practices to support a recommendation to enhance the framework to make it logical, systematic, and coherent for adequate protection that appropriately balances defense-in-depth and risk considerations. It characterized the NRC review as including considerations of design basis requirements, and additional risk reduction requirements and programs for implementing a defense-in-depth philosophy. NTTF states that design-basis events became a central element of the NRC's safety approach almost 50 years ago when the U.S. Atomic Energy Commission formulated the idea of requiring safety systems to address a prescribed set of anticipated operational occurrences and postulated accidents. In addition, the design-basis requirements for nuclear power plants included a set of external challenges including seismic activity and flooding from various sources. That approach and its related concepts of design-basis events and design bases were used in licensing the current generation of nuclear plants in the 1960s and 1970s.

NTTF points out that the concept of design-basis events has been equated to adequate protection, and the concept of beyond-design-basis events has been equated to beyond adequate protection (i.e. safety enhancements). Requirements addressing beyond-design-basis concerns were included when they were found to be associated with a substantial enhancement in safety and justified by cost considerations.

NTTF charted the course of evolution in the regulatory approach through the period after the Three-Mile Island accident with the following observations:

> "*Starting in the 1980s and continuing to the present, the NRC has maintained the design basis approach and expanded it to address issues of concern. The NRC added requirements to address each new issue as it arose but did not change the fundamental concept of design basis events or the list of those events; nor did the NRC typically assign the concept of adequate protection to these changes. The historical development of requirements to address issues beyond the design basis, including the potential loss of all ac power (i.e., SBO) and other issues were beyond what was required for adequate protection.*"

Further, NTTF extended the evolution of the regulatory approach to current times taking into consideration risk-informed regulatory practices as well as the regulatory actions taken to include terrorist threats that impact nuclear safety:

> *"Currently, risk-informed regulation (i.e., regulation using PRAs) serves the limited roles of maintenance rule implementation, Regulatory Analysis Guidelines, the search for vulnerabilities (e.g., through the IPE and IPEEE programs), the Reactor Oversight Process (ROP) and its significance determination process, and voluntary license amendment applications (e.g., risk-informed in-service inspection).*
>
> *In contrast, for new reactors, the Commission has moved further from a largely design-basis accident concept, requiring applicants for design certifications and combined licenses (COLs) under 10 CFR Part 52, "Licenses, Certification, and Approvals for Nuclear Power Plants," to perform a PRA and provide a description and analysis of design features for the prevention and mitigation of severe accidents (10 CFR 52.47(23) and 10 CFR 52.79(48)). Each design certification rule (10 CFR Part 52, Appendix A, "Design Certification Rule for the U.S. Advanced Boiling Water Reactor," and other Part 52 appendices) then codifies the severe accident features of each approved standard design.*
>
> *Following the terrorist events of September 11, 2001, the NRC issued security advisories, orders, license conditions, and ultimately a new regulation (10 CFR 50.54(hh)) to require licensees to develop and implement guidance and strategies to maintain or restore capabilities for core cooling and containment and spent fuel pool cooling under the circumstances associated with the loss of large areas of the plant due to a fire or explosion. These requirements have led to the development*

of extensive damage mitigation guidelines (EDMGs) at all U.S. nuclear power plants. The NRC has inspected the guidelines and strategies that licensees have implemented to meet the requirements of 10 CFR 50.54(hh)(2). However, there are no specific quality requirements associated with these requirements, and the quality assurance requirements of 10 CFR Part 50, Appendix B, do not apply. The EDMGs are requirements for addressing events well beyond those historically considered to be the design basis and were implemented as adequate protection backfits. In order to address the changing security threat environment, the Commission effectively redefined what level of protection should be regarded as adequate. This is a normal and reasonable, albeit infrequent, exercise of the NRC's responsibilities of protecting public health and safety.

All of the above indicate the Commission's desire and commitment to act either through regulatory requirements or voluntary industry initiatives to address concerns related to the design basis or beyond the design basis where appropriate."

Hence, the outcome objective of NRC staff's review of the technical information presented in support of an advanced non-LWR reactor can be distilled into a high-level question on which the review would have to reach a finding:

- Has the applicant presented a safety case that justifies a conclusion of adequate protection of public health and safety, security and the environment?

This question can be addressed using the prescriptive framework in which elements of the safety case are dispersed throughout the regulatory framework, or by taking advantage of the performance-based approach that has become part of NRC's current regulatory practice. It would be expected that probabilistic risk analyses would be employed to assure that all important contributors to risk have been considered. It would also be expected that the safety case would have addressed the currently evolving defense-in-depth framework appropriately incorporating design-basis and beyond-design-basis considerations.

The guidance provided in this paper uses these elements as representing the functional purposes of reactor design and operation that the LMP must address within the documents submitted for licensing review, and eventually constitute the performance objectives that must be fulfilled by an applicant within a safety analysis. The functional purposes of the body of performance elements are contained in the aggregation of acceptance criteria associated with the inspections, tests and analyses required by 10 CFR Part 52. The functional objectives that capture the functional purposes are incorporated in a technology inclusive manner within the structure provided by the Reactor Oversight Process.

10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants"

An important step in the modernization of NRC regulation was the promulgation of 10 CFR Part 52, ""Licenses, Certifications, and Approvals for Nuclear Power Plants," as an alternative to the existing process for reactor licensing under 10 CFR Part 50. The purpose of the update was to increase regulatory certainty and stability and to enhance the NRC's regulatory effectiveness and efficiency in implementing its licensing and regulatory approval processes. This revised licensing and regulatory approval process encouraged design standardization and provided a more predictable licensing process by resolving safety and environmental issues before authorizing plant construction. The licensing process addressed by Part 52 deals with the following topics (among others):

Early Site Permit: An early site permit (ESP) approves a site for one or more nuclear power facilities separate from the filing of an application for a construction permit (CP) or combined license (COL), providing early resolution and finality for siting issues. ESP requirements are contained in Subpart A, "Early Site Permits," to Title 10 of the Code of Federal Regulations (10 CFR) Part 52, "License, Certifications, and Approvals for Nuclear Power Plants." In reviewing an ESP application, the staff addresses site-safety issues, environmental issues, and plans for coping with emergencies, independent of the specific nuclear plant design review. ESPs are valid for 10 to 20 years and can be renewed for an additional 10 to 20 years.

Limited Work Authorization: A limited work authorization (LWA) is a part of the licensing process that provides Commission approval to perform a limited and defined set of construction activities before a COL or construction permit (CP) for the facility is issued. The LWA rule is not specific to 10 CFR Part 52; the applicable definitions and safety provisions are contained in 10 CFR 50.10, "License Required: Limited Work Authorization," which includes provisions for new reactor license applicants. An LWA application may be submitted in conjunction with an ESP or COL application (or a CP application under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"), or in advance of the CP or COL application under 10 CFR 50.10(d)(2). Those applications address the proposed LWA scope of work. Per 10 CFR Part 51, an LWA is a major Federal action that requires the staff to prepare an environmental impact statement.

Design Certification: The design certification (DC) process allows an applicant to obtain Commission approval of a design through rulemaking. For COL applicants, referencing a certified design reduces licensing uncertainty by resolving design issues generically, outside the scope of the COL review. It also facilitates standardization of future plants. The requirements for DCs are contained in Subpart B, "Standard Design Certifications," of 10 CFR Part 52. The review of a standard design is focused on ensuring that the design is safe because of compliance with the Commission's regulations. The DC review does not address site-specific design features, operational programs, and environmental impacts of building the design at a site. The process for a DC concludes with a rulemaking. Once issued, a DC is valid for 15 years.

Combined License: A combined license (COL) is a combined construction permit and conditional operating license. The requirements for a COL are contained in Subpart C, "Combined Licenses," of 10 CFR Part 52. It authorizes both construction and operation of a new nuclear power facility. A COL application can reference an ESP, a certified design, both, or neither, as long as it addresses all applicable requirements and provides sufficient information for the review. Per 10 CFR Part 51, issuance of a COL is a major Federal action that requires the staff to prepare an environmental impact statement.

Part 52 has some noteworthy features from the perspective of a performance-based approach. Part 52 is primarily a process regulation in the sense that most of the technical requirements for a determination of adequate safety occur in 10 CFR Part 50. The structure of regulatory practice causes the technical information reviewed by NRC staff to be dispersed within the topical composition of the review guidance in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition." As a process improvement in relation to advanced LWRs, adjustments in the review standard have been made using the concept of Design Specific Review Standards (DSRS).

