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# Guidance for Performance-Based Regulation

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Prepared by
N. P. Kadambi

**Division of Systems Analysis and Regulatory Effectiveness**
**Office of Nuclear Regulatory Research**
**U.S. Nuclear Regulatory Commission**
**Washington, DC  20555-0001**

# ABSTRACT

This document provides guidance on a process for developing a performance-based alternative for consideration, along with other more prescriptive alternatives, in regulatory decisionmaking. 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 decisionmaking, 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. 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.

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# ABBREVIATIONS

| | |
|---|---|
| ACRS | Advisory Committee on Reactor Safeguards |
| AFWS | auxiliary feedwater system |
| ALARA | as low as reasonably achievable |
| ASME | American Society of Mechanical Engineers |
| BWR | boiling-water reactor |
| CDF | core damage frequency |
| CFR | Code of Federal Regulations |
| DG | draft regulatory guide |
| GPRA | Government Performance and Results Act |
| LERF | large-early-release frequency |
| NRC | U.S. Nuclear Regulatory Commission |
| PRA | probabilistic risk assessment |
| PWR | pressurized-water reactor |
| ROP | Reactor Oversight Process |
| SRM | staff requirements memorandum |

# 1 INTRODUCTION

## 1.1 Background

A performance-based regulatory action achieves defined objectives and focuses on results. It differs significantly from a prescriptive action in which licensees are provided detailed direction on how those results are to be obtained. For example, in the reactor arena, one can envision a U.S. Nuclear Regulatory Commission (NRC) regulatory concern involving the reliability of emergency backup diesels during station blackout accidents. A prescriptive approach would direct the licensee to perform specific detailed maintenance operations, testing procedures, and inspections at precise time intervals. A performance-based approach would simply set a performance objective (e.g., diesel reliability of 95 percent) and allow the licensee considerable freedom in how to achieve that reliability objective. Similarly, the as low as reasonably achievable (ALARA) provisions of Title 10, Part 20, of the *Code of Federal Regulations* (10 CFR Part 20), which impact both materials and reactor licensees, are performance-based in that they allow licensees to meet the specified dose limits in a manner that they deem most appropriate. If the NRC had written a prescriptive Part 20, it might have included specific time limits in specific radiation areas, and required rigid rules concerning the use of respirators and protective suits under defined conditions.

Performance-based regulatory approaches possess inherent strengths that can lead to more effective regulation. Examples include improving the objectivity and transparency of NRC decisionmaking, promoting licensee flexibility in response to regulatory requirements that can reduce licensee burden, and promoting safety by focusing on safety-successful outcomes.

The history of NRC's activity in performance-based regulation began with the staff requirements memorandum (SRM) of January 22, 1997 (Ref. 1), in which the Commission directed the staff to propose a plan to develop performance-based objectives that are not amenable to probabilistic risk assessment.

*Why must the staff consider performance-based regulatory approaches?*

Performance-based regulatory approaches are considered for policy and effectiveness reasons. The policy considerations are based on the 1993 Government Performance and Results Act (GPRA). NRC's Strategic Plan, developed in response to GPRA, provides specific performance goals that drive the agency's regulatory program. Performance-based approaches are mentioned in the goals for reactors, materials, and waste. Regulatory effectiveness has been found to improve when such approaches are used appropriately.

*What is the basis for the guidance in this document?*

The basis for the guidance in this document is the High-Level Guidelines for Performance-Based Regulation (Ref. 4) (hereafter referred to as "the high-level guidelines"). The high-level guidelines cover the three arenas (reactors, materials, waste) and a broad range of issues within each arena. Accordingly, the high-level guidelines are formal and abstract.

*How will this guidance document accomplish its objectives?*

It provides simplified guidance for many of the regulatory issues that NRC staff may be tasked to resolve. It may not cover complex considerations such as defense in depth. Appendix B has been prepared as a reference to support formulation of performance-based alternatives to address broader or more complex issues.

The initiative was given further definition by Direction Setting Issue 12 (Ref. 2) and the White Paper on "Risk-Informed and Performance-Based Regulation," SRM to SECY-98-144 (White Paper) (Ref. 3). The continuing efforts of the staff, which included public workshops, led to the publication of high-level guidelines for performance-based activities (SECY-00-191 (Ref. 4) and 65 FR 26772 (Ref. 5)). These guidelines were developed with interoffice participation by the Performance-Based Regulation Working Group. The developmental aspects of this activity will end with the issuance of this guidance document.

This document describes the use of high-level guidelines for determining whether a performance-based approach can be applied to a given regulatory activity. In addition, it provides insights into the formulation of performance-based alternatives. Although a tendency exits to characterize a regulatory approach as either performance-based or prescriptive, the reality is that the most likely and preferred approach will often be a blend of the two. Thus, when this document refers to making an approach performance-based, the intent is actually to make it as performance-based as possible.

## 1.2 Frame of Reference

The NRC is heavily committed to the identification and evaluation of regulatory actions. Such activities are undertaken in response to a wide array of regulatory issues, and they typically focus on ways to improve performance relative to NRC's goals as articulated in the Strategic Plan (Ref. 6). These activities tend to involve concerns over public health and safety; public confidence; regulatory effectiveness, efficiency, and realism; and unnecessary regulatory burden. When a decision is made to evaluate a regulatory issue, it is standard practice for the staff to use NUREG/BR-0058, Rev. 3, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," (Ref. 7) as guidance. The regulatory analysis prescribed therein is designed to determine whether a regulatory action is needed, to provide adequate justification for the proposed action, and to explain why a particular action was recommended. The heart of the regulatory analysis is a cost-benefit assessment that consists of a systematic evaluation of the consequences associated with a range of alternative responses and the selection of the preferred alternative. It is clear that consideration of the alternatives is critically important in this overall decisionmaking process. NUREG/BR-0058 recognizes the desirability of including a performance-based approach as one of the alternatives to be evaluated. In NUREG/BR-0058, Section 4.2, "Identification and Preliminary Analysis of Alternative Approaches," states –

> 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

*What must the staff do?*

In order to increase regulatory effectiveness, the Commission has directed the staff to consider risk-informed and performance-based alternatives when a choice is being made between different regulatory approaches. The staff can use this document to accomplish the Commission's objective.

*How should the staff proceed?*

The staff can begin with this document to see if concepts such as safety function and safety margin are relatively simple to evaluate in the context of the specific regulatory issue. If the resolution is sensitive to where and how performance is measured, Appendix B should be considered for supplementary guidance. The regulatory analysis, which considers the costs and benefits of each alternative, can document the preferred alternative.

readily measurable quantity[1] and is enforceable, the proposed requirement should merely specify the objective or result to be obtained 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.

For many applications, the guidance in the present document will suffice to support a performance-based approach. For issues whose resolution is sensitive to where and how performance is measured, or in cases involving cross-cutting issues, staff may need to undertake a more considered development as described in Appendix B.

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[1]The "readily measurable quantity" does not necessarily imply that only direct measures of physical parameters (such as length, weight, temperature, pressure, flow rate) are acceptable. Although direct measures (called natural measures) are preferred, objective measures of other sorts should also be considered. This broader interpretation of the term "readily measurable quantity" is based on more recent work on performance-based approaches to regulation.

# 2 HIGH-LEVEL PERFORMANCE-BASED GUIDELINES

In SECY-00-191, September 1, 2000, the NRC issued high-level performance-based guidelines for identifying and assessing potential performance-based regulatory actions. "High-level" means that the guidelines are applicable across the full spectrum of NRC regulatory activity, corresponding to the three NRC arenas, reactor safety, material safety, and waste safety.

The guidelines are meant to raise questions, the answers to which should assist the staff in determining whether and how to pursue a performance-based alternative. The staff may exercise discretion in applying these guidelines, which are classified into three groups (1) viability guidelines, (2) assessment guidelines, and (3) guidelines to ensure consistency with other regulatory principles. A summary follows.

## 2.1 Viability Guidelines

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. 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?)

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

Appropriate regulatory decisionmaking cannot exclude the possibility of prescriptive elements. The characteristic of a performance-based approach, as described in the Commission's White Paper, 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 decisionmaking...." The focus of a performance-based approach is the use of prescriptive elements only when necessary.

*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.

- 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?)

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.

In terms of relative importance, the guideline concerned with performance failure leading to an immediate safety concern is pre-eminent. 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 justify placing this guideline as the first among the viability guidelines. Hence, if sufficient margin exists under the first viability guideline, a broad range of less-prescriptive approaches become viable, including performance-based approaches. The three subsequent viability guidelines characterize the performance-based approach.

The White Paper associates flexibility with the concept of incentives. It states that one of the attributes of a performance-based approach is that licensees have flexibility to determine how to meet the established performance criteria in ways that will "encourage and reward improved outcomes." The coupling of flexibility and licensee incentives has been addressed in the formal guidelines in Appendix A.

## 2.2 Assessment Guidelines

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 net benefit

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.

Many of the considerations that apply to this set of guidelines are also pertinent to the cost-benefit evaluation performed as part of the regulatory analysis. Hence, information developed here could also support the alternatives analysis described in the Regulatory Analysis Guidelines.

## 2.3 Guidelines to Ensure Consistency with Other Regulatory Principles

These guidelines take into account fundamental regulatory principles that have been articulated by the Commission, such as, the Principles of Good Regulation (Ref. 6). 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.

A complete presentation of the guidelines appears in Appendix A.

