NUCLEAR ENGINEERING

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

Review of Applicable U.S. Department of Energy and U.S. Nuclear Regulatory Commission Activities (Project Task 1)

June 1999

MITNE-316

Regulatory Excellence Project:
Performance-Based Regulatory Framework for U.S. Department of Energy Facilities

Review of Applicable U.S. Department of Energy and U.S. Nuclear Regulatory Commission Activities (Project Task 1)

June 1999

MITNE-316

MIT

George Apostolakis (Principal Investigator)
Michael Golay (Principal Investigator)
Emmanuel Chaniotakis
Emanuele Borgonovo
Frank Felder
S. Tina Ghosh
Yu Sui

INEEL

Joy Rempe
Timothy Leahy
Darrell Knudson

Table of Contents

List of Acronyms

ACRS: Advisory Committee on Reactor Safeguards (to the U.S. Nuclear Regulatory Commission)
AEC: Atomic Energy Commission
ALARA: As Low As Reasonably Achievable
AOT: Allowed Outage Times
ATR: Advance Test Reactor
CCFP: Conditional Containment Failure Probability
CCDF: Complementary Cumulative Distribution Function
CCFP: Core Coolant Fission Products
CDF: Core Damage Frequency
CDP: Core Damage Probability
CFR: Code of Federal Regulations
DID: Defense-in-depth
GDC: General Design Criteria
HLW: High-level Waste
IPE: Independent Plant Evaluation
ISA: Integrated Safety Assessment
LB: Licensing Basis
LERF: Large Early Release Frequency
LLW: Low-level Waste
LWR: Light-water Reactor
MITR: MIT Reactor
MOW: Model of the World
NEI: Nuclear Energy Institute
NMSS: Nuclear Material Safety and Safeguards
NPP: Nuclear Power Plant
NRC: United States Nuclear Regulatory Commission
PA: Performance Assessment
PBR: Performance-based Regulation
PI: Performance Indicator
PSA: Probabilistic Safety Assessment
PSHA: Probabilistic Seismic Hazard Analysis
PRA: Probability Risk Assessment
PWR: Pressurized Water Reactor
RG: Regulatory Guide
RI: Risk-informed
RIPBR: Risk-informed, Performance-based Regulation
RIR: Risk-informed Regulation
RI-ISI: Risk-Informed In-Service Inspection
SAR: Safety Analysis Report
SM: Safety Margins
SNF: Spent Nuclear Fuel
SNM: Special Nuclear Material
SRM: Staff Requirements Memorandum
STI: Surveillance Test Intervals

TFI: Technical Facilitator Integrator
TI: Technical Integrator
TMI-2: Three Mile Island Unit 2
TRU: Transuranic Waste
USDOE or DOE: United States Department of Energy
U/TH: Uranium/Thorium
VLLW: Very Low-level Waste

List of Figures

List of Tables

1.0 Overview of the Project

Performance-based regulation (PBR) can potentially enhance safety, minimize costs by avoiding unnecessarily burdensome requirements, and prevent unwarranted interruptions in production or processing. Although some have suggested that the United States Nuclear Regulatory Commission (NRC) should regulate U.S. Department of Energy (DOE) facilities, PBR has significant potential benefits regardless of the regulator's identity. In recognition of the importance of PBR, the Idaho National Engineering and Environmental Laboratory (INEEL) and the Massachusetts Institute of Technology (MIT) have initiated a project to develop a framework for selecting and applying PBR criteria for regulating DOE facilities.

The overall goal of regulation is to ensure safe operation of potentially hazardous facilities. Ensuring safety entails managing risk effectively. While the current regulatory framework for the DOE manages risk effectively, there may be more efficient ways to do so. As was found in the analogous case of NRC regulation of commercial reactors, the DOE's current regulatory system may place undue burden on itself through instances of regulatory requirements that do not improve safety significantly, or whose results could be achieved more efficiently.

Traditionally, regulations have been primarily prescriptive and deterministic, where safety is achieved through conservatism. Design requirements through technical specifications of facility components and other deterministic criteria are set at target levels much higher than necessary to achieve an acceptable level of safety. These conservative criteria come from the concepts of "defense-in-depth" and "safety margins," which were developed to ensure that regulatory compliance is achieved in an uncertain world (see Section 3 for discussion).

Using a performance-based regulatory (PBR) framework instead is one way to regulate effectively and more efficiently. A performance-based approach to regulation relies on "measurable (or calculable) outcomes (i.e., performance results) to be met, but provides more flexibility to the licensee as to the means of meeting those outcomes" [NRC White Paper]. This focus on outcomes and flexibility leads to a more efficient regulatory system, which in turn should lead to cost savings and better allocation of safety-related resources within the regulated organization.

The use of risk information can help allocate resources in accordance with safety significance. "A 'risk-informed' approach to regulatory decision-making represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety" [NRC White Paper].

A Risk-Informed Performance-Based approach (RIPB) would combine the key elements of both risk-informed regulation (RIR) and PBR (as listed above). The use of risk information in PBR should result in additional efficiency in the regulatory system. PBR does not have to be risk-informed. RIR typically implies the use of quantitative safety analyses, such as Probabilistic Risk Assessment (PRA), Performance Assessment (PA), or Integrated Safety Analysis (ISA). Such safety analyses are available for some, but not all, DOE facilities. In the cases where the utility of quantitative safety analysis is low,[1] PBR framework can be developed without such assessments. Thus, the extent to which risk information will be used in our proposed PBR framework may vary from one group of DOE facilities to another.

The first task of this project is to review applicable DOE and NRC regulatory requirements to gain perspective about the intent and scope of existing regulations. In addition, on-going regulatory initiatives, including NRC and industry interactions, are examined. The purpose of this report is to codify efforts to date. Section 2 reviews the current regulatory framework for nuclear facilities highlighting the use of defense-in-depth (DID) and safety margins (SM) in nuclear facilities, primarily commercial nuclear power reactors. In Section 3, we provide more formal definitions of RIR and PBR, and describe on-going NRC and industry initiatives in these areas. Section 4 reviews pilot programs conducted by the NRC and the DOE to determine how new and existing DOE facilities and operations might be regulated to better ensure nuclear safety. Section 5 reports on lessons learned from this review that can be applied when developing a PBR framework for DOE facilities.

[1] This occurs when the benefits of results from such an analysis do not outweigh the costs of performing the analysis.

2.0 Existing Regulations for Nuclear Facilities

2.1 The Management of Uncertainty

The purpose of regulating nuclear facilities is to protect public health and safety. In striving towards this goal, nuclear regulation has always acknowledged the uncertainty inherent in anticipating and guarding against accidents. In the past, the NRC had exclusively used qualitative evaluations of risks, based on engineering judgement and experience, to carry out its mission. The response to uncertainty that cannot be quantified is to use the concepts of defense-in-depth (DID) and safety margins (SM).[2]

The definition of DID has evolved over time. At the start of the nuclear industry (1953-55), DID was commonly defined as the principle that no single element or barrier would be emphasized to the exclusion of others. This definition implies that multiple barriers should exist to prevent release of radioactive material. For light water reactor nuclear power plants, these barriers are the fuel matrix, metal cladding, the reactor coolant pressure boundary, and the containment. More recently, DID has been thought of as an overall safety strategy [Sorenson, *et al*]. It emphasizes the importance of the balance between mitigation and prevention.

Safety margins (SM) ensure the adequate performance of systems structures and components by over designing equipment and systems to account for usage outside of normal operating parameters. This can occur due to abnormal operating conditions or due to the uncertainties associated with measuring parameters.

DID and SM have been the historical approach to the treatment of uncertainty. The completion of the *Reactor Safety Study* [WASH-1400] enabled uncertainty to be quantified and incorporated explicitly into safety analysis, although difficulties remain regarding how to treat model uncertainty. With the ability to treat uncertainty more formally than in the past, the logical question is what should be the role of DID and SM?

2.2 Nuclear Power Plant Safety Goals

The Atomic Energy Act made possible the civilian use of nuclear energy. The act defined responsibilities for ensuring the safe use of nuclear technology in qualitative terms. It instructed the Atomic Energy Commission (AEC) to "provide adequate protection to the health and safety of the public" from radiological hazards but did not specify what was meant by "adequate protection." As a result, the AEC and its successor, the NRC, relied on imprecise criteria such as "adequate protection," or "reasonable assurance of no undue risk" to evaluate applications for plant licenses.[3] The technical staff of the AEC and NRC were left with the task of writing rules and supporting regulatory guides that defined the engineering requirements to be met by applicants to receive licenses to construct and operate a reactor.[4]

---

[2] See, for example, [ACRS Letter 1998] and [ACRS Letter 1997].

[3] "Risk" is defined as the risk related to the "release of radioactive materials from the reactor to the environment during normal as well as accidental situations" [FR, 1986].

[4] The NRC, pursuant to the Atomic Energy Act, promulgates the current regulation concerning civilian nuclear activities. The regulations are largely prescriptive.

Prior to the Three Mile Island Unit 2 (TMI-2) accident in March 1979, there had been a steady increase of interest in the United States in the use of quantitative safety goals to define safety requirements for nuclear power plants. It was not until after the accident, however, that the NRC undertook a large-scale effort to develop safety goals. The accident greatly increased the impetus to determine quantitatively what level of safety was safe enough. Following the accident, the President's Commission on the TMI-2 Accident, the NRC's Advisory Committee on Reactor Safeguards (ACRS), and the NRC's Special Inquiry Group all strongly recommended that the NRC should spell out more clearly its reactor safety objectives by establishing quantitative safety goals. Those recommendations, along with the agency's own recognition of the need to rethink past assumptions and policies in light of the experiences at TMI-2, motivated the NRC to develop safety goals.

The Safety Goal Policy Statement [NRC Aug. 1986] includes two qualitative goals and two quantitative goals. The qualitative goals are the following:

1. Individuals should "bear no significant additional risk to life and health" from nuclear power operation; and
2. Societal risks "should be comparable to or less than the risks of ... viable competing technologies and should not be a significant addition to other societal risks"

The quantitative objectives are the following:

1. The risk to an average individual living near a nuclear plant should not increase the risk of fatality from an accident of more than one-tenth of one percent of the sum of "prompt fatality risks resulting from other accidents"; and
2. The risk to the population within ten miles of a nuclear plant of dying from cancer should not increase by more than one-tenth of one percent beyond the sum of cancer fatality risks from all other causes. It also included a general performance guideline that "the overall mean frequency of a large release of radioactive materials to the environment from a reactor accident should be less than 1 in 1,000,000 per year of reactor operation."

With the experience gained in the application of these safety goals and the advances in Probabilistic Risk Assessment (PRA), the major tool for showing compliance with the safety goals, additional insights about the safety goals and their implementation has been gained. As a result, some modifications have been made including the following:

1. The general performance guideline (the large release frequency guideline) has been removed from the final policy statement because it was found to be much more stringent than the quantitative goals; and
2. Two subsidiary goals that the industry and the NRC staff have agreed to are being used in lieu of the quantitative health objectives. They are a Core Damage Frequency (CDF) goal of 1 in 10,000 per year of reactor operation and a Large Early Release Frequency (LERF) goal of 1 in 100,000 per year of reactor operation.

Some other modifications that the ACRS recommended be given consideration include the following:

1. Elevation of the CDF goal to the status of a fundamental goal;
2. Modification of the quantitative goal treating societal risk;
3. Addition of goals for land contamination and interdiction; and
4. Addition of goals for temporary risk increases (e.g., as may arise from particular plant configurations).

The safety goals presented the Commission's judgment on acceptable risk from nuclear power generation. They gave a definition to "how safe is safe enough" and provided a yardstick for nuclear safety. The safety goals help to identify the systems and activities that are most important with respect to risk, to allocate more efficiently resources both for the regulators and the industry, and to maintain a coherent and consistent regulatory system. It was a major step toward the use of risk-informed insights in making regulatory decisions and an important milestone in the evolution of the NRC's approach to regulation. Despite all the advantages the safety goals may offer, it is generally recognized that safety goals should complement but not replace traditional safety analyses and reliance on DID, which is mainly due to the large uncertainties in PRA analysis and in demonstrating compliance with the goals.

2.3 Types of Facilities Examined

In order to understand better the regulatory problems inherent in the types of facilities used in the DOE's activities, we examined the current regulatory practices at several such facilities.

