Appendix: Considerations for Implementing a Risk-Informed Regulatory Framework

As the agency moves forward toward risk-informed regulation, certain fundamental approaches to safety will continue to shape the agency's decisions. Four of these fundamental principles are defense-in-depth, the use of safety margins to account for uncertainty, the principle of "as low as reasonably achievable" (ALARA) in radiation protection, and the use of safety goals. Important considerations which need to be addressed in utilizing these approaches are discussed below. These are followed by some additional guidance concerning the concept of regulatory analysis and performance-based implementation. The purpose of the discussion in this Appendix is to help ensure a uniform set of considerations is factored into all agency risk-informed initiatives.

I. Defense in Depth

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. Risk information is used to decide whether event frequency hazard consequences warrant defense-in-depth and to suggest appropriate defenses. Defense-in-depth is a philosophy used by the NRC to provide redundancy for facilities with "active" safety systems, as well as the philosophy of a multiple-barrier approach against fission product releases. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges.

The concept of defense in depth has always been and will continue to be a fundamental tenet of regulatory practice in the nuclear field. It is expected that defense in depth for reactors and nuclear materials (which includes activities involving disposal, transportation and storage, processing and fabrication, and industrial and medical applications) may need to be considered differently due to the greater diversity in materials licensed activities and to the differences in safety issues.

In its May 25, 2000 letter to Chairman Meserve, the Advisory Committee on Nuclear Waste (ACNW) provides a perspective on the role of defense-in-depth in risk-informed regulation. "The primary need for improving the implementation of defense in depth in a risk-informed regulatory system is guidance to determine how many compensatory measures are appropriate and how good these should be. To address this need, we believe that the following guiding principles are important:

- Defense in depth is invoked primarily as a strategy to ensure public safety given the unquantified uncertainty in risk assessments. The nature and extent of compensatory measures should be related, in part, to the degree of uncertainty.
- The nature and extent of compensatory measures should depend on the degree of risk posed by the licensed activity
- How good each compensatory measure should be is, to a large extent, a value judgement and, thus, a matter of policy."

The ACNW letter further states that in the reactor arena, defense in depth entailed “placing compensatory measures on important safety cornerstones to satisfy acceptance criteria for defined design-basis accidents that represent the range of important accident sequences.” For the reactor arena, Regulatory Guide 1.174 states that consistency with the defense-in-depth philosophy will be preserved by ensuring that:

- a reasonable balance is preserved among prevention of accidents, prevention of barrier failure, and consequence mitigation,
- an over-reliance on programmatic activities to compensate for weaknesses in equipment or device design is avoided,
- system redundancy, independence, adversity are preserved commensurate with the expected frequency, consequences of challenges to the system, and uncertainties (e.g., no risk outliers),
- the independence of barriers is not degraded such that defenses against potential common cause failures of multiple barriers are preserved, and the potential for the introduction of new common cause failure mechanisms is assessed,
- defenses against human errors are preserved, and
- the intent of the fundamental design features is maintained.

The Advisory Committee on Reactor Safeguards (ACRS) has expressed concerns about the role that defense in depth should have in a risk-informed regulatory scheme. The Committee cites instances in which “seemingly arbitrary appeals to defense in depth have been used to avoid making changes in regulations or regulatory practices that seemed appropriate in the light of results of quantitative risk analyses.” The letter’s attachment describes two models on the scope and nature of defense in depth. “In the structuralist model, defense in depth is primary, with PRA available to measure how well it has been achieved.” (This is the model implicit in the agency’s PRA Policy Statement and in Regulatory Guide 1.174 concerning risk-informed changes to reactor licensing bases.) In the rationalist model, “the purpose of defense in depth is to increase the degree of confidence in the results of the PRA or other analyses supporting the conclusion that adequate safety has been achieved. ...What distinguishes the rationalist model from the structural model is the degree to which it depends on establishing quantitative acceptance criteria, and then carrying formal analyses, including analysis of uncertainties, as far as the analytical methodology permits.” To define the role of defense in depth in risk-informed regulation and to establish a consistent and reasoned approach, the following considerations should be addressed:

- What elements of defense in depth should be independent of risk information; e.g.,
  - provide prevention and mitigation protection?
  - use of good engineering practices (e.g., codes and standards)?
  - number and nature of barriers to radiation release?
  - emergency plans and procedures?

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 degree of protection provided by 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 assessment of the hazard and identification of the individual performance of each defense system in relation to overall performance.

- What elements of defense in depth should be dependent upon risk information; e.g.,
  - the balance between prevention and mitigation?
  - the number of barriers?
  - the need for redundancy, diversity, independence of systems?
  - the events that need to be considered in the design?
- Do the defense-in-depth considerations expressed in Regulatory Guide 1.174 apply?