# 3 PROCESS

## 3.1 Objectives

The objective of this document is to provide a process that can be widely used for decisions concerning performance-based regulatory alternatives. As noted above, the performance-based guidelines are articulated at a high level and are applicable to regulatory issues involving the reactor, materials, and waste arenas. The process must be relatively general for it to have such wide relevancy. More detailed guidance, tailored specifically to individual arenas, is beyond the scope of this document. It is anticipated that each of the major arenas will have additional guidance in the form of office procedures that will effectively supplement this document. Nevertheless, for many regulatory actions, the nature and objectives of the regulatory issue will be clear and the knowledge base large enough that a relatively modest process, such as the one described here, will be sufficient.

Although applicable across all regulatory arenas, considerable leeway exists in the level of adherence to the general process outlined here. For example, in certain instances it may be so clear that a performance-based approach is not feasible that formal application of these guidelines could be largely unnecessary. Circumstances are also likely in which the appropriateness of using a performance-based approach and the characteristics of that approach are very obvious and straightforward. Decisions on these matters are almost always governed by expert-judgment assessments of margins that effectively mimic the substance of the process being spelled out here. In such cases, the staff may simply choose to use these guidelines as a check on the performance-based approach that is being proposed. Similarly, the guidelines may also be useful to test a proposed regulatory action that purports to be performance-based to determine whether the action, under a formal scrutiny, in fact merits the label.

Alternatively, some complex regulatory issues may require that a far more detailed process be used than the one described here. If so, concepts and tools such as decision theory and objectives hierarchies would likely be needed. NRC staff in need of, or interested in, a more systematic and structured process are directed to Appendix B and the references therein for decision theory concepts.

Regardless of the level of effort, some documentation for case-specific applications of this process should be maintained for transparency and efficiency. Individual office procedures should specify the requirements for documentation.

*What is the relationship between risk-informed and performance-based approaches to regulation?*

Risk-informed and performance-based approaches to regulation complement one another. Risk information, when a probabilistic risk assessment (PRA) is available, can be useful in finding the most safety-significant functions and systems. If a PRA is not available, operational experience may provide enough information. Safety would be best served by demanding the highest (i.e., most aggregated) levels of performance from the most safety-significant structures, systems, and components.

In SECY-01-0218, “Update of the Risk-Informed Regulation Implementation Plan” (December 5, 2001) (Ref. 8), the staff has stated that, to the extent appropriate, activities to risk-inform regulations should also incorporate the performance-based approach to regulation. The corollary is also true–performance-based regulations should be risk-informed when possible.

Figure 1 is a schematic representation that characterizes the most important elements of the overall process of addressing a regulatory issue. The guidance presented here is specifically concerned with the development of a performance-based regulatory alternative and corresponds to an entry point at the “Performance-Based” or “Risk-Informed & Performance-Based” boxes of Figure 1. The process contains a number of feedback loops, which is indicative of the iterative nature of this process.

The process is intended to determine whether a given regulatory issue is suited to a performance-based approach, and if so, to identify an alternative that most strongly reflects performance-based attributes. In addition, other competing objectives must be considered, such as setting performance and reliability measures at the highest (i.e., most aggregated) possible level and, to the extent practicable, using multiple parameters to satisfy the defense-in-depth philosophy. Meeting these objectives may require application of the methodology in Appendix B. This process is intended to enable the staff to identify a preferred performance-based alternative based on the consideration of all these objectives. This is accomplished through an iterative process, similar to that depicted in Figure 1. Each iteration should result in more detailed and focused information that can be used toward improving the performance-based alternative.

This document has been prepared as guidance to be used in the context of rulemaking. However, the resolution of a regulatory issue may involve changes to any part of the regulatory framework and may not result in an actual regulation. For example, improvements obtained through the revised reactor oversight process, which is performance-based in nature, were realized mainly by changes to the inspection, assessment, and enforcement aspects of the regulatory framework. Those improvements are considered to be highly effective even though rulemaking was not involved.

*Does a risk-informed and performance-based approach to regulation necessarily involve rulemaking?*

No, any part of the regulatory framework can be considered for modification. According to the Strategic Plan (Ref. 6), 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.

### 3.2 Process Steps

For any given regulatory issue, the design of a performance-based approach depends on five basic considerations that are addressed in detail below. Each of these elements is treated as a step in a process. The answers to the questions provide the basis for developing the required details on a performance-based alternative, if it is feasible.

**Step 1 – Defining the Regulatory Issue and its Context**

Purpose – To define the regulatory issue with clear objectives that are well-understood.

- What is the arena and sub-arena for the regulatory issue?
- Which of the NRC’s performance goals does the regulatory issue address?
- What are the expected outcomes and results from resolution of the regulatory issue?

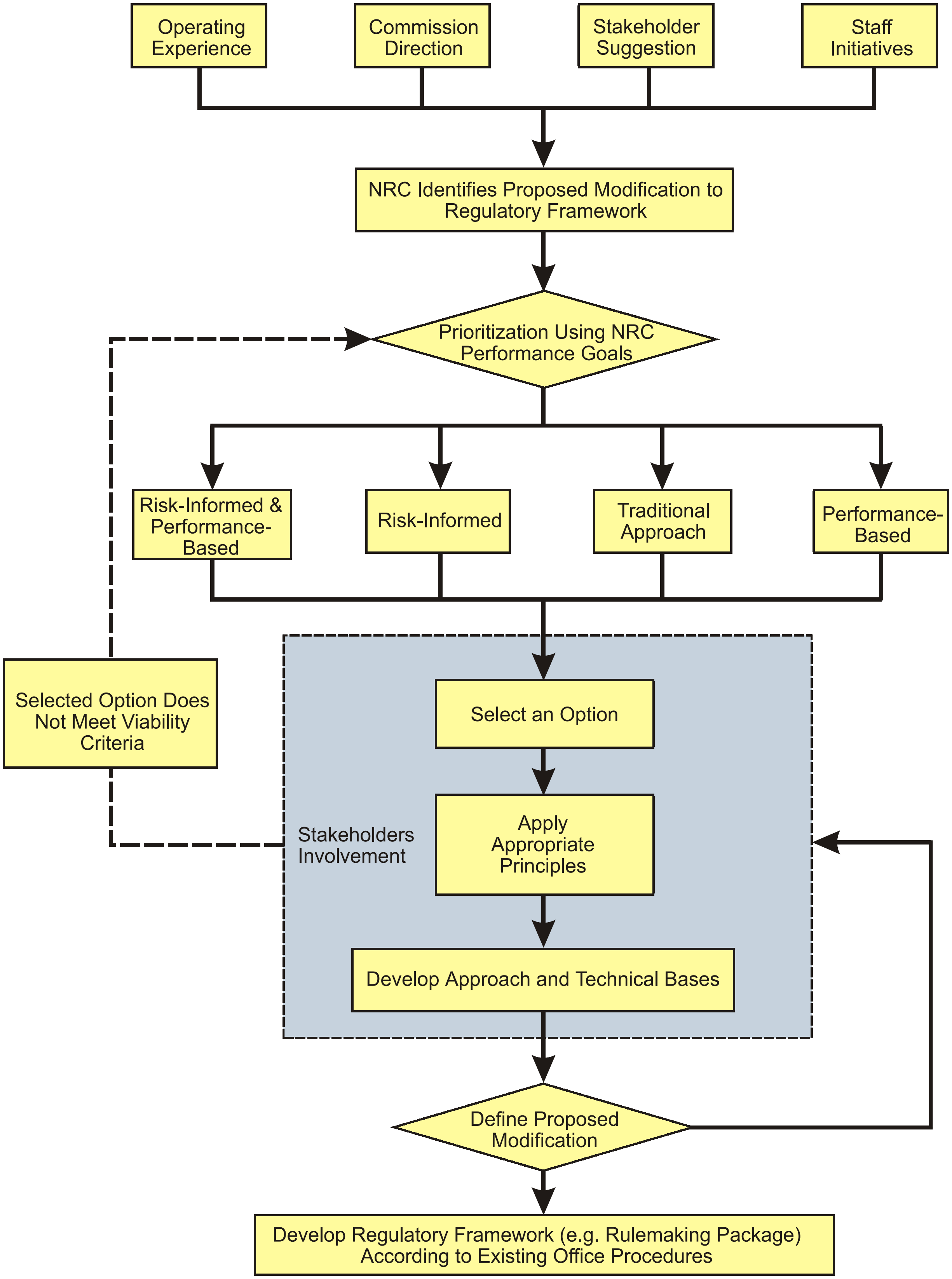



Figure 1: Flow Chart To Address Regulatory Issues

**Step 2 – Identifying the Safety Functions**

Purpose – To identify the safety functions and systems that affect the regulatory issue (directly or indirectly).

- What are the safety functions or concepts that can impact the regulatory issue?

This inquiry should be focused on the nature of the regulatory issue and the expected outcomes. For example, if the regulatory issue is directed at placing appropriate quality requirements on a set of components, the safety functions (which are functions that answer the question, "How is risk mitigated ?") served by the components would have to be considered, along with the sensitivity of the function to the quality level.

- What equipment/systems/procedures are necessary to satisfy the safety function?

- What level of safety (based on appropriate metrics) is required to meet the objectives of the regulatory issue?

For example, if the objective is to maintain safety while relaxing the stringency of a regulatory requirement, an appropriate metric for monitoring safety should be found and monitored when the regulatory requirement is changed.

**Step 3 – Identifying Safety Margins**

Purpose – To evaluate margins and identify performance parameters (if any) that satisfy the regulatory issue objectives.