Even with development of DSRSs, the information remains dispersed as topical reviews within the structure of NUREG-0800. This poses a challenge from the consideration of taking advantage of a distinctively performance-based aspect of Part 52. In paragraph 10 CFR Part 52.47 (b) (1) there is a provision that states with a great deal of clarity the outcome that is sought from application of this regulation. It states that an application must contain: “The proposed inspections, tests, analyses, and acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, a facility that incorporates the design certification has been constructed and will be operated in conformity with the design certification, the provisions of the Act, and the Commission's rules and regulations.” This sets up the outcome of the entire safety review in the form of a necessary and sufficient condition to be met for a favorable conclusion on an application.

The reactor core and associated systems function in an integrated manner to meet the various functional purposes related with producing electric power from heat generated within the core. Additionally, for reasons of safety, which requires provisions for extremely reliable heat removal under a very wide range of conditions, the functional purposes include operation of mitigation systems and integrity of barriers. All this is packaged within ITAACs (inspections, tests, analyses and acceptance criteria) to also provide for completeness, because the regulation requires that the aggregation of ITAACs be what is necessary and sufficient for the certification. Hence, regulatory practice appears to drive the review to be conducted within a prescriptive approach tied to each topical area, while the structure of Part 52, if viewed from the perspective that each ITAAC serve a functional purpose, is amenable to a performance-based approach.

NRC staff performed a study in 2013 to identify lessons learned from the actual implementation of the licensing process under Part 52. By and large, it was found that the goals and objectives of the regulation were met. No significant problems or impediments associated with the Part 52 licensing process were found. However, one of the issues identified is related to standardization of licensing basis information. This issue was addressed in an Interim Staff Guidance, ISG-11, “Finalizing Licensing-basis Information.” The ISG addresses finality of detailed design information to provide a predictable schedule for review of the information and reaching licensing decisions. It states: “The licensing or certification decision will be based on that information which has been provided to the NRC on or before the freeze point established by the applicant.” It is recognized that the review may take many months to complete during which time detailed design information may be subject to refinement. If difficulties arise, the solution discussed is to use processes related to departures and exemption within the licensing framework. The 2013 study undertakes to revisit the provisions of ISG-11. A performance-based approach would seek a solution whereby standardization is viewed at the level of performance objectives and not detailed design information. This could be accomplished by raising the hierarchical level at which the acceptance criteria are set for fitness for service.

10 CFR Part 50.65, “Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants”

In the late 1980s, the Commission developed safety concerns at operating reactors based on findings of Maintenance Team Inspections. It noted that plant events caused by the degradation or failure of plant equipment were continuing to occur as a result of instances of ineffective maintenance. Additionally, operational events were observed to have been exacerbated by or resulted from plant equipment being unavailable due to maintenance activities. Under existing requirements and industry maintenance initiatives, with relatively few exceptions, the availabilities of safety significant structures, systems, and components were not being routinely assessed. Existing regulations did not cover much of this equipment. These events and circumstances indicated to the Commission a need for ongoing results-oriented assessment of maintenance effectiveness since, together with equipment reliability, equipment availability is an important measure of maintenance effectiveness.

A debate arose between the NRC and industry about whether rulemaking was needed, as well as the nature of requirements within a proposed regulation. In 1990, the Commission approved the following four criteria as outcome objectives in determining the need for maintenance rulemaking:

> **Criterion 1:** Licensees have effectively implemented an adequate maintenance program or are committed to and proceeding towards this goal.
>
> **Criterion 2:** Licensees exhibit a favorable trend, in performance related to maintenance.
>
> **Criterion 3:** Licensees are committed to the implementation of a maintenance performance standard acceptable to the NRC.
>
> **Criterion 4:** Licensees have in place or are committed to an evaluation program for ensuring sustained performance in the maintenance area.

Additional factors noted by the Commission in determining the need for maintenance rulemaking were: (1) The ability to enforce maintenance programs or standards; (2) the presence of a strengthened commitment by the industry to monitor equipment performance to identify problematic components, systems, and functions, to conduct root cause analysis, to track corrective actions, and to feedback information into the maintenance program; and (3) provision of a mechanism by which the NRC could verify the effectiveness of the program.

In summary, the difficulty that NRC faced was that highly complex issues needed to be addressed and attempts at developing rule language in the usual way were not successful. An innovative approach was taken to meet the challenge by issuing 10 CFR 50.65 in 1991. It was considered as simple and brief. Specifically, it consisted of requirements that establish which SSCs are included within the scope of the rule, requirements for monitoring the performance or condition of those SSCs within the scope of the rule, and a requirement that licensees periodically assess the effectiveness of maintenance. The rule also encourages licensees to consider the impact on safety when removing equipment from service for preventive maintenance. Licensees establish goals to provide reasonable assurance that SSCs can fulfill their intended function. Licensees are to take appropriate corrective actions when the performance of an SSC does not meet established goals. Scoping was accomplished solely using deterministic criteria, with consideration of risk significance happening only after the scope was established.

When it was issued, 10 CFR 50.65 was described as a results-oriented, performance-based rule, but having prescriptive aspects as well. Specifically, the rule included the SSC scoping criteria and the requirement to periodically evaluate maintenance effectiveness. In the context of the maintenance rule, performance-based referred to two aspects of how the rule is implemented by licensees, and to how the NRC staff would inspect and enforce the rule. From an implementation standpoint, the maintenance rule is performance-based because it gives licensees flexibility and because the regulatory requirements vary with SSC performance, as follows:

Flexibility: The rule gives licensees the flexibility to: 1) establish the performance and condition goals, and the requisite equipment monitoring regimes; 2) modify established goals on the basis of plant or equipment performance; and 3) determine whether to rely on preventive maintenance in lieu of establishing goals and performance or condition monitoring. The rule prescribes no specific methodology to accomplish these activities; it only requires that licensees establish goals that are commensurate with safety.

Regulatory Requirements Vary with SSC Performance: The rule also allows licensees to forego the monitoring requirements of Paragraph (a)(1) if the licensee can demonstrate that the preventive maintenance for an SSC is effective. Therefore, licensees that establish effective preventive maintenance programs can reduce the monitoring activities imposed by the rule. An effective preventive maintenance program can generally be defined as a program that reduces failures to an acceptable level while achieving the appropriate reliability and availability.

At the time the maintenance rule was issued it was considered a performance-based rule; the concept of "risk-informed" was not in general use. While the rule required that licensees establish goals commensurate with safety, the concept of risk-informed thinking was not directly involved. However, NRC clearly expected licensees to consider risk when performing assessments of the impact on safety when removing equipment from service. Also, the maintenance rule includes a feedback mechanism that is self-correcting if safety significance ranking errors are made due to poor quality PRAs.

The staff reviewed the experience with the maintenance rule in SECY-1997-055, "Maintenance Rule Status, Results, and Lessons Learned." As a result of the initial baseline inspections of the maintenance rule, the NRC staff identified the following insights for consideration in the development of other risk-informed, performance-based rules:

- *"Because of the flexibility given to licensees by performance-based rules, effective communication among the NRC staff and between NRC staff, industry and the public is essential to the successful implementation, inspection and enforcement of these rules.*
- *Consideration should be given to conducting a pilot program to test implementation and inspection of these rules.*
- *The NRC staff and licensees should anticipate several iterations of the implementation guidance and inspection procedures to benefit from lessons learned through the pilot program and initial inspections.*
- *A programmatic baseline inspection program may be necessary to provide confidence that the licensees have programs that effectively monitor performance, and that licensees adjust their activities and programs where performance*

indicates changes are necessary. The NRC staff should not take a performance-based approach to inspection unless such confidence has been obtained.

- *NRC resource requirements for these rules are high, and should be acknowledged and committed to up front. Effective communication, development of guidance documents and inspection procedures, training, program oversight, and baseline inspections probably require more resources for performance-based rules than for prescriptive regulations in general.*
- *The rules must be written in a manner to only contain requirements. Other types of language in the rules, such as hortatory provisions, are unenforceable. Where practical, the rules should define the minimum performance standards (this was not practical in the case of the maintenance rule).”*

A.1.3 NRC Policy Directions

In 1995, the Commission initiated an activity termed as the “Strategic Assessment and Re-baselining Project”. The purpose was stated to be to provide a solid foundation for the agency’s direction and decision-making as it positioned itself for the then current and future challenges. The initiative produced studies on 16 so-called Direction-Setting Issues (DSIs). One of them, DSI-12, was entitled “Risk-Informed, Performance-Based Regulation.” The Commission issued its conclusions and decisions in early 1997 to the staff and stakeholders prior to using the decisions in developing a strategic plan to encompass the agency’s priorities, mission and goals.