2.3.1 Commercial Power Reactors

The NRC regulatory policy is based on three basic "lines of defense" for nuclear reactors. These lines of defense are the following [Sorenson, *et al*]:

1. Prevention of accident initiators through superior quality of design, construction and operation;
2. Prevention of accident escalation through engineered safety systems; and
3. Minimization of fission products release through consequence-limiting safety systems.

Most of the current regulations have been developed for commercial light water reactors power plants. They are design-based, that is, they are formulated in terms of required systems and plant features to either prevent or mitigate possible accidents. "Structures, systems, and components must be designed, fabricated, erected, constructed, tested, and inspected to quality standards commensurate with the importance of the safety function to be performed" [10 CFR 50]. This statement clearly reveals the DID philosophy. In fact, if the stated conditions are satisfied, adequate balance between prevention and mitigation is presumed to have been achieved.

Prevention of accidents is the main idea underlying the first line of defense. Accident initiators are to be minimized. In accordance to the DID philosophy, the concept of safety limits is introduced. Safety limits are defined as "limits upon important process variables that are found to be necessary to reasonably protect the integrity of certain of the physical barriers that guard against the uncontrolled release of radiation" [10 CFR 50.36].

To understand better the underlying philosophy, it is useful to look at some of these criteria in detail. 10 CFR 50, Appendix A General Design Criterion (GDC) Criterion 10, Reactor Design, states that "The reactor core and associated coolant shall be designed with appropriate margin to assure that specified acceptable fuel design limits are not exceeded during any condition or normal operation, including the effects of anticipated operational occurrences". Criterion GDC 36, Inspection of Emergency Core Cooling System, states that "The emergency core cooling system shall be designed to permit appropriate periodic inspection of important components, such as spray rings in the reactor pressure vessel, water injection nozzles and piping, to assure the integrity and capability of the system".

Regarding the level of radioactivity in the primary coolant: "...the application shall also identify the design objectives and the means to be employed for keeping levels of radioactive materials...as low as reasonably achievable". "Reasonably achievable" means taking into account the current technology and the economics of improvements in relation to the benefits to society and to the use of nuclear energy.

The second line of defense is intended to guarantee that reactors are equipped with safety systems adequate to inhibit possible accident sequences. These systems are again considered under the DID and SM Principles. Especially after the TMI-2 accident, additional attention has been placed on safety related systems. For example, safety related electric equipment is defined as the equipment that is relied upon to remain functional during and following design basis events to ensure:

1. The integrity of the reactor coolant pressure boundary;
2. The capability to shut down the reactor and maintain it in a safe shutdown condition; and
3. The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure.

The electric equipment qualification is based on physical and technological properties, and sufficient margins are to be applied in dealing with uncertainties. "Margins must be applied to account for unquantified uncertainty, such as the effects of production variations and inaccuracies in test instruments. These margins are in addition to any conservatism applied during the derivation of local environmental conditions of the equipment unless these conservatisms can be quantified and shown to contain appropriate margins" [10CFR50]. In assessing accident progression, several uncertainties appear. The current regulations require uncertainties to be dealt with using a conservative approach. That is, no matter what its probability is, the worst possible scenario will be always examined and designed against. In this conservative approach, design margin is the prescribed means by which safety is reasonably assured.

The third line of defense aims at minimizing fission product release through consequence-limiting safety systems. Reactor containment is the final barrier against radiation release after the core has been damaged. The licensee is required to provide containment isolation. The licensee is also asked to develop a safety study to demonstrate that containment integrity will be maintained during an accident under "worst case scenarios."

2.3.2 Research Reactors and Hot Cells

To provide specific examples of how the NRC regulates non-DOE research reactors and hot cells, the regulatory requirements that apply to MIT's research reactor (MITR), were reviewed.[5] These two types of facilities should be considered together because it is common to have hot cells with a research reactor. Hot cells vary in size and uses but can be simply thought of as compartments consisting of thick walls, usually containing large amount of lead, with thick lead-based glass and remote operating devices to manipulate and process radioactive material. Hot cells may be used for research purposes, such as testing the strength of various materials that have been exposed to significant amounts of radiation in a research reactor, or for industrial uses such as the manufacturing of particular radiochemical materials.

In the case of university reactors, the NRC regulates their design, operation, and use fundamentally similar to the way it regulates power reactors. The regulations are prescriptive, detailed, and require audit and verification by the NRC in order to ensure compliance on a routine basis.

NRC's regulation of university research reactors does, however, acknowledge some of the differences between research and power reactors. One fundamental difference is that research reactors contain significantly less radioactive material than power reactors and, therefore, pose less of a hazard. Research reactors also operate at lower temperatures and pressures than power reactors so there is less stored energy to push radioactive material out in the event of an accident. In addition, their fuel types are different. University research reactors typically use aluminum clad cermet fuels whereas power plants have zircaloy rods containing UO_2 fuel pellets. If a power plant fuel rod ruptures, there is an instantaneous release of fission product gas. If the cladding of a university research reactor element, however, fails, then the fission product gases have to diffuse through the cermet, which is a slower process than what would occur in a power reactor.[6]

As a result of these differences, the corresponding NRC regulatory requirements are different. For example, regional evacuation plans are not required for university research reactors because the amount of fissionable material that can be released to a large area is significantly less than that of a power reactor and therefore does not present a significant hazard to the nearby population. The principal hazard from a research reactor is in radiation of the people who use them for experiments (e.g., as a result of radiation from the beam ports or radiation from the samples, if the samples are used improperly). NRC-regulated research reactors do not have to have a PRA. Such a requirement, it is believed, would be too costly and not necessary given the relatively low amount of radioactive material that exists in the core.

---

[5] This information is based on interviews of various MIT personnel involved in the safety and operation of MIT nuclear facilities.

[6] Other differences that may exist are that research reactors may not produce electricity and may have beam ports whereas commercial reactors do not.

The NRC usually conducts three inspections a year at these MIT facilities. One inspection deals with reactor operations, another addresses health physics and emergency planning, and the third deals with some other issue such as security, special nuclear material, or a topic of interest to the NRC. MIT is obligated to operate its facilities in accordance with NRC approved Technical Specifications and must report any violation to the NRC within 24 hours. The NRC also licenses the reactor operators and administers the associated examinations.

2.3.3 Storage Facilities

The nature and magnitude of risks posed by a radioactive waste storage facility can be very different from those posed by a reactor for several reasons:

- The threat from radio-toxic materials may not be as concentrated as in a reactor core;
- Reactors are active units in operation, while storage units are often passive facilities that are not serviced regularly;
- Waste storage units encompass a very wide range of hazards from very low-level waste (VLLW) all the way to high-level waste (HLW) and spent nuclear fuel (SNF); and
- Waste storage units at DOE sites exist in a diversity of conditions from recently designed and well-characterized storage units in good condition to poorly characterized inherited waste from the cold war years.

Current commercial LLW[7] storage facilities are licensed by either the NRC or Agreement States. Regulations dictate that (1) the LLW be stored in a manner appropriate to its level of hazard, (2) radiation doses to workers and members of the public must be kept below NRC-specified levels, and furthermore, as low as detected by the reasonably achievable (the as low as reasonably achievable (ALARA) principle). Regulatory criteria include administrative details such as requirements for clear markers and postings in areas where LLW is stored, to prevent inadvertent radiation exposure to workers or the public. Regulatory criteria for LLW disposal address such topics as siting, design, and operation requirements, such as mandatory maintenance and monitoring activities and restricted access to the site [NUREG/BR-0216]. A safety analysis in the form of a Performance Assessment (PA) is not required for a LLW storage or disposal facility (see Section 3.6 for discussion on Performance Assessments).

Commercial HLW/SNF storage is regulated by the NRC. NRC licenses both spent fuel pools for wet storage, and metal or concrete casks for dry storage and transportation. Safety analyses are required for HLW/SNF storage systems, but not PAs. No HLW/SNF has been disposed yet in the US, but regulatory criteria (including PA) for a potential HLW/SNF repository, and criteria that the EPA used to license the Waste Isolation Pilot Plant for transuranic waste in May 1998, are discussed in Section 3.6.

Current NRC and some EPA regulations that could be applicable to DOE storage facilities were reviewed. These regulations are identified and brief insights gained are described in the remainder of this section.

---

[7]e.g., from nuclear power plants or hospitals.

NRC's 10 CFR PART 20 contains the Standards For Protection Against Radiation, which reflects NRC's basic protection principles. This rule suggested the idea that some existing regulatory requirements may be utilized in a PBR framework and might enable a smoother transition to a PBR framework. For example, data-keeping and performance prediction requirements in 10 CFR 20 require that whenever a worker is likely to be exposed to radiation above a particular dose level, a pre-activity assessment must be made of the dose that is anticipated to be received. This predicted dose, as well as the actual measured dose received through the activity, must be recorded. Recording the actually measured dose is necessary to track the cumulative yearly dose of each worker. The additional requirement of predicting the dose suggests that we might find such instances of potential in the current regulatory system, e.g., information that is required to be collected anyway, which may be used for more efficient regulation and help smooth the transition to RIPBR.

NRC's 10 CFR PART 72—Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste would be relevant for high risk waste storage units, and was applied to the INEEL TMI-2 Independent Storage Facility Safety Installation. This rule governs the license application, issuance and conditions; records, reports, inspections and enforcements; siting evaluation factors; general design criteria; and quality assurance requirements. These are largely prescriptive criteria in the form of "minimum requirements". However, the licensee has some flexibility in showing how the system to be licensed meets those requirements.

NRC's 10 CFR PART 70—Domestic Licensing of Special Nuclear Materials[8] could be relevant to medium risk waste storage facilities. NRC's PBR-directed revision of this rule is discussed in Section 3.6.

EPA's 40 CFR Part 192, Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings, could be relevant to low to medium risk waste storage facilities as well as contaminated sites. Section 40 CFR 192 suggests cost-benefit analysis for those activities that do not pose high risks to workers and the public. For example, there are primary standards that must be met at Uranium/Thorium (U/Th) mill tailings sites. A licensee does not have to take any action if an assessment shows that there is a reasonable expectation that contamination (e.g., from radon-222) will not exceed harmful levels for 200 to 1,000 years. However, if soil or groundwater sampling or analysis show that the standard will be exceeded, then corrective action must be taken. There are, however, supplemental standards for special situations. For example, the implementing agency may apply different standards if "the estimated cost of remedial action... is unreasonably high relative to the long-term benefits, and the residual radioactive materials do not pose a clear present or future hazard." Different standards may be used if "the restoration of groundwater quality at any designated processing site... is technically impracticable from an engineering perspective." This clearly shows not

[8] Special Nuclear Materials means "(1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission pursuant to the provisions of section 51 of the act, determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing but does not include source material" [10 CFR 70.4]. Source Material means "(1) Uranium or thorium, or any combination thereof, in any physical or chemical form or (2) Ores that contain by weight one twentieth of one percent (0.05%) or more of (i) Uranium, (ii) Thorium, or (iii) any combination thereof. Source material does not include special nuclear material" [10 CFR 72.3].

only a risk-informed framework, but also a regulatory framework that takes cost-benefit tradeoffs into account.

40 CFR 191, 40 CFR 194 and 10 CFR 60 could all be relevant to high-risk storage facilities or contaminated sites. EPA's 40 CFR 191 describes the Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes. EPA's 40 CFR 194 describes the Criteria for the Certification and Re-certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 disposal regulations. NRC's 10 CFR 60 and 10 CFR 63 are applicable for SNF/HLW disposal at Yucca Mountain. All of these use performance-based standards to some extent, and are discussed in Section 3.4 on Performance Assessments.

2.3.4 Other Low Hazard Facilities and End-Use Facilities

How does performance-based regulation mean in the context of very low hazard or other end-use facilities? The subset of DOE facilities that pose very little hazard may be the category for which it is most difficult to construct a PBR scheme. If the risk is very low, how can PBR be applied? Insights derived from PRA are the basis for choosing performance indicators for the proposed PBR of commercial reactors. However, a full-scale PRA (or equivalent analysis) should not be required of facilities that pose little threat to its workers and the communities that surround them. The resource expenditure to complete such a detailed safety analysis would not be justifiable. So performance indicators must be chosen on a different basis.

The category of low hazard facilities suggests the need to develop a systematic way to classify the various DOE facilities. For example, Table 1 is adapted from NUREG/CR-6372 on earthquake hazard analysis for reactors. There are three degrees of complexity of issues:

1. Non-controversial; and/or insignificant hazard;
2. Significant uncertainty and diversity; controversial; and complex; and
3. Highly contentious; significant to hazard; and highly complex.