II. Safety Margins

Existing regulations were developed to ensure that adequate safety margins exist to account for uncertainties in analysis and data. In the reactor arena, Regulatory Guide 1.174 states that acceptable risk-informed changes to a nuclear power reactor's licensing basis will be consistent with the principle that sufficient safety margins are maintained. Improved information from data analysis, research experiments, and the like suggest that excessive safety margins exist given the current state of knowledge and current uncertainties. As regulations in the reactor, materials, and waste arenas are evaluated to improve the focus on safety, regulations that foster excessive safety margins will be candidates for change. To define the role that safety margins play in risk-informed regulation and to establish a consistent and reasoned approach, the following considerations should be addressed:

- How should safety margins be weighed in the context of the radiological hazard?
- How should safety margins be employed to account for uncertainties in engineering analysis:
  - realistic analysis with conservative acceptance criteria?
  - specified confidence level?
  - role of codes and standards (i.e., do they inherently address safety margin)?
- How should safety margins be employed to account for uncertainty in risk:
  - parameter uncertainty – defense in depth (i.e., redundancy, diversity, independence)?
  - incompleteness in risk analysis (e.g., engineering judgment)?
  - model uncertainty (e.g., conservative acceptance criteria)?

III. Radiation Protection and the Principle of "As Low As Reasonably Achievable" (ALARA)

The 1972 report of the Advisory Committee on the Biological Effects of Ionizing Radiations (BEIR) contended that, in the absence of better data, there was no reasonable alternative to a linear hypothesis of radiation protection. The linear hypothesis assumes a straight-line correlation between dose and somatic damage and does not allow for a threshold below which no injury will occur. Indeed, the linear hypothesis might overestimate the risks by failing to account for the effects of dose rate and cell repair. The 1990 BEIR-V report reaffirmed that a linear, no-threshold model of cancer risk (other than leukemia) was most consistent with the data. Consequently, licensees are expected to keep radiation releases to a level as low as reasonably achievable. In keeping with this philosophy of "as low as reasonably achievable," the staff seeks to strike a balance that considers the capabilities of technology and the costs of equipment while providing ample protection to the public. That is, the staff takes into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations in relation to the utilization of atomic energy in the public interest".

IV. Safety Goals

Certain high-level considerations concerning quantitative safety goals need to be addressed in making decisions with respect to the approach and direction of risk-informed changes. First, and most fundamental, is the issue of whether or not a safety goal needs to be established to guide risk-informed changes. In general, a safety goal is useful to define the desired level of safety. In the reactor arena, safety goals were established to define "how safe is safe enough" or, in other words, when additional regulation is not warranted. It is expected that if safety goals (that go beyond adequate protection) are defined for other regulated activities, they would be used in a similar capacity. Currently, there are no explicit safety goals in the Nuclear Materials Safety and Nuclear Waste Safety arenas. The staff is pursuing the review of selected case studies to determine the feasibility and efficacy of safety goals in these arenas.

Notwithstanding questions concerning the need, several issues need to be considered if goals are developed. These issues are relevant across the full spectrum of regulatory applications and can be posed as the following questions:

- What are the risks that the goal will limit? (i.e., early fatalities, latent fatalities, illness, individual risk, societal risk, economic risk, environmental risk)
- What is an acceptable level of risk?
    - some fraction of other risk (i.e., relative risk)?
    - a consequence-based limit (i.e., an absolute risk)?
    - dependent on nature of population?
- Who are the populations at risk?
    - public (specified by proximity, biological vulnerability, current and future generations, etc.)?
    - workers
    - both of these?
- Are the predominant risks from normal operations or accidents or both?
- Over what time frame does the goal apply (e.g., years vs. centuries)?
- What metrics best express the goal?

Once a safety goal is determined, its implementation needs to be considered. Questions regarding implementation include:

- What is the role and relationship of the traditional principles of defense-in-depth, safety margins, and ALARA to the goals and risk-informed regulation?
- What is the role of cost-benefit in implementing the goals?
- What is the nature of the risk assessment needed to measure against the goals?
- How should uncertainties be considered in establishing goals?

As alluded to earlier, a risk-informed approach to regulation can be taken without establishing safety goals. One such approach is to assess relative changes in risk as a result of postulated changes to current regulatory requirements. If an approach such as this is taken, there are additional implementation issues which need to be considered, such as:

- What metrics should be used to measure changes in risk?

- What increases in risk are acceptable?
- What is the role of cost-benefit is identifying and assessing risk-informed regulatory changes?

In its activities that are described in Part 2 of this plan, the staff will address the issue of establishing safety goals beyond those already established.