- How much safety margin is available, and how robust is it, for performance monitoring to provide a basis for granting licensee flexibility?

As mentioned earlier, an effective performance-based approach to regulation provides flexibility to the NRC and licensees provided there is sufficient safety margin. 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.

A temporal margin represents the time available to identify a concern and 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.

"Robustness" of a safety margin means that the margin between two performance levels is significantly greater than uncertainty and normal variability in performance. If this condition is met, a very low probability of the performance parameter crossing the limit exists, unless performance changes in a very significant way. In any case, wherever there is substantial uncertainty, achieving robustness requires that nominal performance levels be set more conservatively than when there is less uncertainty. Depending on the situation, uncertainty can be assessed using explicit models (e.g., PRAs), expert judgment, or actuarial methods based on operating experience.

The term "margin" is employed in this guidance somewhat differently than in its traditional use for health and safety regulation. The significance of "margin" is closely associated with the other factors in the viability guidelines, namely, 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 stakeholders. The NRC and licensees are the principal stakeholders in resolving a regulatory issue.

For example, the initiating event indicator in the reactor oversight process (ROP) for unplanned scrams ranges from 0–25 per 7000 hours of critical operation. The performance of a licensee would be declared as unacceptable from a safety standpoint if such scrams exceed 25 in number. Thus, according to the action matrix, green level performance is limited to 0–3 scrams, white is characterized by 4–6 scrams, yellow is characterized by 7–25 scrams, and red denotes more than 25 scrams. Given the adverse economic consequences of unplanned scrams, reactor licensees have a strong incentive to minimize them and stay in the green band. Almost all licensees accomplish this objective in practice. The licensee will likely view exceeding 3 scrams as a "serious" concern or condition. In this way, a proxy objective has been created that works in NRC's favor because, although crossing the green/white threshold has only a minor adverse safety impact, the licensee has a strong incentive to correct the underlying cause expeditiously.

Hence, an evaluation of the available margin and its robustness should include a search for appropriate performance parameters that provide for operational flexibility as well as the means to fulfill regulatory responsibilities.

- What observable characteristics, quantitative and qualitative, exist within the safety functions identified in Step 2?

Measurable or calculable parameters are generally associated with quantitative observable characteristics. Parameters that are observed directly, such as pressure, temperature, flow, incurred cost, and radiation exposure, are called natural measures. Some natural measures require simple calculation, such as reliability, percentage, and concentration. However, qualitative parameters are also able to support a performance-based approach under appropriate conditions and should not be overlooked.

- Can constructed measures be developed that provide qualitative expressions capable of observation with reasonable objectivity?

*How can qualitative observations be used?*

Qualitative observations present special challenges, but should not be ignored. For example, the quality of housekeeping in a nuclear facility is an important aspect of preventing fire hazards. Qualitative observations can be quite effective in assessing such a characteristic. A linguistically defined measure that represents a level of impact or significance, called a constructed measure, is a way to represent qualitative observations. A constructed measure becomes necessary when natural measures do not exist or are too difficult to use. It is used to describe performance needed to satisfy higher-level objectives. Examples are (1) impact on public confidence is high, medium, or low, or (2) environmental significance is high, medium, or low.

**Step 4 – Selecting Performance Parameters and Criteria**

Purpose – To select a complement of performance parameters and objective criteria (if possible) that both satisfy the viability guidelines and resolve the regulatory issue.

- Can the identified observable characteristics, together with objective criteria, provide measures of safety performance and the opportunity to take corrective action if performance is lacking?

- Can objective criteria be developed that are indicative of performance and that permit corrective action?

• Is flexibility (for NRC and licensees) available consistent with level of margin?

The approach recommended by the Advisory Committee on Reactor Safeguards (ACRS) is to apply the performance criteria at as high a level as practicable (Ref. 9). Setting the criteria at a higher level can allow more flexibility. However, the need to assure opportunity to take appropriate corrective action requires that criteria be set appropriately for the regulatory 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. If the complexity of the regulatory issue increases beyond a certain point, it may be necessary to apply the methodology described in Appendix B.

The set of questions in Step 4 may not be amenable for application exactly in the sequence shown. They should be viewed as requiring iteration when questions of margin, corrective action, and flexibility strongly interact with one another. 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, in the area of quality assurance, the quality of emergency backup power provided by a diesel generator would not necessarily be well-reflected just by the criteria that are applied to each component part of the diesel generator. 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 could adequately meet performance standards even if the component parts are only commercial grade.

**Step 5 – Formulating a Performance-Based Alternative**

Purpose – To determine the appropriate implementation of a performance-based approach within the regulatory framework.

*What happens if incentives are excluded from the regulatory approach?*

Experience shows that absence of proper incentives, or the existence of “perverse” incentives, can result in such emphasis on compliance that safety may be adversely affected. One example of such an occurrence is when licensees, faced with the approach of the end of an allowable outage time for a safety system maintenance, may feel forced into actions that may meet compliance standards, but are not fully supportive of safety. The Commission’s policy on such matters is presented in detail in COMSAJ-97-008, “Discussion on Safety and Compliance” (Ref. 10).

• Does the performance-based regulatory alternative provide necessary and sufficient coverage of the regulatory issue objectives?

One of the important elements of coverage is consideration of defense-in-depth. The ACRS recommendations (Ref. 9) included one that would involve multiple performance parameters that provide redundant information to satisfy the defense-in-depth philosophy. The NRC’s defense-in-depth philosophy also includes consideration of “prevention” and “mitigation” strategies which operate in proper balance. If the regulatory issue involves complex defense-in-depth issues, the needed guidance should be drawn from Appendix B.

• Of the performance parameters selected in Step 4, which of them requires that a prescriptive approach be used to meet regulatory needs? Can a combination of performance-based and prescriptive measures be implemented such that the resolution of the regulatory issue is as performance-based as possible?

• Has the regulatory alternative been considered for implementation within each of the levels of the regulatory framework so that an optimum level is proposed?

For example, a prescribed parameter can be included in a Technical Specification or other license condition. It may be possible to provide flexibility in operation for parameters that do not have to be strictly controlled. Also, as mentioned above, staff may consider one or another type of incentives for licensees to increase the likelihood of improved safety outcomes.

- Are licensees' incentives appropriately aligned, considering the overall complement of performance measures, criteria, the implementation, and the regulatory framework as a whole?

Licensees' 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. Examples of negative incentives occur when NRC's enforcement policy causes licensees to experience undesired consequences when levels of safety or trends in safety are unfavorable.

Regulation that is based on sampling licensee performance needs to be designed with care, in order to avoid incentivizing performance in one important area at the expense of another, with a net adverse outcome. As a hypothetical example, regulation that sought only to minimize the unavailability of components might create an incentive to reduce maintenance to a level at which unreliability performance would be adversely affected. When staff considers a change to the regulatory framework, they must also consider the incentives created by the new overall framework.

- Is it worth modifying the regulatory framework in the manner proposed, considering the particulars of the regulatory issue?

**Summary**

This step-by-step process takes the staff through a series of questions that should lead to answers to the following fundamental questions (1) What is the regulatory issue? (2) Is it possible to use a performance-based approach to resolve the issue? (3) Does it appear worthwhile to pursue a performance-based solution? Although a formal response to the last question requires application of the assessment guidelines, management judgment can be sufficient for considering a performance-based alternative in a regulatory analysis or other appropriate process.

# 4 ILLUSTRATIVE EXAMPLES

For illustration purposes, this section presents actions on three recent regulatory issues are presented below to exemplify application of the process steps. By applying this process, staff can determine whether a regulatory requirement can be made more performance-based. These examples also demonstrate how different elements of the regulatory framework can be targeted for the most effective and efficient application of the guidance steps and hence improve the net benefit from a performance-based proposal.

The first example is a recent proposal to revise 10 CFR 50.44 concerning combustible gas control in containment at nuclear power plants (Ref. 11). The draft regulatory guide provided with the rulemaking package, DG-1117, offers a performance-based approach to meeting the requirement for hydrogen monitors to be functional, reliable, and capable of measuring hydrogen concentration in the containment after an accident.

The second example is a proposed rule that addresses geological and seismological characteristics for siting and design of dry cask independent spent-fuel storage installations and monitored retrievable storage installations (Ref. 12). The regulatory analysis for this rulemaking recommends a performance-based approach in order to meet the safety objectives in a cost-effective manner.

The third example was originally proposed as a risk-based performance indicator for shutdown conditions for use in the ROP. NRC staff is considering Its essential aspects are being considered for use in the significance determination process relative to inspection findings during shutdown conditions (Ref. 13).

The process steps are presented below using specific factors that entered into incorporating performance-based concepts in each of the examples. The examples (identified as Examples 1, 2, and 3) have been employed in each of the process steps introduced in Section 3.2 to the extent that they successfully illustrate the step. In other words, each step does not employ all examples. Example 3 has not been incorporated into the ROP; however, it represents a useful illustration of a way to look for the most effective performance parameters.

**Step 1 – Defining the Regulatory Issue and its Context**

- What is the arena and sub-arena for the regulatory issue?

In the case of Examples 1, 2, and 3, the issues belong in the reactor and waste arenas, with the sub-arenas in rulemaking, spent fuel safety and inspection programs, respectively.

- Which of the NRC's performance goals does the regulatory issue address?

The examples potentially cover all four of the agency's performance goals.

- What are the expected outcomes and results from resolution of the regulatory issue?

The expected outcome in each example is to identify the performance-based alternatives that optimally use the flexibility of the regulatory framework to obtain a cost-effective resolution of each regulatory issue.