For each of these issues, decision factors are identified to help decide the level of study needed for the issue. A similar classification scheme for DOE facilities could be developed.

Table 1: Degrees of Probabilistic Seismic Hazard Analysis (PSHA) Issues and Levels of Study [NUREG/CR-6372]

ISSUE DEGREE	DECISION FACTORS	STUDY LEVEL
A: Non-controversial; and/or insignificant to hazard	Regulatory Concern	**1.** Technical Integrator (TI) evaluates/weights models based on literature review and experience; estimates community distribution
B: Significant uncertainty and diversity; controversial; and complex	Resources Available	**2.** TI interacts with proponents and resource experts to identify issues and interpretations; estimates community distribution
C: Highly contentious; significant to hazard; and highly complex	Public Perception	**3.** TI brings together proponents & resource experts for debate and interaction; TI focuses debate and evaluates alternative interpretations; estimates community distribution
		4. Technical Facilitator Integrator (TFI) organizes panel of experts to interpret and evaluate; focuses discussions; avoids inappropriate behavior on the part of evaluators; draws picture of evaluators' estimate of the community's composite distribution; has ultimate responsibility for project

The idea of classification of risks as a gauge of importance is common. It is similar to classifying various components in a system according to their contribution to safety. For example, licensees of spent fuel storage systems are expected to classify the systems structures, and components (SSCs) into broad categories according to their importance to safety. The NRC guidance on this is contained in NUREG/CR-6407. Table 2 lists the SSC classification categories used. This is similar to SSC classifications that the DOE already uses (e.g., in Safety Analysis Reports (SAR)).

Taking a holistic view of the entire set of DOE facilities, these facilities can be classified according to a similar scheme. Low hazard facilities would fall into the C category, since a failure or mishap at these facilities would not be likely to create a situation adversely affecting public health and safety. One level (presumably a low level) of regulations would apply to these. High hazard facilities would fall into category A, requiring a PRA, or equivalent, along with demonstration of DID. In addition to the pure safety-related classification in Table 2, classification criteria could include non-safety-related factors. One example is the decision factor in Table 1 labeled "public perception." This could be an additional classification criterion or decision factor that leads to a higher level of regulation of a low hazard facility than would be suggested by the nature and level of hazard alone. The question of whether factors other than safety should be considered in a safety regulatory system is ultimately a policy issue that must be resolved by the agency of interest.

Table 2: Description of Classification Categories for Components of Dry Spent Nuclear Fuel Storage Systems [NUREG/CR-6407]

CLASSIFICATION CATEGORY	IMPORTANCE TO SAFETY	DESCRIPTION
A	Critical to operation	Category A items include structures, components, and systems whose failure could directly result in a condition adversely affecting public health and safety. The failure of a single item could cause loss of primary containment leading to release of radioactive material, loss of shielding or unsafe geometry compromising criticality control.
B	Major impact safety	Category B items include structures, components, and systems whose failure or malfunction could indirectly result in a condition adversely affecting public health and safety. The failure of a Category B item, in conjunction with the failure an additional item, could result in an unsafe condition.
C	Minor impact on safety	Category C items include structures, components, and systems whose failure or malfunction would not significantly reduce the packaging effectiveness and would not be likely to create a situation adversely affecting public health and safety.

The issues faced in PBR of low hazard facilities are similar to the issues faced by the NRC Nuclear Material Safety and Safeguards (NMSS) office in regulating nuclear materials. The NMSS office is currently studying how RIPBR can be adapted to nuclear materials regulation, e.g., how and which RIPB regulations can be adapted for nuclear materials, and which uses of NMSS regulatory activities are amenable to RIPBR. (See Section 3.6.)

3.0 Current Regulatory Initiatives

3.1 Basic Concepts and Definitions

In this section we will report the most commonly encountered definitions of PBR and RIR and will discuss how they can be combined with the concepts of DID and SM in the search of a coherent regulatory framework.

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

(1) measurable (or calculable) parameters (i.e., direct measurement of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) exist to monitor system, including licensee, performance against clearly defined, objective criteria;

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

(3) 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."

According to the same document, "a risk-informed approach to decision-making represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety. Risk Information A risk-informed approach enhances the traditional approach by:

(a) allowing explicit consideration of a broader set of potential challenges to safety,

(b) providing a logical means for prioritizing these challenges based on risk significance, operating experience, and/or engineering judgement,

(c) facilitating consideration of a broader set of resources to defend against these challenges,

(d) explicitly identifying and quantifying sources of uncertainty in the analysis, and

(e) leading to better decision-making by providing a means to test the sensitivity of the results to key assumptions.

Where appropriate, a risk-informed regulatory approach can also be used to reduce unnecessary conservatism in deterministic approaches, or can be used to identify areas with insufficient conservatism and provide the bases for additional requirements or regulatory actions" [NRC White Paper, p. 4].

RI and PB regulatory approaches can be used separately. For instance, RI techniques can identify which systems and components should receive most of the regulator's attention but use prescriptive approaches to regulating the maintenance and operation of those components. Similarly, PB approaches can be used without formal RI approaches.

It is worth mentioning how DID fits into RIPBR. According to the NRC Staff, the concept of DID will continue to be a fundamental tenet of its regulatory practice. Risk insights can make the elements of DID clearer by quantifying them to the extent practicable. Although the uncertainties associated with the importance of some elements of DID may be substantial, the fact that these elements and uncertainties have been quantified can aid in determining how much DID makes sense. Furthermore, decisions on the adequacy of or the necessity for elements of DID should reflect risk insights [NRC White Paper, p. 4].

As an alternative to prescriptive regulation, RIPBR uses a new approach for achieving the desired level of nuclear safety performance. It concentrates upon satisfying performance goals rather than upon specific methods. RIPBR uses mutually negotiated performance goals and incentives for judging and rewarding licensee behavior. In the past, the USNRC has used system performance goals in regulation to a limited extent. Important examples include using test-based reliability standards for emergency diesel-generator starting (Brattle and Campbell, 1983), and use of required reactor survival durations in judging the acceptability of systems for withstanding station blackout conditions (Baranowsky, 1985).

RIPBR often, but not exclusively, includes expected risks among the measures of expected safety performance. Analysts estimate these risks using PRAs to evaluate changes in Technical Specifications such as increasing the allowed outage times (AOT) of subsystems or equipment and surveillance test intervals (STI) (i.e., the time between maintenance surveillances). This treatment differs from the existing, prescriptive, regulatory approach, in which regulators are concerned with ensuring that proper hardware, skilled personnel, and comprehensively specified procedures are used in regulated activities. Regulators can apply both the prescriptive and performance-based approaches in all areas of nuclear safety regulation, such as nuclear medicine and nuclear waste disposal.

The effort to introduce RIPBR is progressing. The NRC has stated a commitment to add RIPBR to deterministic analyses, expert judgement, and defense-in-depth to the analytic bases and principles upon which the agency will base future regulatory decisions. See Figure 1.

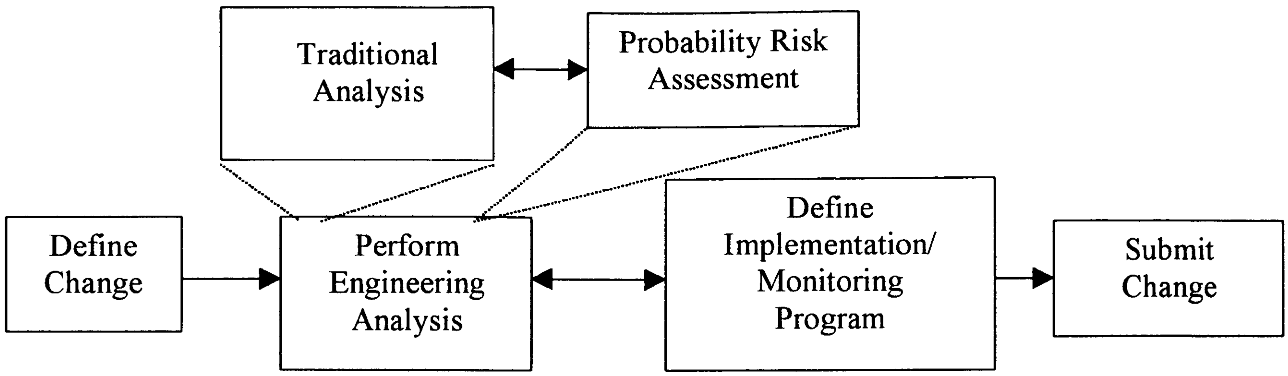

Figure 1: General Description of an Acceptable Approach to Risk-informed Applications (NRC RG 1.174, 1998, p. 7)

3.2 Regulatory Guides

Regulatory Guides are issued to describe and publicize methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants. They are not a substitute for regulation, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if applicants substantiate the findings needed to the issuance or continuance of a permit or license by the commission.[9] In practice, however, compliance with the Regulatory Guides is usually a quicker and less expensive way to gain regulatory approved of a proposed action. Hence, licensees have a strong incentive to comply with Regulatory Guides.

3.2.1 Regulatory Guide 1.174: An Approach for Using Probabilistic Risk Assessment In Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis

NRC Regulatory Guide 1.174 is the first step, and in a certain sense a bridge, towards a risk-informed regulation. As mentioned previously, PRA techniques are not a part of the regulatory system, and the majority of the regulation of nuclear power plants is deterministic. As a result of the Reactor Safety Study (1975), PRA techniques acquired recognition as a valuable tool in dealing with reactor Safety. "...[T]he fault-tree/event-tree methodology is sound, and both can and should be more widely used by the NRC". Since then the PRA methodology has grown in importance while further improving and refining its computational tools. As a consequence of the advances in the methodology, the NRC's policy statement on PRA "encourages greater use of this analysis technique to improve safety decision-making and improve regulatory efficiency" [NRC RG 1.174]. PRA is seen as the most valuable tool to be inserted in the actual regulatory body to reduce unnecessary conservatism, while preserving the DID and SM concepts. RG

[9] The guides are issued in the following ten broad divisions: (1) Power Reactors, (2) Research and Test Reactors, (3) Fuels and Material facilities, (4) Environmental and Siting, (5) Materials and Plant Protection General, (6) Products, (7) Transportation, (8) Occupational health, (9) Antitrust and Financial review, and (10) General.

1.174, for the first time, explicitly suggest using this technique to evaluate the impact of licensing basis changes.

Regulatory Guide 1.174 describes an "acceptable approach for assessing the nature and impact of licensing basis changes by considering engineering issues and applying risk insights" [NRC RG 1.174, p. 4]. The Guide provides the NRC staff's recommendations for using risk information in support of licensee-initiated changes requiring review and approval by the NRC. The acceptance guidelines for the application are based on two metrics: CDF and LERF. The applicant must show that the increase (if any) in each of these two parameters falls under a certain value as specified consistent with the NRC safety goals. In order to demonstrate compliance of the proposed change with these values, the applicant can use a PRA to support its numerical calculation. The licensee risk assessment may be used to address the principle that proposed increases in CDF and risk are small and are consistent with the intent of the NRC's Safety Goal Policy Statement" [NRC RG 1.174].

Figure 2 [RG 1.174] illustrates these concepts. Each block represents one of five principles of acceptance for the design basis change. Notice that the concepts of DID and SM are essential part of the regulation. Block 4 refers in particular to the previous discussion regarding the expected change in the plant CDF. PRA results are used in the decision-making process in two ways. The results address the overall CDF/LERF of the plant and address the change in the CDF/LERF due to the proposed change.

For the results to be considered valuable, a PRA of sufficient quality and detail are required. The quality and level of detail depends on the impact of the proposed change on the plant safety. Obviously major changes will have to be addressed more carefully and will require a higher complexity and completeness of the analysis than minor changes.