The Strategic Assessment and Re-baselining Project (including DSI-12) had the following objectives:

- Take a new look at the NRC by conducting a reassessment of activities in order to redefine the basic nature of the work and the means by which that work is accomplished;
- Screen the redefined activities to produce (or re-baseline) a new set of assumptions, goals and strategies;
- The outcome would be a Strategic Plan developed and implemented to meet current and future challenges;
- Identify and classify issues that affect the basic nature of NRC activities and how the work is accomplished;
- Issues were seen to fall into three categories:
    - Direction-Setting Issues (DSI) affecting management philosophy and principles;
    - Subsumed issues that were considered along with the DSIs
    - Related issues to be considered after the Commission renders a decision on a DSI;
    - Operational issues that are not strategic and appropriately resolved by the staff.
- Develop options with brief summary discussions of the options and consequences;
- Engage interested parties and the public to discuss and receive comments;

- The Commission would make final decisions regarding the DSIs and the options to be reflected in the Strategic Plan.

The NRC staff developed a paper on DSI-12 for consideration by the Commission and described its focus as follows:

> *"Considering the general direction provided by the Commission and Congressional directives to various Government agencies to proceed to use risk-based and cost-benefit criteria, and recognizing the resources needed to implement risk-informed, performance-based approaches to regulation the following direction setting-issue was identified:*
>
>> *What criteria should NRC use in expanding the scope in applying a risk-informed, performance-based approach to rulemaking, licensing, inspection, and enforcement?"*

The DSI-12 paper provided four options for the Commission to consider so as to decide "how fast" and "how far" the agency will go in expanding activities in the application of risk-informed, performance-based regulatory approaches. The four options are identified and characterized below.

1. **Option 1:** Continue the current process
    - This was characterized as an incremental process
2. **Option 2:** More Rigorously Assess Relationship to Public Health and Safety
    - This was characterized as requiring a determination that new initiatives have the potential for substantial increase in overall protection to public health and safety to justify the level of resources necessary to pursue additional risk-informed, performance-based regulatory initiatives.
3. **Option 3:** Perform a Comprehensive Assessment of NRC Regulatory Approaches
    - This was characterized as a proactive, aggressive way to move forward. This option would maximize internal self-assessment and include exploring all regulatory areas to determine whether risk-informed, performance-based regulation should be pursued in that area.
4. **Option 4:** Consider Risk-Informed, Performance-based Approaches Primarily in Response to Stakeholder Initiatives
    - This option was characterized as being most responsive to industry and stakeholder initiatives. Stakeholder demand and ease of implementation would provide the primary bases for setting priority and scope in applying risk-informed, performance-based regulatory approaches.

The SRM for DSI-12 (COMSECY-96-061) provided direction with considerable detail on proceeding with risk-informed, performance-based activities. The opening and concluding paragraphs read as follows:

> *"The Commission recognizes that, in order to accomplish the principal mission of the NRC in an efficient and cost-effective manner, it will in the future have a regulatory focus on those licensee activities that pose the greatest risk to the*

public. This can be accomplished by building upon probabilistic risk assessment (PRA) concepts, where applicable, or other approaches that would allow a risk-graded approach for determining high- and low-risk activities. In general, those activities that are of a higher risk should be the primary focus of the agency's efforts and resources. The level of staff activity associated with lower risk activities should be determined based on a consideration of the cumulative impacts on safety, stakeholder initiatives and burden reduction, and the effect on agency and licensee efficiency. The Commission continues to believe that the use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy. The risk insights could be used to reduce unnecessary regulatory burdens as well as to identify areas where requirements should be increased."

and

"The staff should continue with the current efforts, in cooperation with the industry (Option 1), including pilot programs. The objective of this initiative is to obtain additional information regarding the appropriateness of a risk-informed, performance-based approach for the subject activities. These activities and their schedule, are presently captured in the agency's PRA Implementation Plan. As data from performance monitoring of structures, systems and components are accumulated, the staff should evaluate the performance data to determine the effectiveness of the approach on the subject activity. The staff should evaluate and clarify any technical and/or administrative issues associated with performance-based approaches to regulation (e.g., inspection activities, enforcement, etc.). Also, OGC's analysis of litigative risks requested in the Staff Requirements Memorandum on SECY-96-218 should be factored into future determinations and guidance on the extent to which the NRC implements risk-informed performance-based regulation."

and

"The staff should develop objective standard(s) for the application of risk-informed, performance-based and risk-informed less prescriptive approaches to regulations on an expedited basis. Such standard(s) could be in the form of individual plant safety goals and subsidiary objective performance criteria as discussed in the issue paper. The staff should also describe how any relevant knowledge developed in the implementation of the maintenance rule will be utilized in the development of risk-informed, performance-based regulation."

These directives provided the basis for a set of activities on performance-based regulation carried out by staff involving five Commission papers and three SRMs that were produced over the 1998-2002 period. At the end of this period, NRC staff merged risk-informed and performance-based activities and initiatives within the Risk-informed and Performance-based Plan to pursue coherence within the regulatory framework.

One of the most important of the policy papers issued by the Commission over the 1998-2002 period was the White Paper on Risk-Informed and Performance-Based Regulation as the SRM to SECY-1998-0144. This White Paper, issued at the highest policy level of the agency, provided authoritative definitions to terms that were being used with considerable confusion and ambiguity regarding terminology that could make significant differences in interpretations of policy questions and answers. The definitions have held over many changes in the composition of the Commission over the intervening period to current times. The only definition that has changed a little bit is the one for Defense-in-Depth when 10 CFR Part 50.69 was issued.

This LMP guidance on implementing and assessing performance-based approaches uses a formal approach to adhering to the definitions of "Performance-Based Approach" and "Risk-Informed, Performance-Based Approach". The definitions are reproduced in full below.

> *"Performance-Based Approach: A regulation can be either prescriptive or performance-based. A prescriptive requirement specifies particular features, actions, or programmatic elements to be included in the design or process, as the means for achieving a desired objective. A performance-based requirement relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, but provides more flexibility to the licensee as to the means of meeting those outcomes. A performance-based regulatory approach is one that establishes performance and results as the primary basis for regulatory decision-making, and incorporates the following attributes: (1) measurable (or calculable) parameters (i.e., direct measurement of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) exist to monitor system, including facility and licensee , performance, (2) objective criteria to assess performance are established based on risk insights, deterministic analyses and/or performance history, (3) licensees have flexibility to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes; and (4) a framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern. The measurable (or calculable) parameters may be included in the regulation itself or in formal license conditions, including reference to regulatory guidance adopted by the licensee. This regulatory approach is not new to the NRC. For instance, the Commission previously has approved performance-based approaches in 10 CFR Parts 20, 50 (Option B, Appendix J and the Maintenance Rule,10 CFR50.65) , 60, and 61. In particular, the Commission weighed the relative merits of prescriptive and performance-based regulatory approaches in issuing 10 CFR Part 60."*
>
> *"A performance-based approach can be implemented without the use of risk insights. Such an approach would require that objective performance criteria be based on deterministic safety analysis and performance history. This approach would still provide flexibility to the licensee in determining how to meet the performance criteria. Establishing objective performance criteria for performance monitoring may not be feasible for some applications and, in such cases, a performance-based approach would not be feasible."*

“As applied to inspection, a performance-based approach tends to emphasize results (e.g., can the pump perform its intended function?) over process and method (e.g., was the maintenance technician trained?). Note that a performance-based approach to inspection does not supplant or displace the need for compliance with NRC requirements, nor does it displace the need for enforcement action, as appropriate, when noncompliance occurs.(5)”

“As applied to licensee assessment, a performance-based approach focuses on a licensee's actual performance results (i.e., desired outcomes), rather than on products (i.e., outputs). In the broadest sense, the desired outcome of a performance-based approach to regulatory oversight will be to focus more attention and NRC resources on those licensees whose performance is declining or less than satisfactory.”