**Step 2 – Identifying the Safety Functions**

- What are the safety functions or concepts that can impact the regulatory issue?

In Example 1, the safety functions are accident management to maintain containment integrity and effective emergency planning. In Example 2, the safety functions are stability against soil liquifaction during vibratory motion, and cask sliding and resulting displacements during an earthquake event.

- What equipment/systems/procedures are necessary to satisfy the safety function?

The technical evaluation for Example 1 showed that non-safety-related commercial grade hydrogen monitors that meet lower category requirements than the existing safety-related systems would satisfy the safety function. The evaluation for Example 2 showed that more cost-effective analyses may be possible to satisfy siting criteria than existing prescriptive criteria, which essentially require the same criteria as operation of a nuclear power plant.

- What level of safety (based on appropriate metrics) is required to meet the objectives of the regulatory issue?

For Example 1, the required level of safety is that which meets the objective of reducing, to an acceptable level, the risk of early containment failure from hydrogen combustion. Hence, the metric in this case is the conditional containment failure probability. For Example 3, the required level of safety is to maintain at an acceptable level the core damage risk associated with certain configurations typical of shutdown operations.

**Step 3 – Identifying Safety Margins**

- How much safety margin is available, and how robust is it, for performance monitoring to provide a basis for granting licensee flexibility?

Example 2 exemplifies an instance for which the safety margin can be assessed qualitatively, yet reliably. The casks in question are designed to safely withstand the conditions associated with transportation and handling of spent-fuel operations. The rigors of such operations, and the associated regulatory requirements, can reasonably be expected to envelop, with considerable margin, the challenges posed by vibratory motion and sliding displacements during an earthquake.

A different type of margin can be identified in Example 3. The technical evaluation identified four risk-significant categories of configurations for pressurized-water reactors (PWRs) and three for boiling-water reactors (BWRs). For each reactor type, the categories range from low risk to high risk. Baseline performance levels were established using operating history. In the low-risk configurations, baseline performance is achieved by exiting a configuration within 20 days in PWRs and 2 days in BWRs. At the other end of the spectrum, the threshold for unacceptable performance occurs at 1 day in a high-risk configuration. Applying the concepts of the ROP and its action matrix, under nominal conditions, licensees would expect to operate within the green band, which corresponds, for PWRs, to 21 days in a low-risk configuration and by totally avoiding a high-risk configuration. One day in a high-risk configuration would denote unacceptable performance. Hence, monitoring the time at risk-significant shutdown configurations provides the NRC and the licensee with a performance-based approach for maintaining safety margins at acceptable levels.

- What observable characteristics, quantitative and qualitative, exist within the safety functions identified in Step 2?

For Example 1, the observable characteristics come from the results of periodic servicing, testing, and calibration of hydrogen monitors. The operating margin would come from a comparison between these results and the target values established by the licensee under the maintenance rule. For Example 2, the observations would likely be based on verification of design margins by post-earthquake inspections, and corrective actions as necessary over the extended periods of time over which such sites may be in operation.

- Can constructed measures be developed that provide qualitative expressions capable of observation with reasonable objectivity?

Among the examples considered, Example 2 may require a constructed measure to characterize the response of the storage facility to an actual earthquake.

### Step 4 – Selecting Performance Parameters and Criteria

- Can the identified observable characteristics, together with objective criteria, provide measures of safety performance and the opportunity to take corrective action if performance is lacking?

In Example 1, the recorded results of the maintenance program provide the observable characteristics and also provide the opportunity to take corrective actions if lack of performance is noted by the NRC or the licensees themselves.

The performance criterion in Example 3 is the time period in each of the shutdown configurations. This exemplifies a focused application of the recommendation of the ACRS that the performance parameters should be identified at as high a level as practicable. If this recommendation had not been followed, all systems and sub-systems involved in risk-significant configurations might have been targeted for monitoring. The management of risk in such configurations could still be accomplished. The recommendation to search for parameters at a high level would direct the analyst's attention to other, more cost-effective possibilities. In Example 3, time in risk-significant configurations fulfills the needed attributes. The second ACRS recommendation of providing for defense-in-depth by redundant observations can also be implemented by separately monitoring the safety functions of certain risk-significant components.

- Can objective criteria be developed that are indicative of performance and that permit corrective action?

In both Examples 1 and 3, the regulatory issues are highly amenable to establishment of objective criteria that are indicative of performance, as well as permit sufficient time for corrective action.

- Is flexibility (for NRC and licensees) available consistent with level of margin?

Example 2 exemplifies how the existence of substantial margins enables consideration of higher magnitudes of flexibility. Because of the robustness of the casks, licensees can potentially employ simplified analyses to show that the uncertainties associated with seismicity and cask response can be reliably enveloped to demonstrate conformance with site suitability criteria. Simplified analyses provide greater cost-effectiveness.

Similarly, in Example 3, a range of flexibility is considered, consistent with margin available in each shutdown configuration category. The least flexibility would be available for the high-risk category, which is appropriate from a regulatory perspective.

### Step 5 – Formulating a Performance-Based Alternative

- Does the performance-based regulatory alternative provide necessary and sufficient coverage of the regulatory issue objectives?

In both Examples 1 and 2, the staff determined that sufficient margin is present for NRC staff to confirm directly that licensee performance is adequate in key areas, without requiring compliance with prescriptive requirements in all areas. Therefore, a less-prescriptive, more performance-based approach can provide suitable coverage of the regulatory issue objectives.

- Of the performance parameters selected in Step 4, which of them requires that a prescriptive approach be used to meet regulatory needs? Can a combination of performance-based and prescriptive measures be implemented such that the resolution of the regulatory issue is as performance-based as possible?

Example 3 offers an illustration of how specific prescriptive elements can be incorporated into a less prescriptive regulatory approach. The regulatory framework permits inclusion of prescriptive elements through Technical Specification or License Condition provisions.

- Has the regulatory alternative been considered for implementation within each of the levels of the regulatory framework so that an optimum level is proposed?

In both Examples 1 and 2, various alternative means for implementing a performance-based approach within the regulatory framework were considered. A variety of internal stakeholder input was explicitly included before coming up with the recommendations published in the *Federal Register*.

- Are licensees' incentives appropriately aligned, considering the overall complement of performance measures, criteria, the implementation, and the regulatory framework as a whole?

Inappropriate incentives could potentially occur in the case of Example 3. In NUREG-1753, for the case of PWRs in reduced inventory operation, the threshold times corresponding to green/white and white/yellow threshold are 1 day and 1.08 days, respectively. Licensees might perceive an incentive to inappropriately rush through safety-sensitive operations only to avoid crossing a threshold. The staff is in a better position to structure regulatory provisions that minimize perverse incentives by explicitly considering the possibilities within the regulatory framework and the ROP's action matrix.

- Is it worth modifying the regulatory framework in the manner proposed, considering the particulars of the regulatory issue?

In both Examples 1 and 2, the proposed performance-based alternatives have been published for comment. In both cases, preliminary indications suggest that the proposals enjoy considerable stakeholder support. Hence, the modifications appear worthwhile.

# 5 REFERENCES


1. Nuclear Regulatory Commission (U.S.) (NRC). "Staff Requirements - SECY-96-218 - Quarterly Status Update for the Probabilistic Risk Assessment (PRA) Implementation Plan, Including a Discussion of Four Emerging Policy Issues Associated with Risk-Informed Performance-Based Regulation." NRC: Washington, DC. January 22, 1997.

2. Nuclear Regulatory Commission (U.S.) (NRC). "Staff Requirements - COMSECY-96-061 - Risk-Informed, Performance-Based Regulation (DSI 12)." NRC: Washington, DC. April 15, 1997.

3. Nuclear Regulatory Commission (U.S.) (NRC). "Staff Requirements - SECY-98-144 - White Paper on Risk-Informed and Performance-Based Regulation." NRC: Washington, DC. March 1999.

4. Nuclear Regulatory Commission (U.S.) (NRC). SECY 00-191, "High-Level Guidelines for Performance-Based Activities." NRC: Washington, DC. September 2000.

5. Nuclear Regulatory Commission (U.S.), Washington, DC. "Revised High-Level Guidelines for Performance-Based Activities," Proposed Rule. *Federal Register*: Vol. 65, No. 90. pp. 26772-26776. May 9, 2000.

6. Nuclear Regulatory Commission (U.S.) (NRC). NUREG-1614, Vol. 2, Parts 1 & 2, "Strategic Plan Fiscal Year 2000 - Fiscal Year 2005." (Final Report) NRC: Washington, DC. September 2000.

7. Nuclear Regulatory Commission (U.S.) (NRC). NUREG/BR-0058, Rev. 3, "Regulatory Analysis Guidelines." (Final Report) NRC: Washington, DC. June 2000.

8. Nuclear Regulatory Commission (U.S.) (NRC). SECY 01-0218, "Update of the Risk-Informed Regulation Implementation Plan." NRC: Washington, DC. December 5, 2001.

9. Letter, Dana A. Powers (ACRS) to William D. Travers (EDO, NRC), September 8, 2000. Subject: Proposed High-Level Guidelines for Performance-Based Activities.

10. Nuclear Regulatory Commission (U.S.) (NRC). "Staff Requirements - COMSAJ-97-008 - Discussion on Safety and Compliance." NRC: Washington, DC. August 25, 1997.