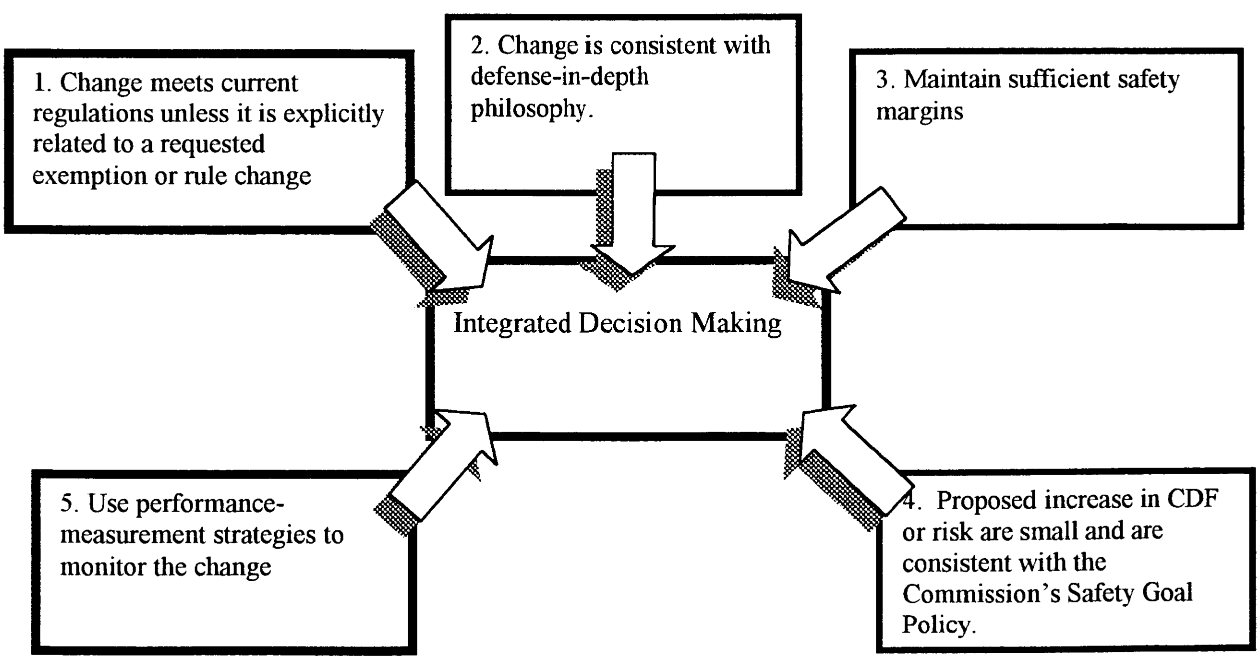

Figure 2: The NRC's Approach to Risk-Informed Decision Making.

PRA "quality" is defined in RG 1.174 to be a "measure of the adequacy of the actual modeling". To assure high quality of its study, one approach a licensee may take is to submit its PRA to peer review. Documentation of the review process, the qualification of the reviewers, the summarized review findings and resolutions to these findings are all to be part of the peer review process. Another approach that RG 1.174 suggests is to adopt an industry-wide PRA certification program.

The NRC staff checks the quality of the PRA based on the following criteria:

1. Use of personnel qualified for the analysis;
2. Use of procedures that ensure control of documentation, including revisions, and provide for independent review, verification, or checking of calculations and information used in the analyses (an independent peer review or certification program can be used as an important element in this process);
3. Provision of documentation and maintenance of records in accordance with the guidelines in Section 3 of the guide;
4. Provision for an independent audit function to verify high quality (an independent peer review or certification program can be used for this purpose);
5. Use of procedures that ensure appropriate attention and corrective actions are taken if assumptions, analyses, or information used in previous decision-making are changed (e.g., licensee voluntary action) or determined to be in error; and
6. Expectation that when performance-monitoring programs are used in the implementation of proposed changes to the LB, those programs will be implemented by using quality assurance provisions commensurate with the safety significance of affected SSCs. An existing PRA or analysis can be utilized to support a proposed LB change, provided it can be shown that the appropriate quality provisions have been met.

Other elements are needed from the licensee to meet NRC requirements. The NRC requires a description of the risk assessment methods used in the analysis, identification of key modeling assumptions that are necessary to support the analysis or that affect the application, the event trees and fault trees necessary to support the analysis, and a list of operator actions modeled in the PRA that affect the application and their error probabilities.

The acceptance guidelines for a licensing basis change are expressed in terms of change in CDF and LERF. The acceptance criteria are illustrated in Figures 3 and 4. The analysis is subject to increased technical review and management attention as indicated by the darkness of the shading of these figures. In the context of integrated decision making, the boundaries between regions should not be interpreted as being definite; the numerical values associated with defining the regions in the figure are to be interpreted as indicative values only.

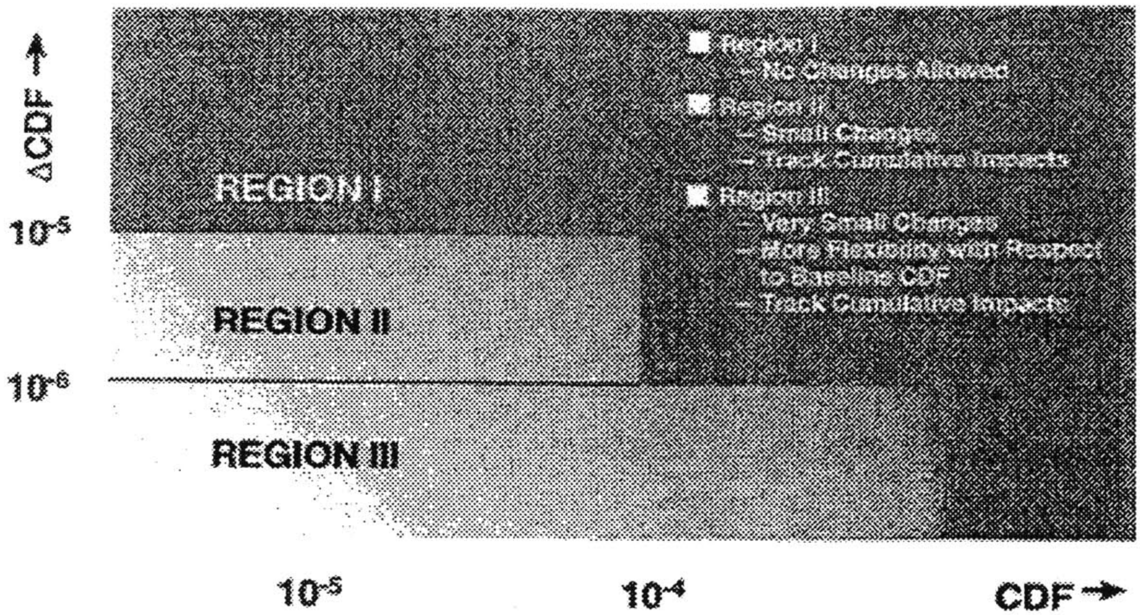

Figure 3: Acceptance guidelines for CDF
(CDF units are in core damage events per year)

The interpretation of these figures is as follows:

- If the application can be shown to result in a decrease in CDF, the change will be considered to have satisfied the relevant principle of risk-informed regulation with respect to CDF.
- When the calculated increase in CDF is very small, which is taken as being less than 10^{-6} per reactor year, the change will be considered regardless of whether there is a calculation of the total CDF (Region III). While there is no requirement to calculate the total CDF, if there is an indication that the CDF may be considerably higher than 10^{-4} per reactor year, the focus should be on finding ways to decrease rather than increase it.
- When the calculated increase in CDF is in the range of 10^{-6} per reactor year to 10^{-5} per reactor year, applications will be considered only if it can be reasonably shown that the total CDF is less than 10^{-4} per reactor year (Region II).
- Applications that result in increases to CDF above 10^{-5} per reactor year (Region I) would not normally be considered.

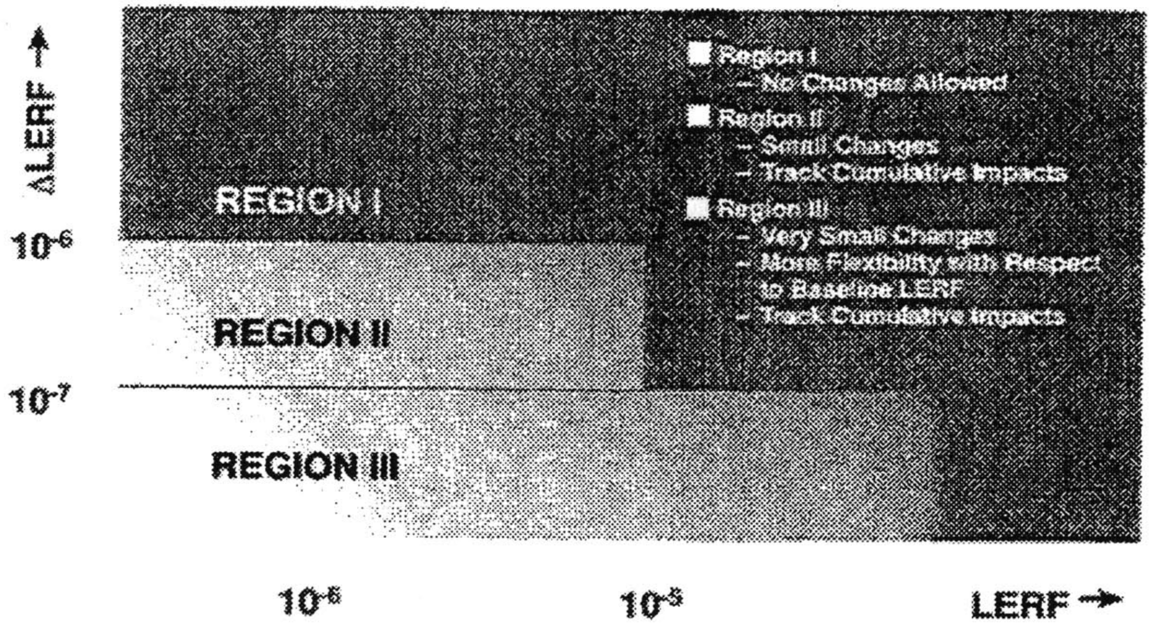

Figure 4: Acceptance Guidelines for LERF

- If the application can be shown to result in a decrease in LERF, the change will be considered to have satisfied the relevant principle of risk-informed regulation with respect to LERF. (Since Figure 4 is drawn with a log scale, this region is not explicitly indicated on the figure.)
- When the calculated increase in LERF is very small, which is taken as being less than 10^{-7} per reactor year, the change will be considered regardless of whether there is a calculation of the total LERF (Region III). While there is no requirement to calculate the total LERF, if there is an indication that the LERF may be considerably higher than 10^{-5} per reactor year, the focus should be on finding ways to decrease rather than increase it.
- When the calculated increase in LERF is in the range of 10^{-7} per reactor year to 10^{-6} per reactor year, applications will be considered only if it can be reasonably shown that the total LERF is less than 10^{-5} per reactor year (Region II).
- Applications that result in increases to LERF above 10^{-6} per reactor year (Region I) would not normally be considered.

In addition to RG 1.174, there are a series of application-specific RGs that provide RI and PB guidance. RG 1.175 addresses the Maintenance Rule, which is discussed below. RG 1.1.76 is concerned with quality assurance practices. RG 1.178 describes an acceptable approach for assessing the nature and impact of proposed permanent technical specification changes.

3.2.2 Uncertainties

Another major change of philosophy found in RG1.174 (and then propagated in RG 1.175, 1.176, 1.177, 1.178) is the explicit consideration of the uncertainties connected with the state of knowledge in the study of reactor safety. Uncertainties are not only mentioned but are qualified and explained. The categorization used consists of the following:

1. Aleatory Uncertainty: which occurs when the events or phenomena being modeled are characterized as occurring in a “random” or “stochastic” manner and probabilistic models [model of the world (MOW)] are adopted to describe their occurrences;
2. Parameter Uncertainty: which reflects the incompleteness of our knowledge of the real value of the MOW parameters;
3. Model Uncertainty: which reflects the incompleteness of our state of knowledge about a certain phenomenon; and
4. Completeness Uncertainty: which is related to the “scope” limitation and refers to those potential risk contributors that we have somehow disregarded in developing the analysis.