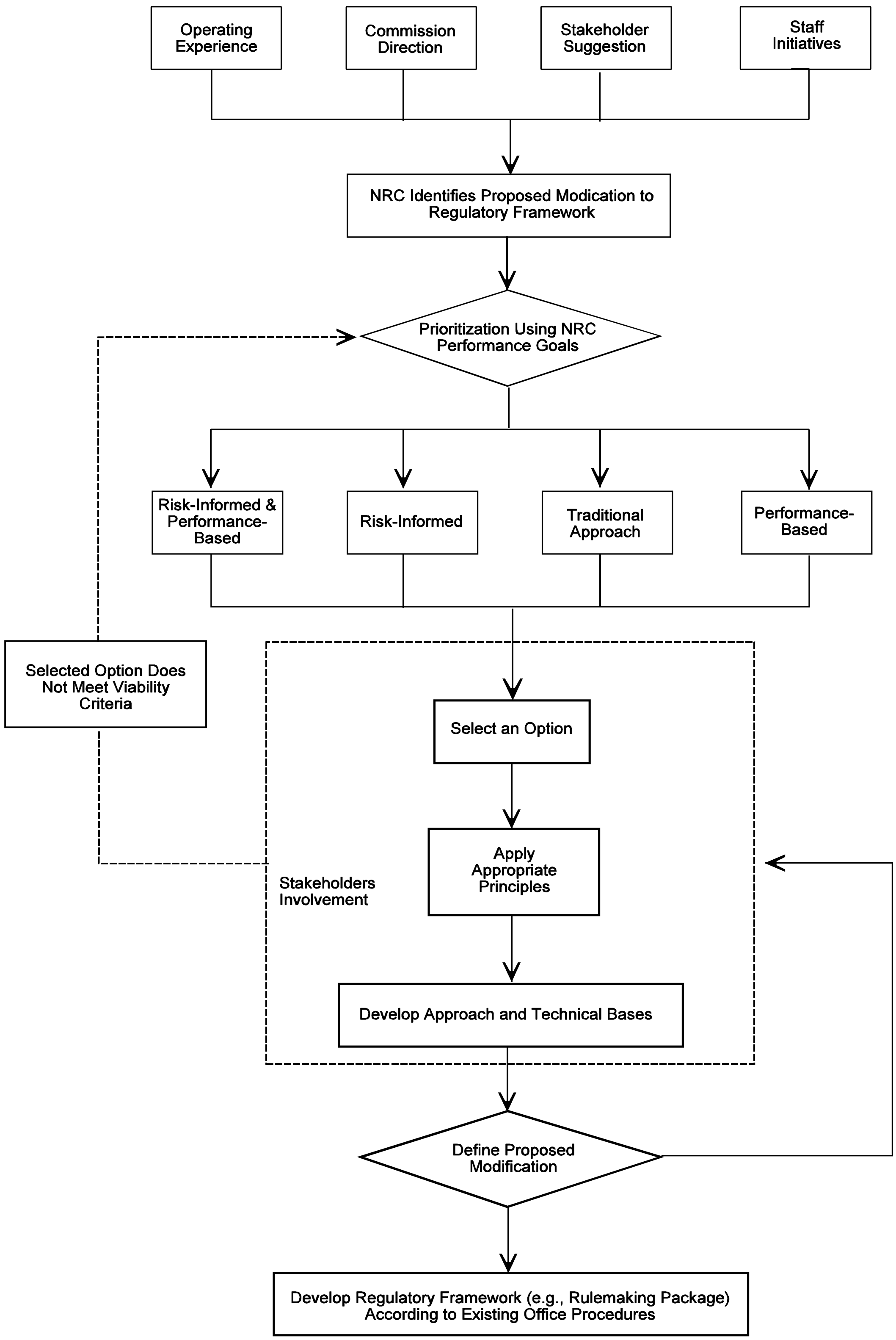
V. Regulatory Analysis

The NRC performs regulatory analyses to support numerous NRC actions affecting reactor and materials licensees. In general, each NRC office ensures that all mechanisms used by the staff to establish or communicate generic requirements, guidance, requests, or staff positions that would affect a change in the use of resources by its licensees, include an accompanying regulatory analysis. In regard to relaxation of requirements, NUREG/BR-0058 states that a regulatory analysis should provide that level of assessment that will demonstrate with sufficient reasonableness that the two following conditions are satisfied:

- The public health and safety and the common defense and security would continue to be adequately protected if the proposed reduction in requirements or positions were implemented
- The cost savings attributed to the action would be substantial enough to justify taking the action

As part of the staff's activities, the role of regulatory analysis in evaluation risk-informed regulatory changes will be established to ensure a consistent and predictable regulatory framework.

VI. Performance-Based Implementation The agency has defined a performance-based requirement as one that "relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, while providing flexibility to the licensee as to the means of meeting these outcomes. A performance-based regulatory approach is one that establishes performance and results as the primary basis for regulatory decision making. To the extent appropriate, risk-informed regulation should incorporate performance-based regulation in that, if risk-informed changes are to be made, they should be made in a performance-based fashion whenever possible. The corollary is also true; performance-based regulations should be risk-informed when possible. Figure 1 illustrates that both risk-informed and performance-based approaches will be pursued as appropriate when modifying the regulatory framework.


Operating Experience
Commission Direction
Stakeholder Suggestion
Staff Initiatives
NRC Identifies Proposed Modication to Regulatory Framework
Prioritization Using NRC Performance Goals
Risk-Informed & Performance-Based
Risk-Informed
Traditional Approach
Performance-Based
Selected Option Does Not Meet Viability Criteria
Select an Option
Stakeholders Involvement
Apply Appropriate Principles
Develop Approach and Technical Bases
Define Proposed Modification
Develop Regulatory Framework (e.g., Rulemaking Package) According to Existing Office Procedures