11. Nuclear Regulatory Commission (U.S.), Washington, DC. "Combustible Gas Control in Containment," Proposed Rule. *Federal Register*: Vol. 67, No. 149. pp. 50374-50383. August 2, 2002.

12. Nuclear Regulatory Commission (U.S.), Washington, DC. "Geological and Seismological Characteristics for Siting and Design of Dry Cask Independent Spent Fuel Storage Installations and Monitored Retrievable Storage Installations," Proposed Rule. *Federal Register*: Vol. 67, No. 140. pp. 47745-47755. July 22, 2002.

13. Nuclear Regulatory Commission (U.S.)(NRC). NUREG-1753, "Risk-Based Performance Indicators; Results of Phase 1 Development." NRC: Washington, DC. April 2002.

# APPENDIX A

# HIGH-LEVEL GUIDELINES FOR PERFORMANCE-BASED ACTIVITIES

# APPENDIX A

## HIGH-LEVEL GUIDELINES FOR PERFORMANCE-BASED ACTIVITIES

The U.S. Nuclear Regulatory Commission (NRC) staff developed, and provided to the Commission and the public, high-level guidelines to identify and assess performance-based activities in SECY-00-191, dated September 1, 2000 (Ref. A-1). These guidelines were developed consistent with the direction in the Staff Requirements Memorandum (SRM) to SECY-99-176, "Plans for Pursuing Performance-Based Initiatives" (Ref. A-2). The staff made presentations on the guidelines to the Advisory Committee on Reactor Safeguards (ACRS) and the Advisory Committee on Nuclear Waste and provided them for information to the Advisory Committee on Medical Use of Isotopes. On September 8, 2000, the ACRS (Ref. A-3) provided conclusions and recommendations that included the following:

- The guidelines should explicitly state that the performance levels and reliability parameters should be set at the highest practical level.
- 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 staff has determined that, in order to meet these recommendations, the guidelines need to be modified and the process that is followed to implement the guidelines must have the following guidance:

1. A hierarchical structure of goals and objectives should be developed that reflects the decisionmaking values of a regulatory issue so that the term "highest practical level" can be interpreted objectively.
2. The development of redundant information to satisfy the defense-in-depth philosophy requires that the association of performance parameters with objectives should be represented in a formal manner so that attributes such as "prevention" and "mitigation" are explicitly treated.

The re-formulated high-level guidelines for performance-based activities are presented below in two versions. The first version is the formal one that maintains similarity and consistency with the guidelines provided to the Commission in SECY-00-191 and published in the *Federal Register* at 65 FR 26772 (Ref. A-4). The only changes made are those needed to implement the ACRS recommendations. The second version is a plain-English rendition of the high-level guidelines that relates more directly to the stepwise process described in Section 3.

**Version 1 (Formal)**

I. Viability Guidelines

A. A framework exists or can be developed 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 will not result.

   (1) An adequate safety margin exists.

   (2) Time is available for taking corrective action to avoid safety concerns.

   (3) The licensee is capable of detecting and correcting performance degradation.

B. Measurable, calculable, or constructable parameters to monitor acceptable plant and licensee performance exist or can be developed.

   (1) Directly measured parameters related to the safety objective are preferred and will typically satisfy this guideline.

(2) Calculated or constructed parameters may also be acceptable if there is a clear relationship to the safety objective.

(3) Parameters that licensees can readily 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.

(4) Acceptable parameters will be consistent with defense-in-depth and uncertainty considerations.

C. Objective criteria to assess performance exist or can be developed.

(1) Objective criteria consistent with the desired outcome are established based on risk insights, deterministic analyses, and/or performance history.

D. Licensee flexibility in meeting the established performance criteria exists or can be developed.

(1) Programs and processes used to achieve the established performance criteria will be at the licensee's discretion.

(2) 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 safety and protect the environment and the common defense and security.

(1) Safety considerations play a primary role in assessing any change arising from the use of performance-based approaches.

(2) Adequate safety margins are maintained using realistic safety analyses, including explicit consideration of uncertainties.

B. Increase public confidence.

(1) An emphasis on results and objective criteria (characteristics of a performance-based approach) can help NRC to be viewed as an independent, open, efficient, clear, and reliable regulator.

(2) A performance-based approach helps provide the public clear and accurate information about, and a meaningful role, in the regulatory programs.

(3) A performance-based approach helps explain NRC's roles and responsibilities and how public concerns are considered.

C. Increase effectiveness, efficiency, and realism of the NRC's activities and decisionmaking.

(1) The level of conservatism existing in the currently applicable regulatory requirements would be assessed, considering analysis methodology and the applicable assumptions. Any proposal to use realistic analysis would take into account uncertainty factors and defense-in-depth relative to the scenario under consideration.

(2) 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 regulatory burden.

(1) A performance-based approach enables the NRC to impose regulatory burden that is commensurate with the safety benefit and that effectively focuses resources on safety issues.

(2) A performance-based approach will enable the costs associated with NRC activities to States, the public, applicants, and licensees to be focused on areas of highest safety priority and avoid burden imposed by overly prescriptive regulatory requirements.

E. The expected result of using a performance-based approach is an overall net benefit.

(1) A reasonable net benefit test begins with a qualitative approach to evaluate whether there is merit in changing the existing regulatory framework. When the net benefit test is approached from the perspective of existing practices, stakeholder input would be sought.

(2) Unless imposition of a safety improvement or other societal benefit is contemplated, expending resources for a change in regulatory practice would be justified only if NRC or licensee operations benefit from such a change. Licensees themselves will be the primary source of initial information and feedback regarding potential benefits.

(3) For the limited purpose of screening potential performance-based changes, consideration of a specific result (such as net reduction in worker radiation exposure) may be sufficient for weighing the immediate implications of a proposed change.

F. The performance-based approach can be incorporated into the regulatory framework.

(1) The regulatory framework may include regulation in the *Code of Federal Regulations*, the associated regulatory guides, NUREGs, standard review plans, technical specifications, and inspection guidance.

(2) A feasible performance-based approach would be directed specifically at changing one, some, or all of these elements.

(3) The proponent of the change to the elements of the regulatory 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 a public meeting.

(4) Inspection and enforcement considerations would be addressed during the formulation of regulatory changes rather than afterwards. Such considerations could include reduced NRC scrutiny if performance so warrants.

G. The performance-based approach would accommodate new technology.

(1) 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.

(2) Advanced proven technologies may provide more economical solutions to a regulatory issue without compromising safety, hence justifying consideration of a performance-based approach.

III. Guidelines for Consistency with Regulatory Principles

A. A proposed change to a more performance-based approach is consistent and coherent with other overriding goals, principles, and approaches in the NRC's regulatory process.

(1) These principles are provided in the Principles of Good Regulation (Ref. A-5); the Probabilistic Risk Assessment Policy Statement (Ref. A-6); Regulatory Guide 1.174, "An Approach for Using PRA in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" (Ref. A-7); and the NRC's Strategic Plan (Ref. A-5).

(2) 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 particular regulatory issues involved.

**Version 2 (Plain English)**

I. Viability Guidelines *(Can a performance-based approach be developed?)*

A. Estimate margin realistically, using quantitative and/or qualitative factors. Is the margin robust, or is it sensitive to unpredictable factors? Is there time to take corrective action if expectations regarding the regulatory issue or the licensee are not borne out? Can the affected licensees reasonably be expected to react appropriately if surprises occur?

B. Are there quantitative or qualitative parameters, using natural or constructed measures, that can be observed and that can promptly reveal an unacceptable reduction in margin? Does the observation of these parameters support the objectives of defense in depth and control of uncertainty?

C. Can objective criteria, consistent with the desired outcome, be established based on risk insights, deterministic analyses, and/or performance history?

D. Is the flexibility afforded to licensees in the existing regulatory framework consistent with the realistic margin estimate? Can a change in the level of flexibility be effected in a way that would encourage and reward improved outcomes, while avoiding inappropriate incentives?

II. Assessment Guidelines *(Is it worthwhile to develop a performance-based change?)*

A. Can a performance-based change to the regulatory framework fulfill the performance goal of "Maintain safety and protect the environment and the common defense and security"?

B. Can a performance-based change to the regulatory framework fulfill the performance goal of "Increase public confidence"?

C. Can a performance-based change to the regulatory framework fulfill the performance goal of "Increase effectiveness, efficiency, and realism of the NRC activities and decisionmaking"?

D. Can a performance-based change to the regulatory framework fulfill the performance goal of "Reduce unnecessary regulatory burden"?

E. Does implementing a performance-based approach yield a net benefit?

F. Where does the performance-based change best fit into the regulatory framework? What are the effects on inspection and enforcement functions?

G. Is accommodation made to employ the best available technology, now and in future?

III. Guidelines for Consistency with Regulatory Principles

A. Is any part of a performance-based approach inconsistent with basic regulatory principles?

## REFERENCES

A-1 Nuclear Regulatory Commission (U.S.) (NRC). SECY 00-191, "High-Level Guidelines for Performance-Based Activities." NRC: Washington, DC. September 2000.

A-2 Nuclear Regulatory Commission (U.S.) (NRC). SECY 99-176, "Plans for Pursuing Performance-Based Initiatives." NRC: Washington, DC. July 12, 1999.

A-3 Letter, Dana A. Powers (ACRS) to William D. Travers (EDO, NRC), September 8, 2000. Subject: Proposed High-Level Guidelines for Performance-Based Activities.

A-4 Nuclear Regulatory Commission (U.S.), Washington, DC. "Revised High-Level Guidelines for Performance-Based Activities," Proposed Rule. *Federal Register*: Vol. 65, No. 90. pp. 26772-26776. May 9, 2000.