In view of the uncertainties related to the PRA methodology, to consider the acceptance guidelines as a pure numerical "table” would be conceptually wrong. Therefore, the approach to these guidelines proposed by the NRC is to complement the numerical results with a full understanding of the contributors in the PRA to these results. Clearly different regions in Figures 3 and 4 require different depths in the analysis. Obviously changes resulting in great differences in CDF or LERF would require a deeper analysis than changes that do not. “The different regions of the acceptance guidelines require different depths of analysis. Changes resulting in a net decrease in the CDF and LERF estimates do not require an assessment of the calculated baseline CDF and LERF. Generally, it should be possible to argue on the basis of an understanding of the contributors and the changes that are being made that the overall impact is indeed a decrease, without the need for a detailed quantitative analysis.... For larger values of CDF and LERF, which lie in the range used to define Region II, an assessment of the baseline CDF and LERF is required”. [NRC RG 1.174]. The NRC’s approach to require an increase in the control of the analytical methodology and results is consistent with DID and SM concepts.

3.3 Some Commercial Nuclear Power Plant Regulatory Initiatives in the US

3.3.1 NRC's Initiative to Improve the Reactor Regulatory Oversight Process

The NRC's Principles of Good Regulation are: (1) Independence, (2) Openness, (3) Efficiency, (4) Clarity, and (5) Reliability. Although commercial nuclear power plants have operated safely, current NRC regulations have not necessarily satisfied the efficiency, clarity or reliability principles. "Despite [success], the [NRC] has noted that the current inspection, assessment, and enforcement processes (1) are at times not clearly focused on the most safety important issues, (2) consist of redundant actions and outputs, and (3) are overly subjective with NRC action taken in a manner that is at times neither scrutable nor predictable" [NRC SECY-99-007].

The NRC staff has undertaken an initiative, fueled by encouragement and input from industry, to develop a new regulatory oversight framework for commercial reactors that better realizes the NRC's regulatory principles. The staff recommended a RIPB regulatory framework to the Commission after over 6 months’ effort in three task groups, focused on (1) Technical Framework, (2) Inspection, and (3) Assessment [NRC SECY-99-007].

The Technical Framework task group first identified and developed “cornerstones of safety”. These safety cornerstones chosen are the following [NRC SECY-99-007]:

1. Initiating Events - "Limit the frequency of initiating events";
2. Mitigating Systems - "Ensure the availability, reliability, and capability of mitigating systems";
3. Barrier Integrity - "Ensure the integrity of the fuel cladding, reactor coolant system, and containment boundaries";
4. Emergency Preparedness - "Ensure the adequacy of the emergency preparedness functions";
5. Public Safety - "Protect the public from exposure to radioactive material releases";
6. Occupational Safety - "Protect nuclear plant workers from exposure to radiation";
7. Physical Protection - "Provide assurance that the physical protection system can protect against the design basis threat of radiological sabotage."

Then within each of these cornerstones, the task group identified and developed the following:

1. Objectives, scope, and key attributes of each cornerstone;
2. Areas to be measured to ensure that the cornerstone objectives are met;
3. Performance Indicators (PI's) for each of these areas;
4. Which areas could be monitored sufficiently by the PI's;
5. Inspection and other informational needs to supplement the PI's and verify the validity of the PI data; and
6. PI thresholds to establish "clear demarcation points for identifying fully acceptable, declining, and unacceptable levels of performance" [NRC SECY-99-007].

The task group also identified "cross-cutting issues", aspects of licensee performance that do not belong to one specific cornerstone but are still important to meeting safety goals. Human performance, establishment of a safety conscious work environment, common cause failure, and effectiveness of licensee problem identification and corrective action programs fell in this category.

Table 3 shows some of the key performance indicators proposed by the study. Table 4 shows the conceptual model for evaluating licensee performance indications. This is similar to the NEI's performance bands, and was developed with NEI's input [NEI 1998]. This is clearly a PBR framework utilizing risk information. In addition, the staff's proposed framework and the utilization of inspections is one way to combine the traditional DID concept within PBR. The cornerstones themselves represent the multi-barrier approach, one aspect of DID. In addition, the baseline inspection scheme combines DID with PBR, through the following three types of inspections: (1) complementary inspections in areas that are not measured by performance indicators; (2) supplementary inspections in areas of safety which can not be captured adequately by performance indicators; (3) verification inspections to verify the accuracy and completeness of data used as the basis for PIs [NRC SECY-99-007].

Table 3: Some Performance Indicators Proposed by NRC Staff [NRC SECY-99-007]

Safety Cornerstone	Performance Indicator
Initiating Event	Loss of feedwater frequency
	Loss of ultimate heat sink frequency
	Loss of offsite power frequency
Mitigating Systems	Reliability and availability of turbine-driven pumps
	Reliability and availability of motor-operated valves
	Common cause failure indicator
	Reliability of on-site emergency ac power
Barriers	Reliability and availability of containment spray system trains
	Reliability and availability of containment cooling system trains
	Reliability and availability of containment isolation system trains

Table 4: Conceptual Model for Evaluating Licensee Performance Indicators [NRC SECY-99-007]

GREEN (Acceptable Performance – Licensee Response Band) Cornerstone objectives fully met Nominal Risk/Nominal Deviation From Expected Performance
WHITE (Acceptable Performance – Increased Regulatory Response Band) Cornerstone objectives met with minimal reduction in safety margin Outside bounds of nominal performance Within technical specification limits Changes in performance consistent with changes in CDF less than E-5 Changes in performance consistent with changes in LERF less than E-5
YELLOW (Acceptable Performance – Required Regulatory Response Band) Cornerstone objectives met with significant reduction in safety margin Technical specification limits reached or exceeded Changes in performance consistent with changes in CDF less than E-5 Changes in performance consistent with changes in LERF less than E-5
RED (Unacceptable Performance – Plants not normally permitted to operate within this band) Plant performance significantly outside design basis Loss of confidence in ability of plant to provide assurance of public health and safety with continued operation Unacceptable margin to safety
UNSAFE PERFORMANCE

3.3.2 The Maintenance Rule

The Maintenance Rule is a risk-informed rule that determines which structures, systems, and components (SSCs) that are to be included within the scope of the rule for a particular power reactor, establishes the requirements by the reactor licensee for monitoring the performance or condition of these SSCs, and encourages the licensee to consider the impact on safety when removing SSCs from service for preventive maintenance.[10]

SSCs that are included within the scope of the Maintenance Rule are those that are relied upon to mitigate accidents or transients or are used in emergency operating procedures, whose failure could prevent safety-related SSCs from fulfilling their safety function, and whose failure could cause a reactor scram or an actuation of safety-related system. Licensees must monitor the performance and condition of SSCs within the scope of the rule against licensee-established goals to provide reasonable assurance that these SSCs are capable of fulfilling their intended functions. These performance goals must be commensurate with the SSC risk significance and, when practical, take into account industry-wide operating experience. Furthermore, licensees must take appropriate corrective actions when performance of an SSC within the scope of the rule does not meet established goals. Licensees are allowed to eliminate goal setting and monitoring activities for specific SSCs when the licensee has demonstrated that the performance of those SSCs is effectively controlled through preventive maintenance such that the SSC remains capable of performing its intended function.[11]

At least once during each refueling cycle, but not less frequently than every twenty-four months, licensees must evaluate their performance and condition monitoring activities and associated goals, as well as preventive maintenance activities. Licensees must adjust their programs when necessary to ensure that the objective of preventing failures of SSCs through maintenance is appropriately balanced against the objective of minimizing unavailability of SSCs due to monitoring or preventive maintenance. Finally, licensees should take into account the total of plant equipment that is out of service in order to determine the overall effect on performance and preventive maintenance activities.

The Maintenance Rule has several performance-based elements. Licensees have the flexibility to establish the performance and condition goals and the requisite equipment monitoring regimes, modify established goals on the basis of plant or equipment performance, determine whether to rely on preventive maintenance in lieu of establishing goals and performance or condition monitoring, and allow, for low safety SSCs, plant-level monitoring. The rule has risk-informed aspects as well. It encourages licensees to use assumptions and results associated with PRAs. PRAs can be used to determine which SSCs are within the scope of the rule and what equipment can be removed simultaneously from service.

---

[10] The Maintenance Rule was published on July 10, 1991 as Section 50.56 of 10 CFR Part 50. It became effective on July 10, 1996. Supporting documents include NUMARC 93-01 and Regulatory Guide 1.160.

[11] See 10 CFR 50.65, Paragraph (a)(2).

The NRC is reviewing the regulations contained in 10 CFR Part 50 (Part 50).[12] It is considering three major options for a high-level approach for incorporating risk-informed attributes into the Part 50 regulations. These three options are to make no change to Part 50, to make changes to the scope of systems, structures, and components covered by those sections of Part 50 requiring special treatment, or to change specific regulatory requirements. The NRC staff has recommended the second option to the Commission and that the NRC should proceed with a phased implementation strategy with two objectives: First, to develop a risk-informed regulatory framework that will enhance safety; Second, to reduce unnecessary staff and licensee burden.

To advance this process, the NRC staff has recommended to the Commission that licensee conformity with a modified Part 50 should be voluntary rather than mandatory, industry pilot studies with selected exemptions to Part 50 should be utilized as part of the risk-informed development process, the scope of the Maintenance Rule should be changed as an early part of the risk-informed program, and the NRC staff should develop clarification of its authority for applying risk-informed decision making in areas beyond those associated with licensee initiated risk-informed licensing actions. Not only are the regulations regarding existing reactors being reviewed to be made more risk-based, but so are the regulations and the licensing process for new reactors are being reviewed.

3.3.3 The Systematic Assessment of Licensee Performance Program

To assure the conformity of licensee's behavior with the NRC's safety philosophy, the NRC implemented an oversight process known as "Systematic Assessment of Licensee Performance" (SALP). Four plant functional areas are identified: Plant Operations, Maintenance, Engineering and Plant Support. NRC's inspectors evaluated plant safety performance in each of these areas. Procedural adherence, safety related plant equipment maintenance, control room deficiencies, root cause investigation and corrective actions, design activities, worker's sensitivity towards and understanding of radiological controls and alarms were some of the investigated aspects. Performance was ranked in four categories from 4 to 1, where ranking 4 meant a very poor safety performance. As a result the SALP was intended to document" the NRC's observations and insights on a licensee performance" and to "communicate the results to the licensee and the public". It should have provided a vehicle for clear communication with licensee management to focus on plant performance relative to safety risk perspectives. The NRC has utilized SALP results when allocating NRC inspection resources at licensee facilities. [Clinton Power Station, SALP, 1995].

The SALP process has been recently criticized. Redundant actions and outcomes, non-safety-focused inspections, subjectivity were listed among the criticisms. Conceptually, this came from the lack of unanimous agreement on the meaning of "safety-performance".

The issuing in March 1998 of SECY-98-045, "Status of the Integrated Review of the NRC Assessment Process (IRAP) for Operating Commercial Nuclear Power Plants" marked a decisive step in the NRC implementation of a new integrated assessment process. In September

[12] SECY-98-300, December 23, 1998.

1998 the previously used Safety Assessment of Licensee Performance (SALP) process was officially suspended, and it will be definitely terminated in case of success of the pilot program [NRC SECY-99-007].

3.3.4 US Commercial Nuclear Power Industry Initiatives

The US Commercial Nuclear Power Industry has advanced several initiatives to improve current regulations and practices. The focus of these initiatives have been to identify areas "where regulations or regulatory guidance are out of date, where operating experience or improved technology provide a better understanding of a source of risk, and where areas of marginal safety significance can be found that are highly resource intensive [NEI 1998]."

Some of these initiatives include pilot programs to consider changes in allowable equipment outages times, changes to equipment testing intervals, changes to the types, locations and frequency of piping inspections, and reduced quality assurance measures on specific equipment.[13] For example, the nuclear industry, through the Nuclear Energy Institute (NEI), requested that the NRC staff reviews and approves two topical reports that address methods for developing a risk-informed in-service (RI-ISI) program for piping. Lessons learned from pilot plants along with public and staff comments have been used to revise Regulatory Guide 1.178, which provides guidance to reactor licensees on acceptable approaches for developing and implementing a and the Standard Review Plan Section 3.9.8, which provides guidance to the staff on the review of RI-ISI submittals. [NRC SECY-98-139].

In parallel with the NRC staff's development of the IRAP proposal, the Nuclear Energy Institute (NEI) developed an independent proposal for improving the assessment process. The proposed NEI approach conceptually focused on maintaining the barriers to radionuclide release, minimizing events that could challenge the barriers, and ensuring that systems can perform their intended functions. Performance would be measured through reliance on high-level, objective indicators with thresholds set for each indicator to form a utility response band, a regulator response band, and a band of unacceptable performance (performance tiers). In response to the NEI proposal a public 60 days comment period (ended October 6th 1998) was issued by the NRC and after a 4-day public workshop September 28 - October 1, 1998 consensus was reached on the overall philosophy for regulatory oversight. (See section 3.4).