“Footnote (5): Not every aspect of licensed activities can or should be inspected using this approach. For example, if a licensee is unsuccessful in meeting the criteria defined by a performance-based regulation, the inspector should then focus on the licensee's process and method, to understand the root cause of the breakdown in performance, and to understand how future poor performance may be avoided.”

and

"Risk-Informed, Performance-Based Approach: A risk-informed, performance-based approach to regulatory decision-making combines the "risk-informed" and "performance-based" elements discussed in Items 5 (Risk-Informed Approach) and 7 (Performance-Based Approach), above, and applies these concepts to NRC rulemaking, licensing, inspection, assessment, enforcement, and other decision-making. Stated succinctly, a risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment including the principle of defense-in-depth and the incorporation of safety margins, and performance history are used, to (1) focus attention on the most important activities, (2) establish objective criteria for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, (4) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and (5) focus on the results as the primary basis for regulatory decision-making.”

The policy basis contained in the White Paper of the SRM to SECY-1998-0144 was translated into a technical basis and logic for the NRC’s guidance on performance-based approaches issued in December 2002 as NUREG/BR-0303 and entitled “Guidance for Performance-Based Regulation”. SECY-1999-0176, “Plans for Pursuing Performance-Based Initiatives” requested Commission approval for a broad based plan to develop high-level guidelines for performance-based approaches to regulation and apply them agency-wide. In the SRM, the Commission disapproved the broad based plan (because it lacked sufficient specificity), but approved development of the high-level guidelines to identify and assess the viability of candidate performance-based activities, with input from stakeholders and staff offices. It directed that the guidelines include discussion on how risk information might assist in the development of performance-based initiatives.

The follow-on paper, SECY-2000-0191, “High-Level Guidelines for Performance-Based Activities” provided to the Commission for information the guidelines and some testing of them to make elements of the regulatory framework more performance-based. The regulatory framework was defined to include the regulation and its supporting regulatory guides, standard review plans, technical specifications, NUREGs, and inspection guidance. The paper identified that a key aspect of employing performance-based approaches is selecting or formulating performance parameters and associated performance criteria appropriate to the regulatory issue being addressed. For example, the guidelines facilitate identifying the level (i.e., for example, the component, train, system level) at which performance criteria should be set.

The next step in the evolution of performance-based methodology at NRC was preparation of NUREG/BR-0303, “Guidance for Performance-based Regulation” incorporating and extending Commission approved (relying on the SRM to SECY-1999-0176) guidelines. The NUREG/BR format was chosen so the guidance could parallel and support NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission”. NUREG/BR-0058 is of significance because it applies essentially to all activities that could generate new requirements. In parts, NUREG/BR-0058 states the following:

- This document contains a number of policy decisions that have broad implications for the NRC and its licensees. These include the use of a safety goal evaluation, which is intended to eliminate some proposed requirements from further consideration because the residual risk is already acceptably low, the use of a $2000 per person-rem conversion factor, and the use of criteria for the treatment of individual requirements.
- If the objective or intended result of a proposed generic requirement or staff position can be achieved by setting a readily quantifiable standard that has an unambiguous relationship to a readily measurable quantity and is enforceable, the proposed requirement should merely specify the objective or result to be attained rather than prescribe to the licensee how the objective or result is to be attained. In other words, requirements should be performance-based, and highly prescriptive rules and requirements should be avoided absent good cause to the contrary.
- The alternatives section of the regulatory analysis document should list all significant alternatives considered by the staff. A brief explanation of the reason for elimination should be included for alternatives not selected for further study. Further guidance on implementation of performance-based requirements is available in NUREG/BR-0303, “Guidance for Performance- Based Regulation,” issued December 2002.

An important aspect of incorporating NUREG/BR-0303 as a reference is that guidance is provided for observation and assessment of performance in a way that could include qualitative parameters. In addition, for complex issues, the guidance suggested use of a hierarchically structured set of performance objectives based on the prevailing Reactor Oversight Process.

A.1.4 NRC Guidance

Nuclear Regulatory Commission (1999). Elements of an Approach to Performance-Based Regulatory Oversight. Nuclear Regulatory Commission, NUREG/CR-5392.

The abstract states, "This report discusses an approach to performance-based regulatory oversight. One key issue in developing a performance-based approach is choosing a collection of performance measures that is highly results-oriented and will support the capability to detect and act upon emerging performance problems before they lead to adverse consequences. A related issue is the role of institutional factors, and how to reflect institutional factors in a results-oriented, performance-based approach. These issues are explored through discussion of examples. Based on these discussions, an approach is recommended. The approach entails (1) careful formulation of a safety case, which shows what the challenges are to plant safety and what the plant capability is for responding to those challenges, (2) allocation of performance goals over elements of the safety case, (3) formulation of a "diamond tree," which is an integrated, hierarchical presentation of hardware, human, and institutional performance areas that indicates how institutional performance supports the safety case, and (4) application of the diamond tree to select a set of performance measures that is as results-oriented as possible, given the levels and kinds of performance needed in order to support the safety case, and the need to respond to emergent problems before adverse consequences develop."

A benefit of performance-based regulatory oversight is that a performance-based approach would be more efficient for licensees and for regulators than the prescriptive approach seems to be. The level of NRC involvement with details of plant operation would depend on the current assessment of licensee performance. Evidence of ongoing satisfactory safety performance would indicate that there is no current need for additional involvement of NRC staff with a licensee's operations. Evidence of performance problems would be grounds for increased NRC involvement with a licensee, perhaps beginning with briefings and proceeding thereafter to detailed inspections.

One major focus of this report is the search for a workable balance between two of the four attributes of a performance-based approach as provided by the Commission in the SRM to SECY-98-0144. The first attribute is that measurable parameters exist to monitor with clearly defined objective criteria against which plant and licensee performance can be assessed. The other attribute is that a framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in adverse consequences. Arguably it is not a good regulatory approach to presume satisfactory safety performance until safety functions are not only compromised but failed. An example based on the safety function of decay heat removal is offered. Relative to the first attribute, an objective criterion on decay heat removal is easy to articulate and easy in principle to measure and report. On the other hand, the other attribute (no adverse consequences) is another (more complex) matter. Treatment of the example based on reduced-inventory operation at shutdown with actual water temperature as the parameter concludes that function-level monitoring of the kind that had been proposed would not provide adequate ongoing assurance of satisfactory safety performance. The report proposes a "leading-indicator rule" as a rule-of-thumb to resolve such issues.

The report offers a structured process for developing candidate sets of performance measures for application in performance-based regulation. The general idea is that, since it is impractical to measure fulfillment of top-level measures (e.g., large early release from reactor events) directly, the top-level measure is decomposed into a hierarchy of lower-level objectives, and eventually identify a set of those lower-level objectives having the properties that (1) satisfaction of the set should correlate strongly with satisfaction of the top-level objective, and (2) some periodic assurance can be derived regarding the satisfaction of these lower-level objectives, either through performance-based oversight or through oversight of fulfillment of prescriptive requirements.

The process is motivated by a need to develop performance-based approaches and tends to identify performance-based approaches preferentially. By this, it is meant that the approach begins by considering the most results-oriented measures possible, and proceeds to less results-oriented measures only if the more results-oriented measures are inappropriate for some reason. Where performance-based approaches are arguably inappropriate, the process is intended to address this also.

Reasonable performance toward the top objective should correlate with reasonable performance at lower levels. In a structure of performance nodes, reasonable performance may not need to be assured at every node always (as would be required within a deterministic and prescriptive framework). Bad performance at any single node may erode the performance of the nodes above it to which it is coupled, but it should not propagate un-attenuated to the top of the tree if other nodes are performing adequately.

In such a system, licensees should have the prerogative to decide which of the systems need to carry more of the performance burden than others. The process of deciding how much safety burden is carried by each system is called “allocation”. Licensees can use the allocation process to optimize distribution of safety resources while ensuring that the top-level goals are met. This discussion makes most sense if risk-informed performance goals are articulated for systems. Allocation can also address defense-in-depth by assuring that excessive performance expectations are not associated with barriers or systems that lack suitable redundancy and diversity.

The result of the allocation could be a logical construct equivalent to a portion of a PRA providing a more thorough presentation of success paths. The construct represents what credit is being taken for which systems and how much credit is being taken for things like preventing common cause failures. The construct can be used to formulate a “safety case” that explains what the safety challenges are, what the plant capabilities are for responding to these challenges, and how reliably these capabilities are required to respond to satisfy top-level safety objectives.