A-5 Nuclear Regulatory Commission (U.S.) (NRC). NUREG-1614, Vol. 2, Parts 1 & 2, "Strategic Plan Fiscal Year 2000 - Fiscal Year 2005." (Final Report) NRC: Washington, DC. September 2000.

A-6 Nuclear Regulatory Commission (U.S.), Washington, DC. "Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement." *Federal Register*: Vol. 60, No.158. pp. 42622–42629. August 16, 1995.

A-7 Nuclear Regulatory Commission (U.S.) (NRC). Regulatory Guide 1.174, "An Approach for Using PRA in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis." NRC: Washington, DC. July 1998.

# APPENDIX B

# SUPPLEMENTARY GUIDANCE FOR MORE COMPLEX ISSUES

# APPENDIX B

## SUPPLEMENTARY GUIDANCE FOR MORE COMPLEX ISSUES

### B.1 Background

In some cases, the general guidance offered in Section 3 of this document is 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 these conditions are present, a more considered approach, based on decision analysis, is warranted (Ref. B-1). The application of this type of analysis to nuclear technology has recently appeared in the technical literature (Refs. B-2, B-3, B-4). The purpose of this appendix is to discuss selected elements of such an approach.

As mentioned in Section 3, the purpose of this document is to support the development of a performance-based regulatory alternative, if one is appropriate. Generally, a performance-based regulatory alternative needs to:

1. allocate performance across relevant functions, systems, or barriers, in order to assess whether the target safety objectives are satisfied

2. 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

Part of implementation is confirmation of ongoing performance.

Accordingly, this appendix is aimed at a more rigorous development of Step 2 in Section 3, which called for "identifying the safety functions." Depending on the individual case, this level of rigor may vary. For example, where an issue affects many areas and different objectives, this added complexity may justify the explicit development of a more detailed objectives hierarchy (see text box).

> *What is an "objectives hierarchy?"*
>
> An objectives hierarchy is a diagram representing the relationships and dependencies between goals, top-level fundamental objectives, lower-level fundamental objectives, and means objectives. Fundamental objectives are ends in themselves; means objectives are things that are desirable because they support fundamental objectives. An example of a goal is "protection of the health and safety of the public;" an example of a fundamental objective is "protection of the public from excessive radiological exposures;" and an example of a means objective is "reliability of safety systems." These are examples from the structure of the Reactor Oversight Process (ROP), which makes use of an objectives hierarchy.

With an objectives hierarchy in hand, it becomes easier to assess the levels of performance needed from each element. And, in conjunction with the viability guidelines, one can determine those cases in which performance can appropriately be monitored through inspections or performance indicators, and where it cannot, which would suggest that a more prescriptive approach is warranted.

The approach discussed below is intended to promote adequate coverage of key performance areas with performance measures in a way that qualitatively addresses defense-in-depth considerations.

## B.2 Development of the Objectives Hierarchy

Decisionmaking, and in particular the development of performance-based approaches to regulation, conventionally begins with clarification of the objectives (Refs. B-1, B-4). This is especially important when competing objectives are involved as is often the case in regulatory decisionmaking. A common instance of competing objectives occurs when there is a need to weigh safety benefits against burden (unless the issue is related to adequate protection considerations). In the present case, two reasons exist for emphasizing this consideration. First, the viability guidelines focus on parameters in terms of which criteria can be specified; a clear picture of the desired functional attributes is necessary in order to carry out this step properly. Second, determining these objectives also establishes the scope of the net benefit test applied under the assessment guidelines, which constitutes the second step in a three-step application of the high-level guidelines.

Even if an issue is not concerned with a safety enhancement (that is, the current level of safety is considered appropriate), regulatory proposals to resolve the issue must address safety so as to confirm that it is being maintained. Alternatively, if an issue initially involves only safety, regulatory proposals to resolve it must address burden, public confidence, and efficiency and effectiveness (except when the issue is deemed to be one of adequate protection).

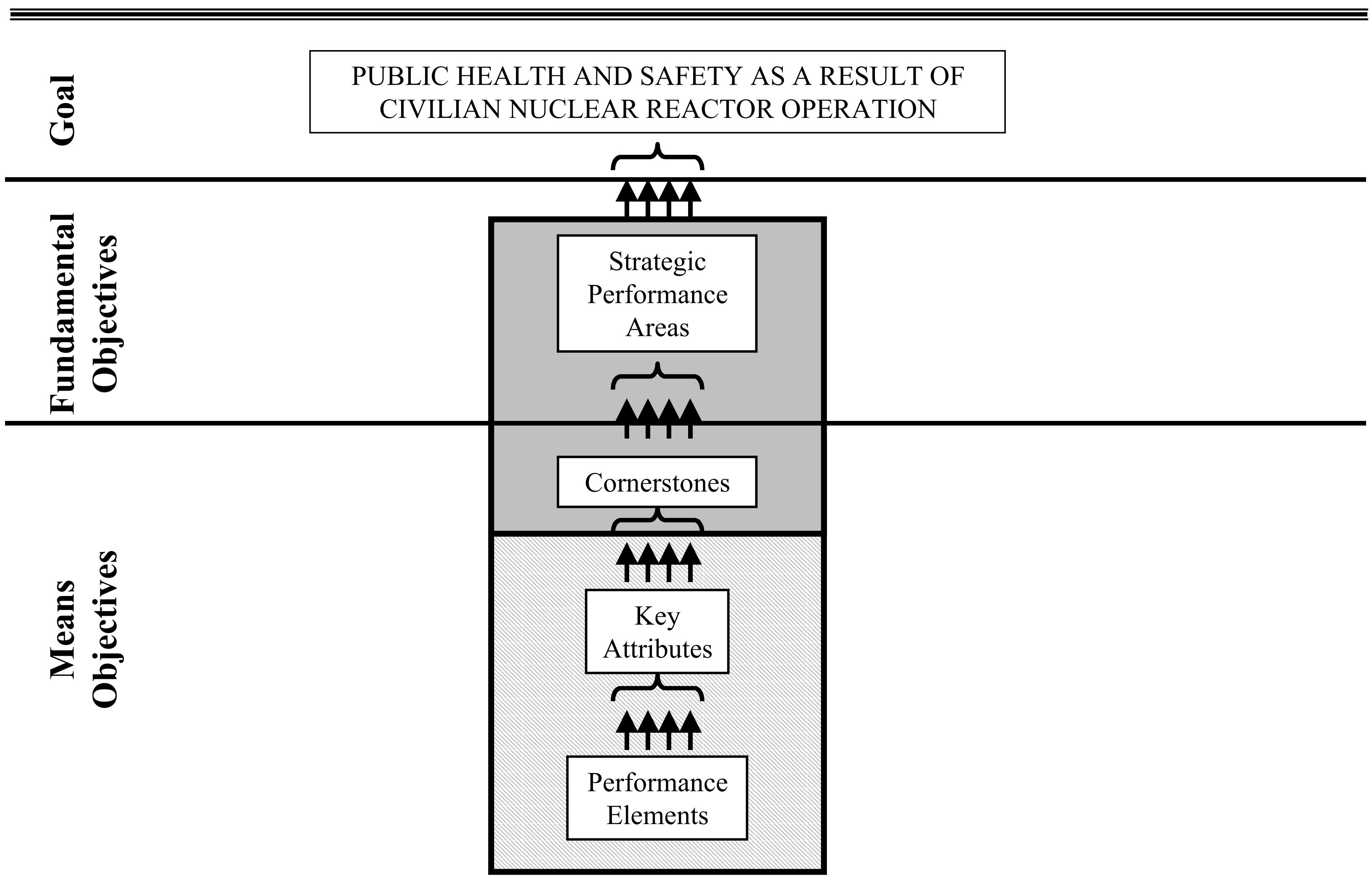
Figures B-1 through B-3, based in part on the ROP (Ref. B-5), illustrate concepts of an objectives hierarchy. Figure B-1 shows the goal, fundamental objectives, and means objectives of an objectives hierarchy. Figure B-2 presents more detail of the ROP. The cornerstone areas identified in Figure B-2 are intended to be a complete set of key performance areas affecting safety. The key attributes identified within each cornerstone are likewise intended to be a complete set. Completeness is one of the reasons to pursue such a systematic development. In Figure B-2, consideration of the different cornerstone areas also illustrates how the implicit underlying allocation of performance addresses defense-in-depth at a high level. 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.