The NEI has also proposed a major initiative in the area of RIPB regulation [NEI 1998] as discussed in Section 3.3.1.

3.4 Swedish Study on a Risk-Based Performance Monitoring System for Commercial Nuclear Power Plants

The Swedish Nuclear Power Inspectorate[14] has undertaken a similar study to move towards RIPB regulation of commercial reactors. The purpose of this study is to develop "methodology for monitoring the safety performance of nuclear power plants... (1) based on probabilistic

---

[13] Other initiatives include

[14] NRC's equivalent in Sweden

safety assessment (PSA) methodology; (2) identifying the most promising organizational and operational-based safety-related performance indicators, and developing quantitative relationships between values of the performance indicators and changes in PSA inputs (i.e., reliability measures consisting of component failure rates and initiating event frequencies); (3) demonstrating the detailed implementation of the approach and quantitative relationships to a case-study plant; and (4) developing programmatic and decision making guidelines, as well as needed software, for implementing the performance monitoring system at all Swedish NPPs and for making regulatory use of the system" [ERI/SKI 99-401].

Parts 1 and 2 of this study have been completed thus far. The result, after extensive expert elicitation, is a set of 11 key performance indicators, and a final list of five high-worth PI's shown in Table 5. The cross-cutting issues in NRC staff's recommendations for reactor oversight were also identified in the ERI/SKI's study as critical parameters in nuclear power plant (NPP) operation. In the interim, the study concludes that a PBR framework, based on PSA results, is feasible for NPP's [ERI/SKI 99-401].

Table 5: Final List of High-Worth Performance Indicators [ERI/SKI 99-401]

No.	Performance indicator	Mean Worth
1	Annual rate of safety-significant errors (i.e., reportable violations of technical specifications) by plant personnel, contractors, and others.	87
2	Annual rate of maintenance problems (defined as maintenance rework or overdue maintenance)	71
3	Ratio of corrective versus preventative maintenance work requests on safety equipment.	70
4	Annual rate of problems (deviations/failures) with repeated root cause (i.e., a cause previously identified by a vendor, the plant, another plant, the regulator, etc., for a similar plant or group of plants, or for similar components)	80
5	Annual rate of plant changes that are not incorporated into design-basis documents by the time of the next outage following the change.	70

3.5 Performance Assessment of Storage Facilities

Performance Assessments are used for SNF/HLW repositories. A Performance Assessment (PA) is the equivalent of a PRA for a HLW repository. The PA is a quantitative assessment of the long-term behavior of the whole waste disposal system, "with the objective of demonstrating that the chosen system and site are safe" [Savage, 1995]. The nature of the quantitative assessment can vary from country to country; because of the EPA regulatory criteria used in the US, PAs include a probabilistic treatment of aleatory and epistemic uncertainties. PBR regulation of DOE HLW or SNF storage facilities could also use insights from a PA, or existing Hazards Assessments similar to a PA where available.

The form of EPA regulations for the disposal of HLW/SNF and transuranic waste (TRU), presented in 40 CFR 191, leaves a lot of flexibility to the licensee in how to achieve the results. The main guidance, which limits the cumulative release of various radionuclides into the accessible environment over a 10,000 year frame, is the following (40 CFR 191.13), as illustrated in Figure 5:

(a) Disposal systems for spent nuclear fuel or high-level or transuranic radioactive wastes shall be designed to provide a reasonable expectation, based upon performance assessments, that the cumulative releases of radionuclides to the accessible environment for 10,000 years after disposal from all significant processes and events that may affect the disposal system:

(1) Shall have a likelihood of less than one chance in 10 of exceeding the quantities calculated according to Table 1 (appendix A) [designated by R_o, cumulative normalized release limit for the 10,000 year compliance period]; and

(2) Shall have a likelihood of less than one chance in 1,000 of exceeding ten times the quantities calculated according to Table 1 (Appendix A).

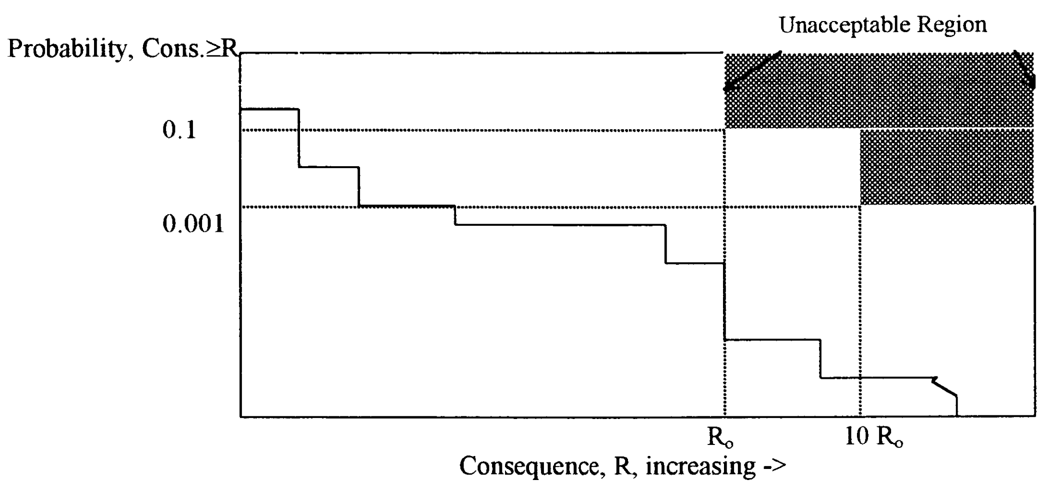

Figure 5: Complementary Consequence Cumulative Distribution Function (CCDF) Curve (where consequence is normalized release of radioactive material, R, to the environment over 10,000 years)

The key words here are "reasonable expectation." They appear again in 40 CFR 191.15 which limits the committed dose to the public: "Disposal systems for waste and any associated radioactive material shall be designed to provide a reasonable expectation that, for 10,000 years after disposal, undisturbed performance of the disposal system shall not cause the annual committed effective dose, received through all potential pathways from the disposal system, to any member of the public in the accessible environment, to exceed 15 millirems." This part goes on to say that assessments need not provide "complete assurance" because of the difficulty of "substantial uncertainties in projecting disposal system performance" over such a long period of time. "Instead what is required in a reasonable expectation" that compliance will be achieved. In addition, the multi-barrier (and heterogeneity of barriers) approach to defense-in-depth is required by Part 191.14: "Disposal systems shall use different types of barriers to isolate the wastes from the accessible environment. Both engineered and natural barriers shall be included."

40 CFR 194 (for the certification of the Waste Isolation Pilot Plant for TRU) then requires that the results of PAs be assembled into a Complementary Cumulative Distribution Function (CCDF) (as in Figure 5) "that represent the probability of exceeding various levels of cumulative release caused by all significant processes and events." These CCDF's represent both aleatory (random) uncertainty, from not knowing which scenarios may occur in the future for example, as well as epistemic (state-of-knowledge) uncertainty, for example from not understanding fully all the thermomechanical-chemical-physical mechanisms that drive the disposal system.

One on-going debate in the PA regulatory community is that of how to account for those uncertainties that can not be quantified. One example of this involves future risks due to events of human intrusion into the repository. Since there is insufficient basis to predict the future state of human society, technological advances, and subsequent resource demands thousands or even hundreds of years into the future, an effective regulatory scheme must include guidance on these scenarios that cannot be handled through the CCDF risk curves. In the case of the Yucca Mountain High Level Waste Repository, the EPA and NRC have proposed (under the National Academy of Science's guidance), to require the repository licensee to analyze one representative human intrusion scenario in order to assess the possible risks from the class of human intrusion events. Whether this is the most effective way to ensure repository safety is still under debate. What is most important for us is to benefit from this debate by gaining perspectives on all sides of the issue, and seeing the possible ways to use a RIPB framework for problems that can not be put explicitly into probabilistic safety analysis. For example, the regulator may require more defense-in-depth, e.g., through multiple barriers, for those cases where there is potential for a large hazard of unknown or uncertain probability.

In the case of facilities in operation, this should be even easier to achieve. For example, large contributors of large potential risk may require more frequent inspections or sampling (e.g., of soil or groundwater underlying a storage site). The safety case of a SNF/HLW repository prepared to remain relatively intact over a 100,000-year history is much harder to demonstrate than the safety case for a facility under active institutional control. So the PA regulatory problem in some sense represents one extreme, a limit, of problems that could be encountered in PBR or RIPBR of DOE facilities.

3.6 Nuclear Materials Safety and Safeguards (NMSS)

In an April 15, 1997 Staff Requirements Memorandum (SRM), the staff was directed to "perform a review of the basis for nuclear materials regulations and processes, and should identify and prioritize those areas that are either now, or could be made, amenable to risk-informed performance-based or risk-informed less prescriptive approaches with minimal staff effort/resources" [NRC SECY-98-138].

In SECY-98-138, the staff made the following preliminary conclusions (which are also applicable to waste storage units and low hazard facilities in general):

PRA may be applicable to only a few specific uses and, for most licensed uses, other system analysis methods that address the three risk questions[15] will need to be considered instead; and

1. Integrating deterministic and probabilistic considerations will likely be a much less important issue, and other issues, such as relating the level of analytic sophistication to the risk associated with specific nuclear materials uses, will likely be much more important in the materials framework [NRC SECY-98-138].

The staff also pointed out the following:

1. Nothing equivalent to the cornerstones for reactors has been issued for nuclear materials;[16]
2. Staff is not aware of any current inadequacies in protecting public health and safety (regarding nuclear materials);
3. Nuclear materials licensees are not anxious for a RIPB regulatory framework (perhaps because they do not have the technical and economic resources to complete the analyses they perceive as necessary under such a regulatory framework); and
4. Experience with system analysis methods will be essential to successful implementation of a RIPB approach to nuclear materials.

With regard to the last point, using system analysis technology, the staff also stated the following:

> ...any increase in the use of system analysis technology must occur within a framework that will ensure that:
> Fundamental regulatory principles are not overlooked in specific applications
> 1. The development of processes and procedures for consistent implementation takes place
> 2. Pilot projects are used for testing of regulatory applications of PRA
> 3. There is an appropriate alignment of level of sophistication of analytic techniques (and their attendant costs and benefits) with risks (real and perceived). The staff also recognizes that any such increase must be accomplished with a commitment of only minimal additional resources [NRC SECY-98-138].

The NRC staff has revised 10 CFR Part 70, Domestic Licensing of Special Nuclear Materials (SNM). The proposed amended rule was released last year, after suggestions from the Nuclear Energy Institute (NEI), and iterative discussions between the NRC staff and the NEI [NRC SECY-97-137]. In the staff's memo to the commissioners, the staff states: "The staff's proposed revisions to Part 70 are intended to provide a risk-informed, performance-based approach for increasing confidence in the margin of safety..." [NRC SECY-98-138]. The major provisions of the revision are:

---

[15] The three risk questions are the following: (1) What can happen? (2) How likely is it to happen? and (3) What are the consequences?

[16] The cornerstones for power reactors are initiating events, mitigation systems, barrier integrity, and emergency preparedness. See Section 5 of this report.

1) Performance of a formal ISA (Integrated Safety Assessment), which would form the basis for a licensee's safety program. This requirement would apply to all licensed facilities (except reactors and the gaseous diffusion plants) or activities, subject to NRC regulation, that are authorized to possess SNM in quantities sufficient to constitute a potential for nuclear criticality;
2) Establishment of limits to identify the adverse consequences that licensees must protect against;
3) Inclusion of the safety bases in the license application (i.e., the identification of the potential accidents, the items relied on for safety to prevent or mitigate these accidents, and the measures needed to the continuous availability and reliability of these items). (This is in contrast to the [NEI's] petition's where the ISA results would not be included in the license application.);
4) Ability of licensees, based on the results of an ISA, to make certain changes without NRC prior approval; and
5) Consideration by the Commission, after initial conduct and implementation of the ISA by the licensees, of a qualitative backfitting mechanism to enhance regulatory stability. [NRC SECY-98-185].