The next step is to examine the performance nodes to identify suitable monitoring points. Monitoring at the higher levels offers the most results-oriented options. However, monitoring at the highest levels may be inappropriate because failure would have unacceptable adverse consequences. The examination moves through the hierarchy until failure would not be considered to have unacceptable consequences. A suitable monitoring node would be one that is challenged often enough that a “zero failures” statistic has some meaning.

Link to document: https://www.nrc.gov/reading-rm/doc-collections/nuregs/contract/cr5392/cr5392.pdf

Nuclear Regulatory Commission (2002). Guidance for Performance-Based Regulation. Nuclear Regulatory Commission. NUREG/BR-0303.

The abstract states in part, "This document provides guidance on a process for developing a performance-based alternative for consideration, along with other more prescriptive alternatives, in regulatory decision making. The U.S. Nuclear Regulatory Commission (NRC) Management Directive 6.3, "Rulemaking," calls for the consideration of a performance-based alternative. Such an alternative differs significantly from a prescriptive one in which licensees are provided detailed direction for obtaining safety results. Performance-based approaches focus primarily on results. They can improve the objectivity and transparency of NRC decision making, promote flexibility that can reduce licensee burden, and promote safety by focusing on safety-successful outcomes. These attributes are reflected in the process described in this document. The process is set up to develop answers to questions that, in turn, provide the information to formulate an alternative that can be compared against others in a management review process."

The five steps in the process are:

1. Defining the regulatory issue and its context,
2. Identifying the safety functions,
3. Identifying safety margins,
4. Selecting performance parameters and criteria, and
5. Formulating a performance-based alternative.

The development of NUREG/BR-0303 was based on staff activities that followed Commission direction in the SRM to SECY-96-0218: "Performance-based initiatives that do not explicitly reference criteria derived from PRA insights should not be excluded from consideration. The staff should include in the PRA implementation plan, or in a separate plan, how these performance-based initiatives will be phased into the overall regulatory improvement and oversight program."

The substance of the guidance in NUREG/BR-0303 was developed in work reported to the Commission in SECY-2000-0191, "High-Level Guidelines for Performance-Based Activities".

High-level performance-based guidelines have been developed that the NRC states are applicable across the full spectrum of regulatory activity, corresponding to the three NRC arenas, reactor safety, material safety, and waste safety. The guidelines are classified into three groups, (1) viability guidelines, (2) assessment guidelines, and (3) guidelines to ensure consistency with other regulatory principles.

In addition, the NRC staff answers the following two questions:

1. *Can a "performance-based approach" have prescriptive elements?*

   "Appropriate regulatory decision-making cannot exclude the possibility of prescriptive elements. The characteristic of a performance-based approach, as described in the Commission's White Paper (SECY-98-0144) is a reliance on performance and results. This is evident from the following statement in the White

Paper, “A performance-based regulatory approach is one that establishes performance and results as the primary basis for regulatory decision-making....” The focus of a performance-based approach is the use of prescriptive elements only when necessary.”

2. *How does “margin” enter into a “performance-based approach?”*

   “One of the White Paper attributes of a performance-based approach is that, “...a framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern.” Such a framework contains the concept of “margin.” In this construct, “margin” is a quantity that expresses the difference between performance within the limits of a “criterion” and performance that is representative of a “concern.” The word “immediate” requires that a time element be considered in the development of a performance-based approach. The high-level guidelines incorporate this understanding. They are also consistent with the NRC’s regulatory responsibility to monitor potential erosion of margin, as well as licensee responsibility for prompt corrective actions. These interpretations have been discussed with the public and presented to the Commission.

Viability Guidelines

The NRC states, “Viability guidelines ask questions that enable the regulator to determine whether a specific regulatory issue is amenable to a performance-based approach based on how well the regulator can construct a regulatory alternative that has the four attributes discussed in the Commission’s White Paper SECY-98-0144”.

These attributes are:

- Failure to meet the predetermined performance standard will not result in an immediate safety concern. (Can margin be estimated realistically, and if so, what is known about it?)
- Measurable or calculable parameters are available to determine whether the performance standard is met. (Can performance parameters be identified that provide measures of performance and the opportunity to take corrective action if performance is lacking?)
- The performance standard is based on objective criteria. (Can objective criteria be developed that are indicative of performance?)
- The licensee or the NRC has flexibility in the method used to achieve the desired performance level. (Is flexibility for the NRC or licensees available consistent with the level of margin?)

Examples are provided to illustrate the process. The formal high-level guidelines for performance-based activities are shown in Appendix A. For broadly scoped and complex issues, a more rigorous consideration of performance issues may be appropriate; accordingly, Appendix B provides supplementary guidance and background information.”

The NRC further states, “If a regulatory alternative can be designed with these three attributes, a performance-based approach is judged to be feasible. This assessment would be applied on a case-by-case basis and would be based on an integrated consideration of these guidelines, rather than on strict adherence to each individual guideline.”

Assessment Guidelines

The NRC states, “If a performance-based approach is deemed viable, the regulatory activity would be evaluated against guidelines that assess whether such an approach results in opportunities for regulatory improvement. Regulatory improvement is a positive contribution to NRC’s performance goals and achievement of a net societal benefit. Thus, the assessment guidelines question whether the regulatory alternative achieves the following”:

- maintains safety
- increases public confidence
- increases effectiveness, efficiency, and realism
- reduces unnecessary regulatory burden
- Results in a benefit

Further, the staff states, “Additional assessment guidelines include the ability of the proposal to be incorporated into the regulatory framework and the ability to accommodate new technology. This evaluation is to be based on an integrated assessment of the individual guidelines within this grouping.”

Guidelines to Ensure Consistency with Other Regulatory Principles

The NRC states, “These guidelines take into account fundamental regulatory principles that have been articulated by the Commission, such as, the Principles of Good Regulation. The intent is to ensure that a performance-based regulatory alternative that conforms to the viability and assessment guidelines does not compromise any of NRC’s basic regulatory principles. Although it is not generally necessary to remind staff of these principles, this third set of guidelines provides a reasonable check. The third set of guidelines need only be applied if the candidate activity passes the first two sets of guidelines.”

Supplementary Guidance for More Complex Activities

The general guidance offered in the body of NUREG/BR-0303 may be found to be insufficient because the treatment of the regulatory issue is affected by one or more of the following:

- complexity
- uncertainty
- multiple objectives, especially competing objectives
- different stakeholder perspectives

When such conditions are present, a more considered approach based on decision analysis is warranted. Using this approach, a performance-based regulatory approach needs to:

- Allocate performance across relevant functions, systems or barriers in order to assess whether the target safety objectives are satisfied;
- Then implement that allocation of performance which entails identifying the steps to be taken by licensees and/or NRC to make the performance allocation “come true” in practice.

Where an issue affects various areas and different objectives the added complexity may justify the explicit development of a more detailed objectives hierarchy. An objectives hierarchy makes it easier to assess the levels of performance needed from each element.

NUREG/BR-0303, Appendix B demonstrates that the structure and elements of the NRC’s Reactor Oversight Process (ROP) offer a suitable objectives hierarchy to implement a performance-based approach relative to reactor safety issues. The cornerstones of safety identified in the ROP are intended to be a complete set of key performance areas affecting safety. Completeness is one of the reasons to pursue such a systematic development. Consideration of the cornerstone areas also illustrates how the implicit underlying allocation of performance addresses defense-in-depth. Balance between prevention and mitigation is shown by the presence of cornerstones addressing initiating events, mitigating systems, and emergency preparedness; the additional consideration of barrier integrity further reinforces defense-in-depth.

Analogous to logic tree development, each level of the objectives’ hierarchy is derived from the level above by decomposing each node into constituent elements. Each objective relates to an objective above it on the hierarchy, in that it answers the question, “How is the higher-level objective to be accomplished?” (Question: How will safety function X be accomplished? Answer: By reliable function of systems A, B, and C.) In fact, a system reliability model developed hierarchically and expressed in “success space” is essentially a partial objectives hierarchy. It is “partial” because it addresses only safety performance, and because, even within safety, a logic model does not usually address cross-cutting programmatic issues.

It is necessary to determine what kind of performance and what level of performance is needed from each performance area to enable selection of performance measures. Defense-in-depth is supported by strong performance in each of the safety cornerstone areas (initiating events, mitigating systems, barrier integrity, emergency preparedness) because to some extent, performance in one area can compensate for lack of performance in another.