*What value does an objectives hierarchy add to the process of formulating a regulatory alternative?*

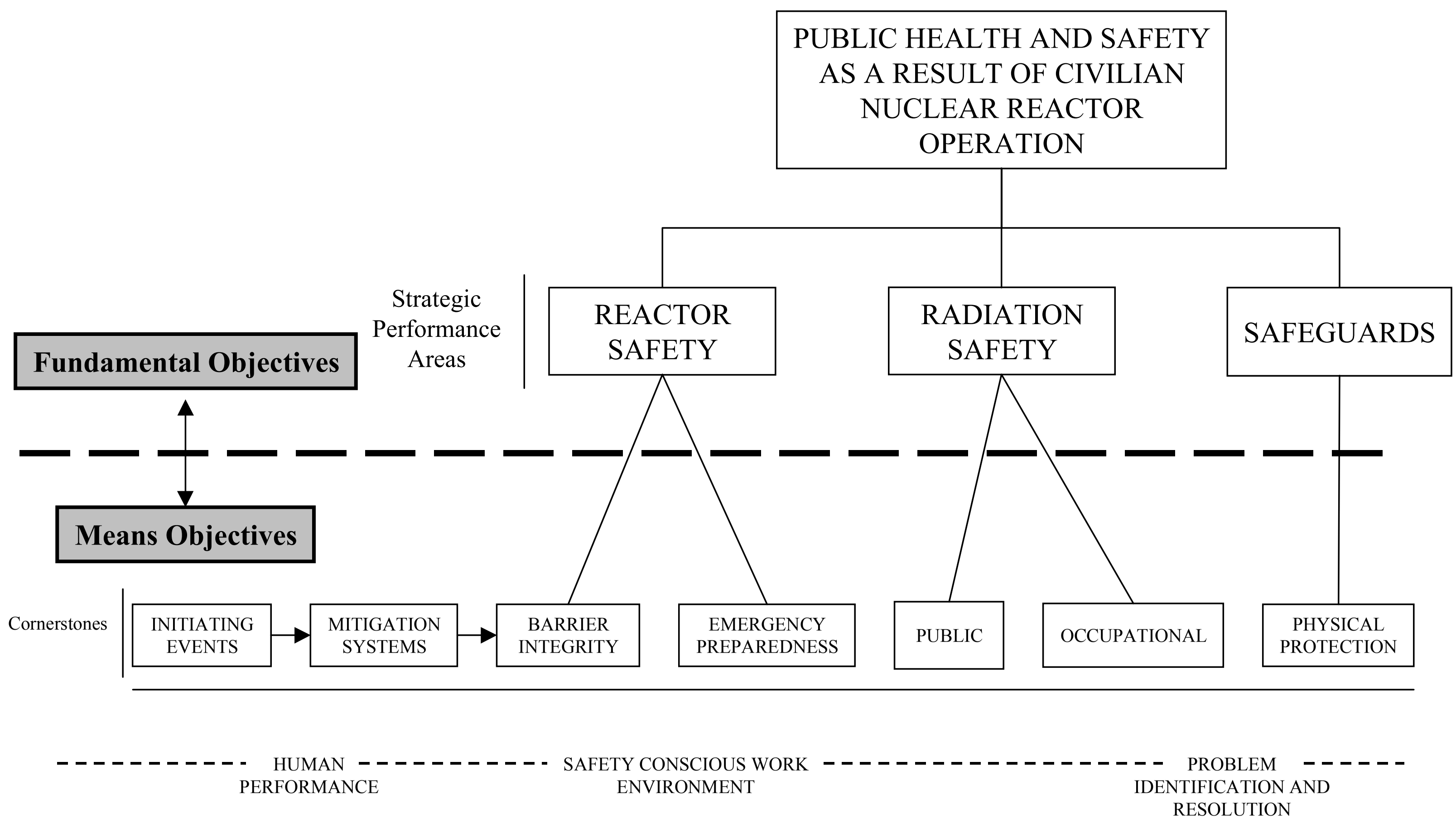
Formulation of a performance-based alternative is supported directly by an objectives hierarchy. First, systematic consideration of the objectives hierarchy fosters completeness in the set of performance areas considered. Second, the hierarchy structure segments the objectives that are more suitable for performance-based and prescriptive alternatives which typically correspond to the upper and lower levels of the hierarchy, respectively. Finally, in the allocation step, the objectives hierarchy helps to keep track of the satisfaction of each safety objective at each level in the objectives hierarchy.

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 means 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 of the sort that appear at the bottom of Figure B-3.

## Figure B-1
## Overview of Objectives Hierarchy



# Figure B-2
# Reactor Oversight Process Objectives Hierarchy



## Figure B-3
## More Detailed Decomposition of Means Objectives

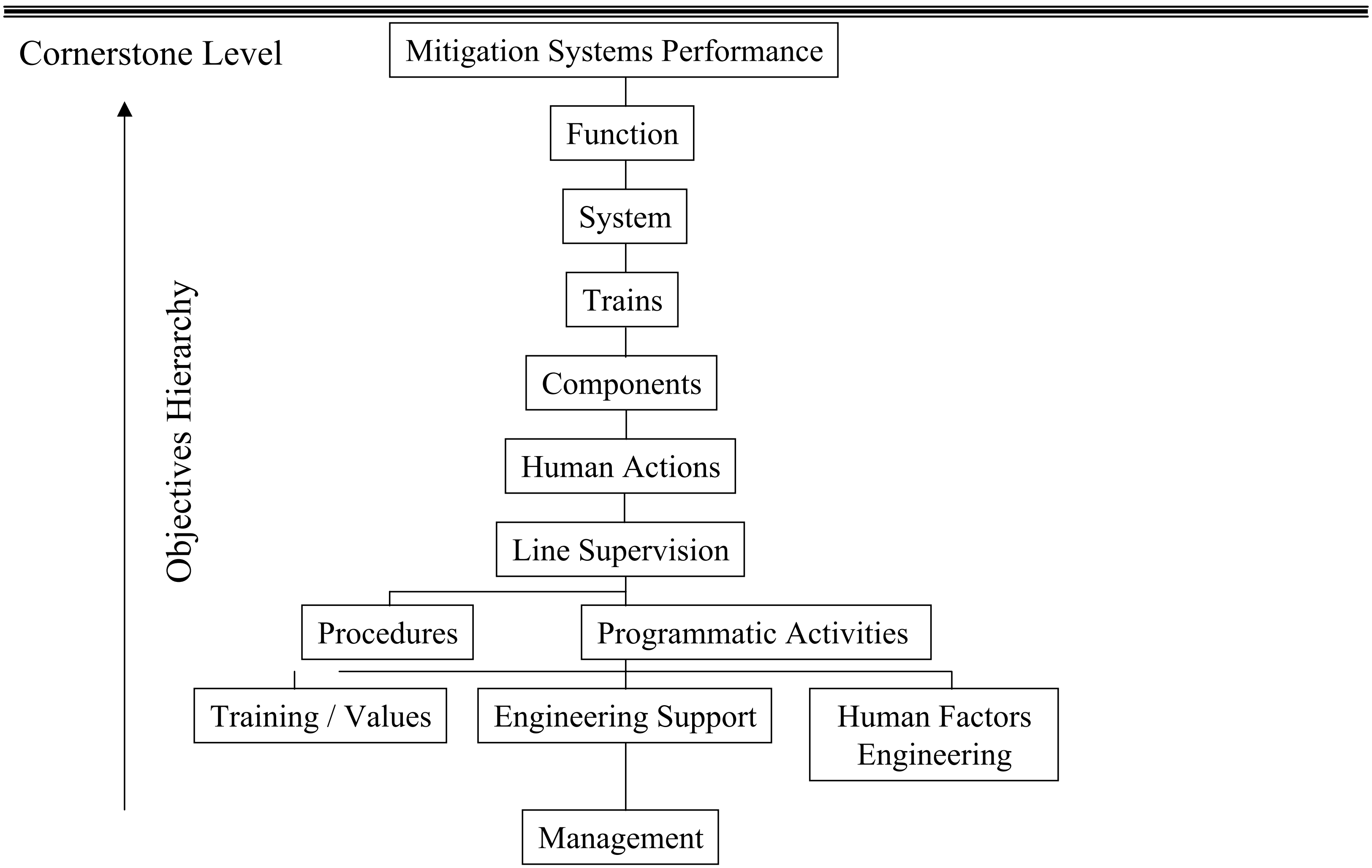


Figure B-3 illustrates levels of a hierarchy applicable to many issues involving safety assessments. A complete and explicit development of all hardware and programs involved in accomplishing high-level safety functions would be a significant undertaking. The point of the present guidance is not to mandate such an explicit, detailed, and laborious development, but to point out how the concepts can apply even if the development exists only in the abstract or in a qualitative way. The value of this construct will be clearer in light of the discussion in the following subsection.

## B.3 Allocation of Performance

Before selecting performance measures, it is logically necessary to determine what kind of performance and what level of performance is needed from each performance area. For example, in the reactor arena, each of the cornerstone areas (initiating events, mitigating systems, barrier integrity, emergency preparedness) receives attention. Performance is expected in each cornerstone area. Strong performance in all areas provides an important defense-in-depth component, because to some extent, performance in one area can compensate for lack of performance in another. For example, an increase in initiating events frequency will not typically be a safety issue, if the mitigating systems' performance is satisfactory. This approach is fully consistent with the Commission's White Paper definition of defense-in-depth, which states:

> Defense-in-depth is an element of the NRC's Safety Philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges (Ref. B-6).

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.

### B.3.1 Example

In order to understand what it means to allocate performance, and why performance may need to be allocated, consider the following example. The quantitative analysis presented in the Reactor Safety Study (Ref. B-7) showed that resources were allocated in an imbalanced way. Much attention had previously been focused on plant response conditional on a design-basis loss-of-coolant accident, while somewhat less attention had been focused on decay heat removal in scenarios initiated by transients or small breaks. This was addressed in a TMI requirement (Ref. B-8), as a result of which auxiliary feedwater systems (AFWS) in pressurized-water reactors (PWRs) licensed during the 1980s were expected to demonstrate low unreliability "in the range of 1E-4 to 1E-5 per demand" (Ref. B-9). Assuming reasonable initiating event frequencies, satisfaction of this requirement would mean that a certain class of accident sequences was being controlled reasonably well.

This is a specific example of an allocation. Performance in the initiating events area was tacitly allocated at then-current levels, while target performance in AFWS reliability was set at a level somewhat better than was then being achieved at certain plants. Note that this was a design and licensing issue, not a "performance" issue.