4.0 External Regulation of DOE Facilities: DOE/NRC Pilot Plant Interactions

4.1 Introduction

As part of its defense and non-defense missions, the DOE owns and operates approximately 3500 nuclear facilities, involving approximately 34 individual sites across 13 states. These facilities include nuclear research and production reactors, nuclear weapons assembly and disassembly facilities, chemical processing facilities, nuclear material storage vaults, reactor fuel fabrication facilities, tritium recovery facilities, particle accelerators, and research laboratories. A key part of this project is to understand how the DOE currently regulates its facilities and what might be required if the DOE facilities were externally regulated. Results from recent DOE/NRC pilot plant efforts are useful to assess what would be required if DOE facilities were externally regulated. This section summarizes results from this review.

4.2 Current DOE Facility Regulation

Historically, the DOE regulates the design, construction, and operation of its nuclear facilities with statutory authority under the Atomic Energy Act (AEA) to develop and impose requirements to protect the environment and the health and safety of personnel at its facilities. Unlike NRC's authority under the AEA, the DOE self-regulates all radiological, chemical, and physical hazards at its nuclear facilities. The DOE implements this self-regulation through a system of Orders it imposes on DOE contractors through contract provisions. Typically, the Orders are documents prepared by DOE with limited or no public involvement, other than comments received from DOE contractors. This system has gradually developed into an uncoordinated collection of approximately 270 Orders, covering a wide variety of areas, and differing in level of detail, format, and approach. Recently, the DOE has taken steps to reduce or consolidate the Orders. Stimulated by the Price-Anderson Amendments Act of 1988, the DOE has initiated a process to replace the Orders system by one utilizing rules that are promulgated under the public notice and comment requirements of the Administrative Procedures Act. These rules, which will address facility safety, worker health and safety, and environmental protection, will be codified in 10CFR800.

The DOE regulations typically were derived from existing regulations developed by NRC or other agencies. Traditionally, a DOE facility is regulated using selected criteria that exist at the time the facility is built. Because of financial constraints, the DOE typically doesn't make any effort to update facility standards recommended in more-recently-developed criteria.

The DOE's self-regulation is limited to oversight by the Defense Nuclear Facilities Safety Board (DNFSB). The DNFSB is an independent agency that exercises an advisory role with respect to the safety of DOE nuclear defense facilities. The five-member Board was established in 1988 by the Defense Authorization Act. To date, the DNFSB has issued more than 100 formal recommendations to the Secretary. Although all of these recommendations have been accepted by the Secretary of Energy, the DNFSB has no enforcement mechanism and it has not established any new nuclear safety standards during its existence since 1986.

The DOE oversight programs typically contain three components: line management oversight, independent oversight, and enforcement. Line management oversight is provided by the DOE (e.g., Office of Energy Research, Office of Nuclear Energy, Science and Technology, etc.). Typically, this responsibility is assigned to a DOE field office, and DOE headquarters monitors the field office and the contractor's performance. The DOE's Office of Environment, Safety and Health provides independent oversight according to the requirements in DOE's contract with the operating organization for a facility and according to applicable rules (Orders). Formal DOE enforcement is applicable through the Price-Anderson Amendments Act (PAAA) and its implementing regulations. The PAAA of 1988 amended the Atomic Energy Act (AEA) to add Section 234A to provide for a system of civil penalties for contractors who have entered into an agreement of indemnification with the DOE.

Several other organizations have oversight responsibilities for selected DOE facilities. For example, some states have regulatory oversight responsibility for non-radiological air and water quality as well as solid/hazardous waste management activities. This oversight is typically invoked through legislatively mandated state permitting processes. The Environmental Protection Agency (EPA) provides regulations for radiological air quality and toxic substance control.[17]

4.3 Pilot Plant Interactions Exploring External DOE Facility Regulation

In 1995, the DOE created an Advisory Committee on External Regulation (Advisory Committee) to advise and make recommendations on whether and how new and existing DOE facilities and operations might be regulated to better ensure nuclear safety. The Advisory Committee recommended that essentially all aspects of safety at DOE nuclear facilities and sites should be externally regulated and that existing agencies, rather than a new one, should become responsible for such regulation [DOE Advisory Committee], [DOE 1995]. Specifically, the DOE's Advisory Committee recommended that either the NRC or a restructured DNFSB should regulate facility safety at DOE nuclear facilities. In [Hoyle], the NRC endorsed the recommendation that the Commission should have oversight of certain DOE facilities.

To support this effort, it was decided to conduct six DOE facility pilot projects to determine the feasibility of NRC regulatory oversight of DOE nuclear facilities and to support a decision on whether to seek legislation to authorize NRC regulation of DOE nuclear facilities [Hoyle]. The Pilot program tests regulatory concepts at several DOE facilities through simulated regulation by evaluating each pilot facility and its standards, requirements, procedures, practices, and activities against the standards that NRC believes would be appropriate for this type of facility. On November 21, 1997, the DOE Secretary Federico Peña and US NRC Chairman Shirley Jackson signed a DOE/NRC Memorandum of Understanding (MOU) that details the specific conditions and activities associated with the pilot program. The MOU identified eight objectives for the Pilot Program:

1. Determining the value added by NRC regulatory oversight;

---

[17] Note that in many cases, such as at INEEL, DOE implements and ensures compliance with EPA requirements without actual EPA involvement.

2. Testing various regulatory approaches (e.g., licensing, certification);
3. Determining the status of DOE pilot facilities with respect to meeting existing NRC requirements, or acceptable alternatives, and identifying any significant safety issues;
4. Determining the costs (to the DOE and NRC) of NRC regulation;
5. Evaluating alternative regulatory relations and determining DOE contract changes that might be necessary to provide for NRC oversight;
6. Identifying transition issues and solutions;
7. Identifying legislative and regulatory changes needed; and
8. Evaluating the appropriate process for stakeholder involvement, should the NRC be given broad external regulatory authority over DOE nuclear facilities.

The Lawrence Berkeley National Laboratory (LBNL) pilot program began in the fall of 1997 [NRC SECY-98-080]. On-site work for the LBNL pilot was completed on January 15, 1998, and the site report was issued in Spring 1998. No significant safety issues were observed at LBNL. The second pilot plant was the Radiochemical Engineering Development Center (REDC), at the Oak Ridge National Laboratory (ORNL). Fieldwork for this program was completed in June 1998. A draft report summarizing conclusions from this project indicate that the REDC is licensable without significant changes to the facilities or to their radiation safety programs. The third pilot was the Receiving Basin for Offsite Fuel (RBOF) at the Savannah River Site in South Carolina. Results from this project indicate that the DOE and its contractor, Westinghouse, were controlling risks to acceptable levels and that the facility, as it currently exists, is amenable to NRC regulation. The Pacific Northwest National Laboratory (PNNL) in Washington was selected as the fourth pilot plant. However, this pilot project, which was scheduled to start in the fall of 1998, was postponed in order to involve the participation of state agencies as well as the Occupational Safety and Health Administration [Weapons Complex Monitor, Feb. 1999]. The remaining two pilot plants were never announced (although NRC Chairman Jackson indicated that a non-power reactor and an Environmental Management facility were planned to address concerns that more complex facilities should be considered).

Although the Congress allocated $1 million to the NRC to continue the pilot plant interactions in FY99, this program was delayed indefinitely because of the DOE Secretary Richardson's decision to put external regulation plans and additional studies on hold [Inside NRC] and [Weapons Complex Monitor, Mar. 1999]. Senate Armed Services Committee Chair John Warner, R-VA, stated at a March 15, 1999 hearing on the DOE's FY2000 budget request that he endorsed Energy Secretary Richardson's decision. However, it is not clear if this decision is supported by the House of Representatives or if this decision will be reconsidered in future years.

4.4 Insights gained from Pilot Plant Interactions

A team consisting of DOE, NRC, facility/site operating contractors, and other regulatory bodies (e.g., state government) conducted the pilot plant studies. To compare how the current regulations for a facility/site compared with NRC requirements, the pilot plant studies considered employee training, facility/site organization, procedures, waste management and treatment, emergency preparedness, environmental and personnel monitoring, decommissioning plans, radioactive materials control, and current oversight procedures. Studies focussed on issues unique to the facility/site and issues applicable to all pilot plants. Issues were addressed through facility/site visits, independent review of facility information, and team discussions. A stakeholder requirements elicitation process was used to identify and address local issues and obtain information for a preferred stakeholder involvement model under potential NRC regulation.

Rather than trying to assess what was required to meet an applicable NRC regulation, the review team often assessed whether the current process was "comparable" or what additional measures were necessary to obtain a level of safety comparable with NRC requirements.

4.4.1 Key Criteria and Principles

The following examples provide insights into key criteria and principles that NRC considers necessary for safe facility operation and possible methods for demonstrating compliance [Predecisonal Draft Document]:

1. In order to avoid unnecessary costs associated with the label of "special nuclear materials," the ORNL REDC review proposed to simply apply the requirements noted in 10CFR Parts 70, 73, and 74 without any materials designation. 10CFR73 requirements for physical protection of nuclear material would be required for materials at fixed sites and during transportation.

2. NRC expects employee training to be commensurate with instructions outlined in 10 CFR 19.12 so that employees can conduct activities in a safe manner consistent with ALARA principals.

3. Criteria must be comparable to 10 CFR 20 personnel radiation requirements (dose limits, personnel monitoring, and posting). It was noted in the REDC review that some analytical techniques, such as use of dose weighting factors for different body regions, differ and would require NRC review and approval.

4. 10CFR20 requirements for waste characterization, treatment, and disposal must be met.

5. Environmental monitoring programs must meet NRC program requirements to assure that no individual in the public receives a dose in excess of 10 CFR 20 dose limits.

6. Safety systems must consider principles such as defense-in-depth and adequate margin of safety. These principles were explicitly noted in the ORNL REDC review of criticality safety.

7. 10CFR30 decommissioning requirements would be applicable to DOE facilities. Specifically, financial assurance for decommission must be provided, which requires a decommissioning funding plan, a cost estimate, and a description of the method for assuring funds for decommissioning. In addition, 10CFR 30.35 requires that records important for decommissioning be maintained. Such records include records of spills, as-built drawings

and modifications of structures and equipment where radioactive materials are used or stored, and locations of possible inaccessible contamination.

4.4.2 Recurring Issues

Several key issues surfaced during the pilot plant interactions. Although the INEEL/MIT program will not attempt to address these issues, they are summarized in this document to provide perspective.

Who should be the regulator?

The DOE Advisory Committee considered this issue with support from the White House Council on Environmental Quality. Their evaluation considered a range of stakeholders (public, federal, state, tribal, industrial, union and academic sectors). The Advisory Committee held eight 2-day public meetings at major DOE sites around the country. In their final report, they recommended that DOE nuclear safety should be externally regulated, and that the external regulator should be either NRC or DNFSB. After a DOE working group reviewed the Advisory Committee report, the DOE accepted the Advisory Committee's recommendations and initiated a process for phasing in NRC regulation within a 10 year period (and phasing out DNFSB). In March 1997, NRC issued a Staff Requirements Memorandum favoring NRC oversight.

Advantages of NRC regulation include:

1. Uniformity in requirements and regulatory programs across the DOE complex.; and
2. Most public comments favored NRC oversight.

Disadvantages of NRC oversight include:

1. Most of the local community (including facility employees) did not favor NRC oversight;
2. Conflict of Interest issues may arise because the NRC uses the DOE laboratory personnel and facilities (hot cells, reactors, etc.) to carry out its research. However, this is likely to become less important as the NRC research program shrinks.

Who should be the licensee?

The DOE owns the facilities, materials, and land on which facilities reside. Typically, the DOE contracts the management and operation of its facilities to organizations, which may be replaced when the DOE contract expires or it is terminated. The contracting organization is responsible for many "typical" licensee decisions, such as when to shutdown a facility for repairs, when to start up a plant, and spending level estimates. However, the DOE must provide the licensee funding required to operate and maintain the facility within regulatory requirements.

Typically, NRC licenses the entity that owns the facilities and materials and holds licensees responsible for all licensed activities, even if some activities are carried out by contractors. However, on-going changes associated with deregulation led NRC to develop criteria for licensing non-owner operators for 10CFR50 licenses for power reactors.

In the ORNL REDC pilot plant interactions, various stakeholders were asked to consider various licensee options: DOE-only license, dual license between the DOE and its operating contractor and contractor-only license. Most stakeholders (NRC, DOE, contractor, and state representatives) preferred the contractor-only license. Reasons cited for this preference include

1. The contractor, who is involved in the daily operations of a DOE facility is best suited to implement nuclear safety standards;
2. A DOE-only license and a dual license would result in duplication of staff (the DOE and the contractor would retain staffs with technical and nuclear safety expertise so that the DOE could find and report potential violations and discrepancies before the NRC found them);
3. A dual (the DOE and contractor) license would complicate compliance and accountability issues.