Generally, it is desirable to specify and monitor performance targets as high on the objectives hierarchy as possible, consistent with the viability guidelines. Allocating performance too far down on the hierarchy reduces licensee flexibility. Arriving at an implementation that maintains safety while appropriately balancing licensee flexibility with the need for regulatory assurance of ongoing performance will require some iteration with the allocation step.

Nuclear Regulatory Commission (2003). Formal Methods of Decision Analysis Applied to Prioritization of Research and Other Topics, NUREG/CR-6833.

The abstract states, “This report discusses the application of methods of formal decision analysis to prioritization of research to be carried out in support of licensing of advanced reactor designs. Formal decision methods are useful in this area for two reasons. (1) Prioritization is a special case of decision-making. (2) Prioritization of safety research is closely related to safety decision-making, and formal analysis of safety decisions points the way more clearly to specific research tasks needed to support safety decisions. The report is presented in three main parts. Part I provides an overview of prioritization. Two main themes emerge from this overview: (1) the effect of uncertainty on decisions, and (2) the need to clarify decision objectives and carefully formulate decision alternatives. The first theme is taken up in Part II, and the latter in Part III. Specific topics considered include the development and use of an objectives’ hierarchy, kinds of performance measures, and the value of information to reduce uncertainty, including a discussion of hypothesis testing and "Receiver Operating Characteristic Curves." Many agency decisions could arguably benefit from application of individual tools discussed here, although application of the full suite of formal decision-analysis tools may not be warranted in all cases.”

Licensing of advanced reactors will require investments in research and development to assure availability of sufficient high-quality information to support safety decision making. In SECY-2003-0059 the staff has indicated what such investments may entail: “In general, the staff will determine what information must be provided by the applicant as part of their license application, and what additional NRC research is needed to support the licensing offices. The general principle that will be used for research activities is (a) if research data are needed to support the safety case for a particular reactor design, the applicant will be responsible for providing the data, and (b) if the NRC believes the research is important to independently assess applicants’ submittals or to provide the technical bases needed to develop the regulatory requirements that these designs must meet, NRC resources will be used.”

Risk-informed, performance-based approaches offer more modern methods to support such decision making for greater efficiency, effectiveness, and transparency. However, the scope and content of risk information is not just radiological risk that typically is the main consideration with many types of risk-informed decision making. Whether the decision making is by the organization applying for a license or the NRC which is charged with reviewing the application, NRC’s strategic performance goals represent a real-life example of multiple attributes that need to be fulfilled simultaneously as part of organizational decision making. NUREG/CR-6833 addresses use of formal decision methods helping with decision-making on advanced reactor infrastructure development.

The existing infrastructure for decision making relative to developing information to support licensing uses the process called PIRT (Phenomena Identification and Ranking Tables). The methods addressed in NUREG/CR-6833 provide a starting point for guiding the use of formal decision methods to support a PIRT process by extracting relevant methodologies from the literature. Formal decision methods can help significantly with certain key aspects of goals related to conducting a process of multi-attribute decision making effectively, efficiently, and at the same time, openly with all stakeholders. The reason for this is the unique ways in which formal methods apply combinations of qualitative and quantitative information. The credibility of such a decision process depends on transparency in defining the process elements, repeatability of the process elements consistently across applications, and reproducibility of the results from Implementing the process.

Safety decisions, in the organizational context, are made invariably with less than the desired amount of information. It is generally the case that perceived inadequacies of information are compensated, in a safety context, with resort to conservative and deterministic methods, often employing a prescriptive approach. In terms of complementing a PIRT or similar process, an important question addressed in NUREG/CR-6833 is, “How conservative will a decision have to be if the Information is not obtained or uncertainties are large?” If an applicant significantly underestimates the degree of conservatism required to pass regulatory muster, project costs could be adversely affected equally significantly.

One of the factors that complicates decision-making in many cases, and drives the need for formal approaches, is uncertainty regarding the probabilities and consequences of various outcomes associated with decision alternatives. Reduction of significant technical uncertainties is a key driver for research prioritization. "Value of information," is a concept that relates the potential worth of a research program to the effect of the subject uncertainty on safety decisions. The discussion of the value of information sheds light on the value of reducing uncertainty regarding (for example) phenomenological issues in the context of specific design decisions.

Activities on research programs may not be called "decision-making" even though they entail setting priorities and making choices. Prioritization is a special case of general decision analysis. It is likely to be of potential interest in a research organization responsible for reducing technical uncertainty. Also, many of the tools and ideas that apply to prioritization apply much more broadly to safety decision-making. Two key themes emerge in NUREG/CR-6833, viz.: (1) the treatment of uncertainty, and (2) the formulation and application of the objectives’ hierarchy.

Uncertainty limits the expected utility of a decision (i.e., creates some potential for adverse consequences resulting from the decision). Treatment of uncertainty in NUREG/CR-6833 begins by presenting some essential results from the basic theory of hypothesis testing. Deciding which of two hypotheses is correct, given evidence that suggests, but does not prove conclusively, which is correct is a common issue confronting decision makers. In this context, "Receiver Operating Characteristic" (ROC) curves may find useful application. ROCs are widely studied because of the insight that they afford into a broad spectrum of decision situations. Such approaches may help a designer formulate safety arguments within a safety case for a licensing application where validation of an important design parameter is questioned. ROC curves enable estimation of “false positive” or “false negative” likelihoods and hence assess costs and benefits of decisions quantitatively.

A general approach to prioritization considers formulation of the fundamental and means objectives that the decision-maker needs to address. NUREG/CR-6833 identifies defense-in-depth as an important issue that a safety decision-maker is likely to confront. Decision theory can, in principle, improve the way in which defense in depth is handled in design and regulatory practices.

Consider the hypothetical case of whether a reactor design ought to be required to have a containment and suppose temporarily that "yes" or "no" are the only two alternatives. Suppose that the design promises a very low frequency of significant release of radioactivity from the fuel, and that taken at face value, this frequency would easily meet goals on large release frequency from the plant. Taking this release frequency at face value, one might consider not requiring a containment. However, on any of three possible grounds – uncertainty in the frequency, balance between prevention and mitigation, and the need for multiple barriers - traditional defense in depth arguments might be brought to bear to defend a requirement for containment.

NUREG/CR-6833 offers technical bases for an applicant to develop arguments in favor of an alternative to the traditional defense-in-depth arguments. Formal decision methods and associated tools may be of help in the following ways:

1. Clarification of the objectives of stakeholders for greater effectiveness and efficiency is within the purview of formal decision methods. This would include objectives of all kinds (safety, cost, common defense and security, ...). Apart from being interesting in its own right, the exercise would support the following steps.
2. Creation of improved alternatives (e.g., confinement, but there is no reason to stop there) is within the purview of formal decision methods.
3. Mainstream decision analysis suggests that construction of a utility function can and should be done in this case. It would be useful to explore the implications of biasing a utility function more in favor of benefits, as done by the British.
4. An honest assessment of the uncertainties, including uncertainties other than the merely parametric (i.e., modeling, completeness, ...), would be important. This would require stepping outside of the conceptual framework of the engineering models to contemplate whether the models themselves are adequate.
5. Given the uncertainties and an improved set of objectives, either “value of information” formalism itself or an analog could be used to assess the change in utility associated with the various decision alternatives, including at least one based on defense-in-depth employing the high-level guidelines for a performance-based approach.

Within the context of long standing discussions regarding “rationalist” and “structuralist” approaches within the NRC, these recommendations generally comport with the thrust of the "rationalist" option but go beyond a purely “rationalist” option in two ways: (1) taking a more structured and formal decision-theoretic approach, and (2) in doing so, trying to implement standard methods in a way that folds in concerns regarding residual risk.

A.2 INTERNATIONAL AUTHORITIES & DIRECTIVES FOR PERFORMANCE-BASED APPROACHES

A.2.1 IAEA Documents

The International Atomic Energy Agency (IAEA) is authorized to “establish or adopt…standards of safety for protection of health and minimization of danger to life and property” — standards that member States can apply by means of their regulatory provisions for nuclear and radiation safety. Regulating safety is considered a national responsibility. The IAEA commenced its safety standards program in 1958 to develop a stable and sustainable global safety regime with an emphasis placed on quality, fitness for purpose and continuous improvement. The IAEA’s safety activities encompass design, siting and engineering safety, operational safety, radiation safety, safe transport of radioactive material and safe management of radioactive waste, as well as governmental organization, regulatory matters and safety culture in organizations.