This example serves to illustrate the previous comments regarding licensee flexibility. Refer again to Figure B-3. Some flexibility was made available in the application of this requirement to AFWS systems, provided that alternative methods of core cooling were shown to be available (e.g., feed and bleed). Thus, the real allocation was pitched at the functional level (decay heat removal), with alternative allocations available at the systems level (allocate all performance to AFWS, or alternatively, allocate some to AFWS and some to high-pressure injection and primary depressurization).

Carried down to lower levels, these requirements have implications for such areas as inservice testing and inspection, and technical specifications.

B.3.2 Process

A thought process analogous to the above should be carried out, at least implicitly or qualitatively, whenever regulatory requirements are being formulated. The stringency of requirements at a given level needs to be related to the top-level safety objectives being addressed.

*What do we mean by "allocation?"*

Given a top-level safety objective (such as CDF, or dose limits, or frequency of overexposure), the "allocation" of performance among barriers, structures, systems, and components (SSCs), etc., is the choice of performance targets set by a regulatory alternative in order to assure that the safety objective is met. A choice among possible allocations must often be made, because it may be formally possible to meet a safety objective in more than one way. However, cost and practicality significantly restrict the possibilities that need to be considered.

*Does allocation always require setting explicit numerical targets?*

No. But the history of the development of regulations at NRC suggests that it is helpful to work with performance targets that are at least implicitly numerical. Otherwise, it is difficult to determine how stringent the performance requirements need to be, or whether performance monitoring is a viable option in some areas.

The starting point is an allocation of performance at the upper levels of the hierarchy. This allocation should appropriately balance prevention and mitigation, while satisfying agency safety objectives. In the reactor arena, this top-level allocation step frequently begins with core damage frequency (CDF) and large-early-release frequency (LERF) objectives, and then infers practical limits on the frequencies of various accident sequence families from the heuristic guideline such that no single sequence type dominates risk. This sort of insight can inform performance allocation over initiating event types, mitigating systems performance, and emergency preparedness.

At this point, the allocation continues by segmenting each high-level performance objective into sub-objectives corresponding to the performance elements on the adjacent lower level. The collective satisfaction of these sub-objectives assures performance at the higher level. This entails making choices, because this decomposition is not unique. This process is continued on down the objectives hierarchy, until a point is reached at which it is no longer appropriate to articulate objectives, because there would be no net benefit to measuring performance at that level. The operational character of this guidance means that meaningful allocation must be done iteratively with the selection of performance measures and their implementation.

In the reactor arena, because of variations in plant design, it will be difficult to perform this kind of allocation generically below the functional level. As illustrated in the AFWS example cited above, the requirement was actually formulated at the functional level, with the expectation that either the AFWS alone would meet it, or additional systems would be credited in a more flexible evaluation. On the other hand, system-level, train-level, and component-level requirements clearly derive from an implicit allocation of performance that is not numerically precise, but derives from implicit consideration of safety objectives. Improving the alignment of regulatory requirements with real safety objectives is the essence of “risk-informing” regulatory practice. Significant progress can be made in this area without overly detailed developments of objectives hierarchies or allocations.

## B.4 Formulation of an Appropriate Implementation: Selecting Performance Measures

Given an allocation, one must still decide on an implementation, i.e., a suitable combination of regulatory requirements, inspections, and performance indicators, collectively aimed at assuring performance at (or better than) the stated target levels. These elements then need to be captured within appropriate parts of the regulatory framework.

It is useful to illustrate this point by continuing with the AFWS example introduced above, in which a target range for unreliability was given. Once that objective was fixed, very different implementations could have been chosen. The implementation actually selected allowed considerable flexibility in design, and this flexibility is reflected in the variety of system topologies to be found among U.S. nuclear power reactors. However, the implementation was not fully performance-based. Instead, the implementation followed the traditional regulatory approach; system reliability was achieved through numerous prescriptive American Society of Mechanical Engineers (ASME) code requirements on testing and inspection, and Technical Specifications addressed allowed outage time in the usual way. Essentially, the effect of the top-level requirement on unreliability was first to drive performance to a level better than that of a typical, active two-train fluid system with no backup, and second, to provide improved guidance on the formulation of the traditional prescriptive requirements.The aim of the present guidance is to foster choices in implementation that are as performance-based as appropriate, in light of the high-level guidelines. Therefore, given the objectives hierarchy and the allocation, one uses the objectives hierarchy once again to select promising performance areas that are high up the hierarch as possible. If it is impractical to determine performance at a particular level, the next level down is tried. In the case of the AFWS, it is readily established that it is impractical to measure unreliability at the system level, because too few system demands occur to support a useful measurement. One must measure or prescribe at a level lower than that of the AFWS, and the complement of measures and prescriptive requirements must collectively

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*How does defense in depth affect allocation of performance?*

Part of defense in depth is avoiding over-reliance on any one performance area in satisfying the top-level safety objectives. Therefore, defense-in-depth considerations favor allocations that spread out performance over redundant and diverse barriers and SSCs.

*What is the relationship between nominal performance, performance criteria, and allocated performance?*

The allocated performance level is the level of performance that is needed in order to satisfy safety objectives. In general, normal performance will be significantly better than this level. In order for a performance-based approach to be viable, the performance criterion needs to be set at a level having significant margin to the allocated level, in order for problems to be detected and addressed before a safety issue arises. In order for this approach to be practical, there must also be some margin must also exist between the normal performance level and the criterion.

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provide the needed assurance of performance.

The actual process may have to rely on some amount of trial and error or iteration, making repeated use of the viability guidelines. Trying to work directly at the level of a highly reliable system will typically fail the test of viability, because risk-significant changes in the operation of such a system cannot be identified and addressed in a timely fashion. Therefore, the process must seek a level on the objectives hierarchy at which performance can be objectively determined through prescriptive requirements, and/or confirmed either by inspection or through direct confirmation of performance (performance in tests or in actual demands). Once such performance elements have been identified, performance parameters and associated criteria can be determined, and the viability guidelines can be applied as discussed in Section 3. Note that the "criteria" discussed in the viability guidelines are not the target allocations discussed above, but thresholds whose violation signals declining performance well before a significant safety problem has developed, i.e., the allocated performance levels are violated.

When moving down the hierarchy, looking for a level at which an explicit allocation can be addressed either by monitoring or by prescriptive requirements, it is important to recognize that it is possible to underperform at a higher level, even if redundant elements at lower levels nominally succeed. To see why this is true, return once again to the AFWS example. Even if all trains are highly reliable and available, performance at the system level can suffer if (for example) the trains' unavailabilities are sometimes concurrent, or the contributors to train unreliability include shared hardware or common cause contributions affecting more than one train. Concurrent unavailability is addressed through technical specifications, and the possibility of common cause mechanisms is one reason for prescriptive requirements on testing and inspection. This example serves to illustrate the ineffectiveness of excessively prescriptive approaches without a disciplined analysis of the outcomes and results sought to be achieved.

## B.5 Summary

Three major activities have been described:

1. formulation of an objectives hierarchy
2. allocation of performance
3. selection of an appropriate complement of prescriptive requirements and performance measurements

The regulatory alternative developed by this process is intended to have the following properties.

1. The top-level safety objectives are satisfied by the performance levels targeted by the performance allocation.
2. The performance allocation is consistent with defense in depth: no single performance area is relied on excessively.
3. The complement of prescriptive requirements and performance measures also reflects defense in depth, in that it samples performance in enough areas and in sufficient depth to support a reliable assessment of safety performance.
4. Prescriptive requirements are imposed only when considerations of viability or net benefit preclude using performance measures.
5. Performance measures and prescriptive requirements are implemented as high on the objectives hierarchy as possible, in order to maximize licensee flexibility consistent with the viability guidelines.

## REFERENCES


B-1 Clemen, R. T. *Making Hard Decisions*. 2nd Edition. Belmont, California: Wadsworth Publishing Company. 1996.

B-2 Weil, R. and G. E. Apostolakis. "A Methodology for the Prioritization of Operating Experience in Nuclear Power Plants." *Reliability Engineering and System Safety*. Vol. 74, pp. 23-42. Elsevier. 2001.

B-3 Apostolakis, G. E. and S. E. Pickett. "Deliberation: Integrating Analytical Results into Environmental Decisions Involving Multiple Stakeholders." *Risk Analysis*. Vol. 18, No. 5, pp. 621-634. Society for Risk Analysis. 1998.

B-4 Keeney, R. L. *Value-Focused Thinking*. Cambridge, Massachusetts: Harvard University Press. 1992.

B-5 Nuclear Regulatory Commission (U.S.) (NRC). SECY 99-007, "Recommendations for Reactor Oversight Process Improvements." NRC: Washington, DC. January 8, 1999.

B-6 Nuclear Regulatory Commission (U.S.) (NRC). "Staff Requirements - SECY-98-144 - White Paper on Risk-Informed and Performance-Based Regulation." NRC: Washington, DC. March 1999.

B-7 Nuclear Regulatory Commission (U.S.) (NRC). WASH-1400, NUREG-75/014, "Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants." NRC: Washington, DC. October 1975.

B-8 Code of Federal Regulations, *Title 10, Energy*, Part 50.34(f)(1)(ii)(A), "Contents of Applications; Technical Information."

B-9 Nuclear Regulatory Commission (U.S.) (NRC). NUREG-0800, "Standard Review Plan," Section 10.4.9. NRC: Washington, DC. July 1981.