The IAEA is distinctive because the emphasis placed on structured approaches. Toward the top of the structure are Fundamental Safety Objectives or Principles, which represent an international consensus on what must constitute an elevated level of protection and safety. The focus on fitness for purpose gives the IAEA a great deal in common with performance-based approaches to regulation. One observes that implementation activities employ well defined processes that are designed to be consistent with the structured goals. Frequently, the processes are where the guidance from IAEA ends, perhaps because regulating safety is a national responsibility. In the US, the NRC has generally insisted that processes be taken further to develop measures and criteria to enable enforcement. Hence, there is much to be gained by looking to IAEA documents for well thought-out structures and processes to which US performance objectives form a highly beneficial complement.

The IAEA has been working for some time to develop a framework for safety goals that would be composed of a hierarchical structure so as to enable a more consistent and holistic consideration of qualitative concepts (e.g. defense-in-depth, various safety requirements) and quantitative risk metrics. The development of the framework for nuclear installations had been started before the Fukushima accident happened but this accident enhanced the need to enhance the ability to assess the safety level of a multi-unit site with nuclear power plants or a site with different types of nuclear installations. The role and interpretation of quantitative safety goals varies from country to country, but some degree of harmonization was seen to be possible applying a structured framework. It was felt that such a framework would:

- Help designers, vendors, operators and regulators to achieve consistent levels of safety across different facilities and technologies including site – wide considerations;
- Provide the public with assurance that sufficient, uniform, high levels of protection are being achieved.

IAEA sees safety goals as helping to answer the questions “how safe is safe enough?” and “has the required level of safety been achieved in practice?” IAEA sees a mandate for requiring that the safety goals hierarchy shall be applicable to all nuclear installations during their entire lifetime, that it shall cover both operational states and accident conditions, and that it shall consider all sources of radioactivity on the site.

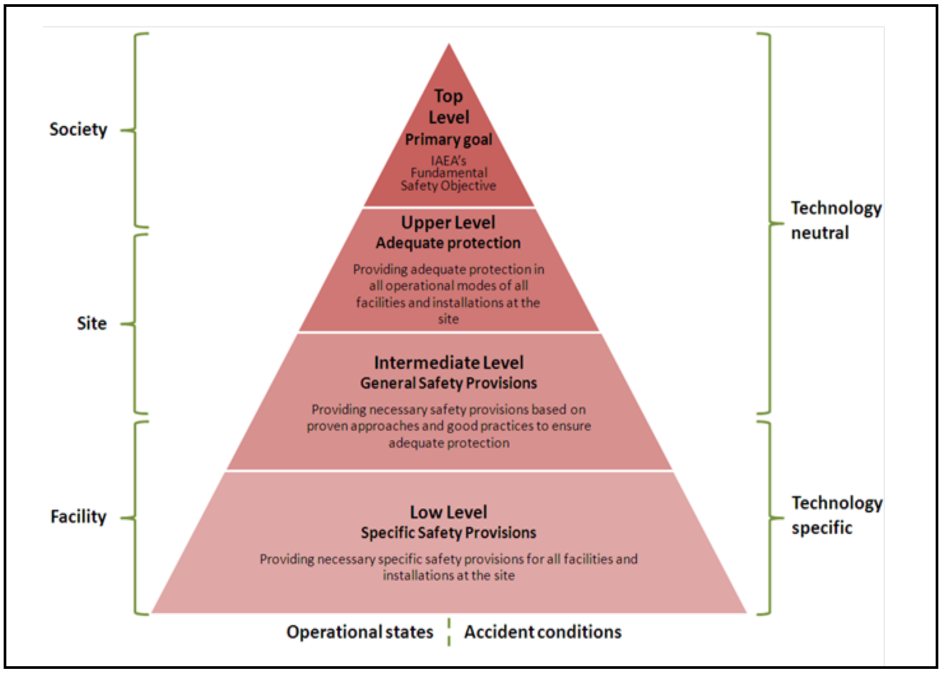

Figure A1. Proposed IAEA Safety Goals Framework

Figure A1 is a rendition of IAEA's proposal for a safety goal framework that has been published and is apparently being considered within the organizational process within the agency. The levels of safety goals have been characterized and explained in relation to an example from Germany. The application of this framework requires that a relatively high level of cohesion exist within a country's society on the perceptions regarding acceptable risks from industrial activities that are presumed to benefit the society and are seen to be so by the society. For example, it appears that IAEA assumes that higher level goals could be both technology neutral and considered acceptable by society. On matters related to nuclear hazards and radiation effects it seems clear that this kind of coherence does not exist and is unlikely to come about in the foreseeable future. Many countries accept relatively high levels of health risks from some industries (for example, chemical plants) while exhibiting highly risk-averse behavior toward radioactive materials. However, at the lower levels it appears quite reasonable to consider technology specific safety provisions for all the facilities and installations at a site. Also, rigorously taking into consideration all relevant operational states and accident conditions, as well as potential cross-interactions between facilities, seems to be the right approach. However, it is important to recognize that all such considerations can be applied within prescriptive or performance-based approaches. While examples of the prescriptive approach abound, it is quite difficult to find performance-based applications.

IAEA has elaborated on the safety goal levels by characterizing the different levels. Parallels in the US are to be found at the "Intermediate" and "Low" levels.

Table A1. Characterization of levels of safety goals

Level	Overall Objective	Nature of Safety Goals and Examples
Top Level **Primary Safety Goal**	Protecting people and the environment from harmful effect of ionizing radiation	Requirements on this level are expressed qualitatively and may presuppose, e.g., the prevention of unreasonable harm to the public and the environment. These safety goals may have wider scope than nuclear. The Safety goals at this level are technology neutral.
Upper Level **Adequate Protection**	Ensuring adequate protection in all operational modes for all facilities and installations at the site	Upper level safety goals are high level and used as a bridge to support the development of intermediate and low level safety goals from the top level In some countries, this is done by relating to levels of risks from other involuntary sources of risk, using quantitative or semi-quantitative expressions of relation between risks from nuclear installations an risks from other sources of energy production The safety goals at this level are typically technology neutral and have a site-wide scope
Intermediate Level **General Safety Provisions**	Providing general safety provisions including technical and organizational measures based on proven approaches and good practices to ensure adequate protection	Intermediate level safety goals typically include principles related to defence in depth, safety margins, physical barriers, considerations related to independence and protection barriers, redundancy and independence, doses for normal operations, amounts of radioactive waste generated, etc. This level also includes the definition of some high-level quantitative safety goals, e.g., overall large early release frequency (LERF) for the site. The safety goals at this level are still largely technology neutral
Low Level **Specific Safety Provisions**	Providing specific safety provisions for each facility and installation at the site to ensure adequate protection	A large number of specific deterministic safety goals are in use, e.g. related to maximum fuel cladding temperature in a LWR. This level may also include quantitative probabilistic safety goals, e.g. for frequency of large release, core or fuel damage, barrier strength, or SSC reliability. Technology and facility specific safety goals aimed at assuring the nuclear installation meets the higher level safety goals

At the "Intermediate Level" general safety provisions would be addressed by IAEA's NS-R-1. For example, "Fundamental Safety Functions" are addressed by:

> *"Fulfilment of the following fundamental safety functions shall be ensured for all plant states:*
>
> *(1) control of reactivity;*
>
> *(2) removal of heat from the core;*
>
> *(3) confinement of radioactive material, provision of shielding against radiation and control of planned radioactive releases, as well as limitation of accidental radioactive releases."*

Additionally, Specific Safety Requirements, No. SSR-2/1 has the following provisions:

> *"A systematic approach shall be taken to identifying those items important to safety that are necessary to fulfil the fundamental safety functions and to identifying the inherent features that are contributing to fulfilling, or that are affecting, the fundamental safety functions for all plant states."*

and

> *"Means of monitoring the status of the plant shall be provided for ensuring that the required safety functions are fulfilled."*

Such safety provisions are made differently in the US. However, at the functional level and in terms of addressing fitness of purpose, there is a high degree of congruence between US regulations and the IAEA approach. Basic safety functions are addressed in the context of 10 CFR Parts 50.2, 50.49, 50.55 (e), 50.65 and 21. For example, 10 CFR Part 50.2 states:

> *"Safety-related structures systems and components means those structures, systems and components that are relied upon to remain functional during and following design basis events to assure:*
>
> *(i) The integrity of the reactor coolant pressure boundary,*
>
> *(ii) The capability to shut down the reactor and maintain it in a safe shutdown condition, or*
>
> *(iii) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in § 50.34(a)(1), or § 100.11 of this chapter, as applicable."*

Functionally, safety-related SSCs are important to safety because they assure heat removal, criticality control, and accident prevention and mitigation. In 10 CFR 50.65 (The Maintenance Rule) these are identified in Paragraph (b) as part of the scope. The performance requirements are distributed among a wide range of documents that cover all aspects of the US regulatory framework. They are also covered by the so-called "Cornerstones of Safety" within the Reactor Oversight Process.

A.3 APPLICABLE NRC PRECEDENTS

A.3.1 Reactor Oversight Process

On April 2, 2000, the NRC implemented a new Reactor Oversight Process at all operating commercial nuclear power plants. The objectives in developing the various components of this new process were to provide tools for inspecting and assessing licensee performance in a manner that was more risk-informed, objective, predictable, and understandable than the previous oversight processes. The ROP was also developed to meet the four agency performance goals to: (1) maintain safety, (2) increase openness, (3) make NRC activities and decisions more effective, efficient, and realistic, and (4) reduce unnecessary regulatory burden.

Several years of intensive efforts with the active engagement of the Commission and external stakeholders preceded the launching of the new oversight process. Defining the desired outcome for the process included going back to first principles as well as Principles of Good Regulation developed later on. First principles included the Atomic Energy Act of 1954, as amended. The process needed to support the mission to ensure that commercial nuclear power plants are operated in a manner that provides adequate protection of public health and safety and the environment and protects against radiological sabotage and the theft or diversion of special nuclear materials.

The new ROP used a top-down, hierarchical approach to develop the concept for a new regulatory oversight framework that implements the NRC’s vision and addresses the agency’s regulatory principles. This approach started with a desired outcome, identified performance goals to achieve the outcome, and then identified specific objectives and information needs to meet each performance goal. The regulatory oversight framework developed using this approach is represented in Figure A-2. This framework starts at the highest level, with the NRC’s overall mission to ensure that commercial nuclear power plants are operated in a manner that provides adequate protection of public health and safety.

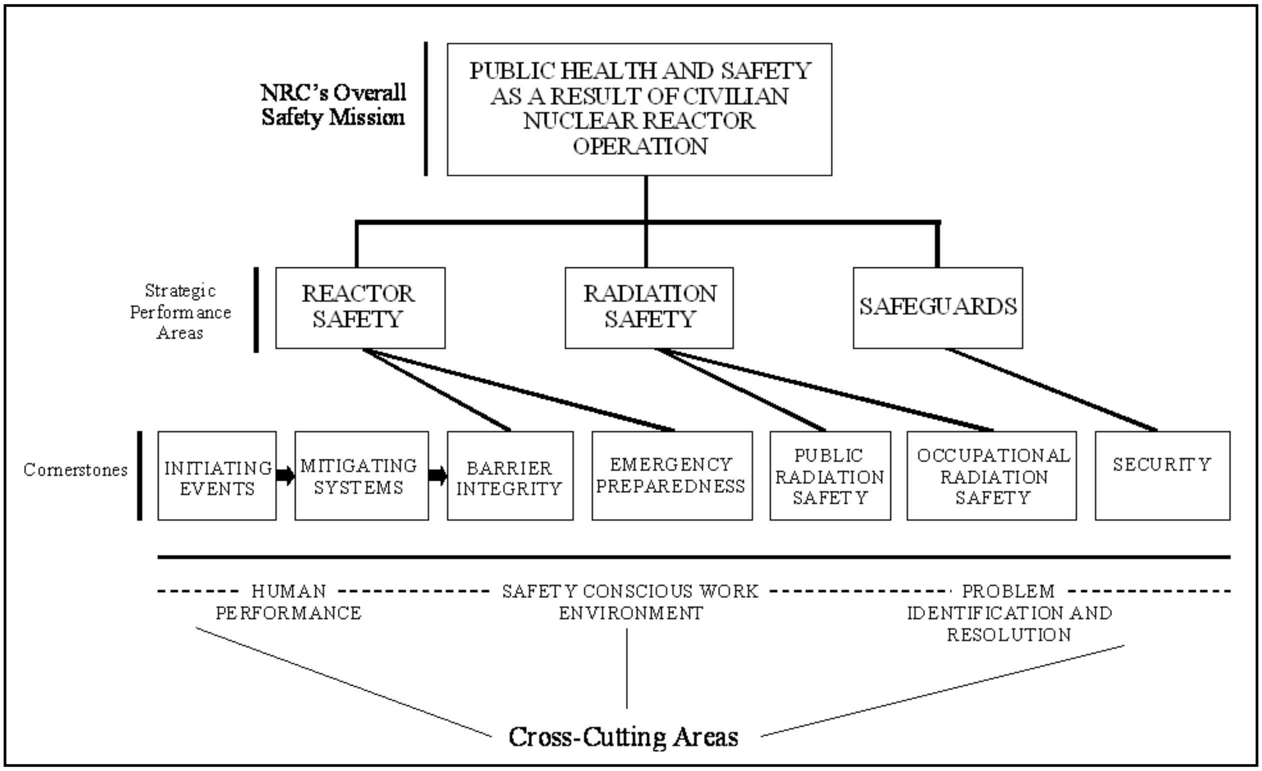

Figure A2. Hierarchical Structure of the Reactor Oversight Process

The staff identified those aspects of licensee performance that are important to the mission and therefore merit regulatory oversight. The performance goals to be met for ensuring nuclear reactor safety were drawn from the Strategic Plan current at the time, and include the following:

- Maintain a low frequency of events that could lead to a nuclear reactor accident;
- Zero significant radiation exposures resulting from civilian nuclear reactors;
- No increase in the number of offsite releases of radioactive material from civilian nuclear reactors that exceed 10 CFR Part 20 limits; and
- No substantiated breakdown of physical protection that significantly weakens protection against radiological sabotage, or theft or diversion of special nuclear materials.

These performance goals reflect those areas of performance for which the NRC has regulatory responsibility in support of the overall agency mission. These performance goals formed the second level of the regulatory oversight framework.

The most important elements in each of these performance areas which form the foundation for meeting the overall agency mission were identified from a risk-informed perspective. These elements were identified as the cornerstones in the third level of the regulatory oversight framework structure. These cornerstones serve as the fundamental building blocks for the regulatory oversight process, and acceptable licensee performance in these cornerstones should provide reasonable assurance that the overall mission of adequate protection of public health and safety is met.

The staff carried the decomposition of performance to each cornerstone area using a top-down, hierarchical, risk-informed approach to:

- identify the objective and scope of the cornerstone;
- identify the desired results and important attributes of the cornerstone;
- identify what should be measured to ensure that the cornerstone objectives are met;
- determine which of the areas to be measured can be monitored adequately by performance indicators;
- determine whether inspection or other information sources are needed to supplement the performance indicators, and
- determine the thresholds of performance for each cornerstone, below which additional NRC actions would be taken.

The staff sought to identify performance indicators where ever possible as a means of measuring the performance of key attributes in each of the cornerstone areas. Where such a performance indicator could not be identified, the staff proposed a “complementary” inspection activity. Where a performance indicator was identified, but was not sufficiently comprehensive, the staff proposed “supplementary” inspection activities. The staff also identified the need for “verification” type inspections to verify the accuracy and completeness of the reported performance indicator data. The staff also identified aspects of licensee performance (such as human performance, the establishment of a safety conscious work environment, common cause failure, and the effectiveness of licensee problem identification and corrective action programs) that are not identified as specific cornerstones but are important to meeting the safety mission. The staff concluded that these items generally manifest themselves as the root causes of performance problems. It was concluded that adequate performance in these crosscutting areas can be inferred through cornerstone performance results from both performance indicators and inspection findings.

APPENDIX REFERENCES

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4. “Development of a framework of safety goals for nuclear installations and its application in Germany,” Berg, HP and Kuzmina, I, *Journal of Polish Safety and Reliability Association Summer Safety and Reliability Seminars*, *Volume 6, Number1-2, 2015*
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