However, several issues require resolution before contractors could become licensees [Lockheed Martin]:

1. The DOE must be able to define a process for determining that future contractors are qualified to maintain an NRC license;
2. A process for transferring a license to another contractor must be defined. ;
3. The DOE must modify existing maintenance and operation contracts if a facility or site becomes externally regulated by NRC;
4. The DOE must provide firm funding arrangements and commitments to ensure that contractors are guaranteed adequate funding to meeting costs associated with the licensing process, license fees, and compliance obligations;
5. Indemnification of DOE contractors under the PAAA must be continued (or the potential for unlimited liability will deter responsible private companies from competing to construct or operate DOE nuclear facilities); and
6. DOE contractors must not be held financially responsible for decommissioning and decontamination of facilities that they operate on behalf of the DOE.

5.0 Lessons Learned and Future Research Directions

Our review of DOE and NRC regulation has identified several important issues that will assist us in applying PBR to DOE facilities. In the case of the NRC, the principles of requiring DID and maintaining SM have been the basis for the treatment of uncertainties by the current regulatory system. This conservative approach has ensured public health and safety, but it (and the NRC's operational practices) also has caused undue regulatory burdens. A major pitfall in the current framework is that qualitative evaluation of risk does not permit an effective allocation of resources because, prior to PRAs, uncertainties were not quantified. Traditional engineering analysis integrated with PRA, however, has revealed a potentially successful means of addressing and quantifying uncertainties, although many issues of practical implementation remain.

In moving to a RIPBR regulatory structure, two conflicting conceptual concerns have been raised:

- Requirements for DID could be undermined by the introduction of risk-informed regulation; and
- The benefits of the risk-informed regulation could become restricted by the DID philosophy.

The critical question is how to make use of the information available from PRA studies without undermining the DID and SM concepts.

To address this question, two models have been proposed: the "structuralist" and "rationalist". The structuralist model, which has been the historical approach to nuclear regulation, asserts that "defense in depth is embodied in the structure of the regulations and in the design of the facilities built to comply with those regulations" [Sorenson, *et al*]. No matter what the probability is that containment or emergency planning will be required, both have to be provided. DID is primary and PRA is one of the tools employed to assure that DID has been achieved.

The rationalist model establishes quantitative acceptance criteria, such as health objectives, CDF, and LERF as its first step. The second step is to evaluate the uncertainties in the analysis and determine which steps should be taken to compensate for these uncertainties. The role of DID in this model is to "increase the degree of confidence in the PRA results" [Sorenson, *et al*] in supporting the conclusion that adequate safety has been achieved. The fundamental difference between the structuralist and the rationalist models, therefore, is that the structural model accepts defense in depth as the fundamental value, whereas the rationalist model would place DID in a subsidiary role.

The question is how to find a solution to these apparently conflicting ways of looking at the problem of safety. These two models are not generally in conflict, and neither of them provides a perfect answer to this problem. Recently [Sorensen, *et al*], proposed two options. The first option recommends DID as a supplement to risk analysis, which is very similar to the rationalist model. The second option is to combine a high-level structuralist view with a low-level rationalist view. This second approach is more compatible with the current regulatory structure, although the first option would offer a stronger theoretical foundation for risk-informed regulation [Sorenson, *et al*].

In the combined approach, quantitative goals would be set at a low level or the "Cornerstone Level". This could include goals on initiating event frequencies, safety function or safety systems unavailability [Sorenson, *et al*]. The rationalist approach is concerned with lower levels than the cornerstones as illustrated in Figure 6. Notice that uncertainties increase moving from the left-hand side of this figure to the right-hand side. DID in this approach plays a role in two ways. For events or processes modeled by the PRA, it would be part of the treatment of uncertainties to assure quality of the analysis. In practice in this first role, DID will become part of the overall safety analysis. For systems or events not modeled in the PRA, the structuralist approach would be used to maintain the traditional DID concept. This high-level structuralist and low-level rationalist model can be considered as a pragmatic way of integrating DID and risk-informed approaches.

On a more practical note, although many initiatives have been taken to apply PBR and RI regulation to commercial power reactors, numerous important issues of practical implementation remain. The level of effort, data, and regulatory change that is necessary to move towards PBR and RI regulation is significant. It has only been very recent that proposed PB measures for commercial nuclear power plants have been proposed. Further work in evaluating these measures is necessary including accumulation of data. Incorporating human judgement formally into risk models is another major area that needs additional work. Moreover, the DOE facilities are substantially different from commercial power reactors. Even within certain types of DOE facilities, the range of differences is tremendous. For example, DOE waste storage facilities encompass a very wide set of conditions.

The DOE pilot plant interactions have provided several key insights about DOE facility regulation. Results from that effort suggest that our performance-based regulatory framework should encompass a broad range of issues (waste management and treatment, emergency preparedness, environmental and personnel monitoring, radioactive materials control, etc.). In addition, key NRC regulations (10CFR Parts 19, 20, 30, 70, 73, 74) and principles (ALARA, DID, and SM) referenced in the pilot plant interactions will be considered in our project. Finally, our program should select facilities that will eliminate one criticism of the pilot plant interactions. Specifically, the INEEL/MIT program should consider a nuclear reactor and an environmental management facility to ensure that more complex issues will be addressed.

When considering the merit of a new PBR framework, we must consider the cost of transition to and implementation of the new framework as well. The benefits of the new framework would have to outweigh these costs in order to be lucrative for the regulated entity (the DOE).

In formulating our PBR framework for well-characterized complex DOE facilities (e.g., the ATR or ISFSI), we can draw from the substantial progress in PBR studies for commercial nuclear power plants and long-term HLW/SNF repositories. There is less guidance available for PBR of less complex, lower potential hazard facilities, for which risk assessments may exist in a less formal format. In addition, it will be challenging to formulate a PBR framework for those

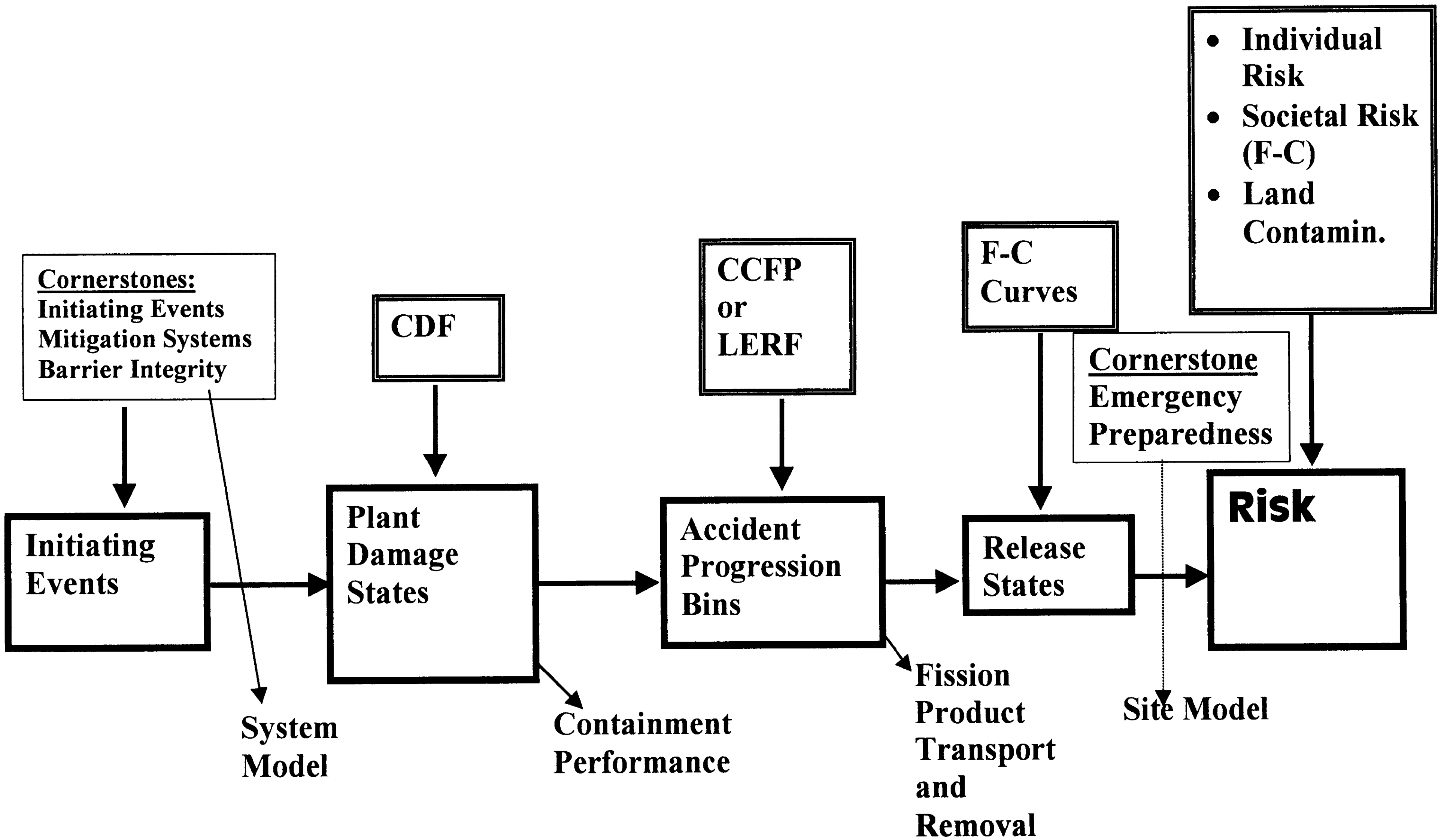

Figure 6: Possible Implementation of the Structural Model at a High Level for Reactors

inherited DOE facilities which keep/kept few operational records, and may contain poorly characterized materials (e.g., the Hanford HLW tanks).

6.0 References

[10 CFR 20] United State Code of Federal Regulations, 10 CFR Part 20, Standards for Protection against Radiation (January 1998). www.access.gpo.gov/nara/cfr.

[10 CFR 50] Code of Federal Regulation volume 10: Energy, part 50: Nuclear reactors, 1998.

[10 CFR 60] United State Code of Federal Regulations, Disposal of high-level radioactive wastes in geologic repositories (January 1998). www.access.gpo.gov/nara/cfr.

[10 CFR 63 proposed] United State Code of Federal Regulations, Disposal of high-level radioactive wastes in Yucca Mountain (January 1998). www.access.gpo.gov/nara/cfr.

[10 CFR 70] United State Code of Federal Regulations, Domestic Licensing of Special Nuclear Materials, (January 1998). www.access.gpo.gov/nara/cfr.

[10 CFR 72] United State Code of Federal Regulations, Licensing requirements for the independent storage of spent nuclear fuel and high-level radioactive waste (January 1998). www.access.gpo.gov/nara/cfr.

[40 CFR 191] United State Code of Federal Regulations, Environmental radiation protection standards for management and disposal of spent nuclear fuel, high-level and transuranic radioactive wastes (July 1998). www.access.gpo.gov/nara/cfr.

[40 CFR 192] United State Code of Federal Regulations, Health and environmental protection standards for uranium and thorium mill tailings (July 1998). www.access.gpo.gov/nara/cfr.

[40 CFR 194] United State Code of Federal Regulations, Criteria for the certification and re-certification of the Waste Isolation Pilot Plant's compliance with the 40 CFR Part 191 disposal regulations (July 1998). www.access.gpo.gov/nara/cfr.

[40 CFR 197 proposed] United State Code of Federal Regulations, Environmental radiation protection standards for management and disposal of spent nuclear fuel, high-level and radioactive wastes at Yucca Mountain (July 1998). www.access.gpo.gov/nara/cfr.

[ACRS Letter 1998] *Impact of Probabilistic Risk Assessment: Results and Insights of the Regulatory System*, Letter to the Chair of the NRC, the Honorable Shirley Ann Jackson, from the ACRS, R. L. Seale, September 30, 1998.

[ACRS Letter 1997] *Treatment of Uncertainties Versus Point Values in the PRA-Related Decisionmaking Process*, Letter to the Chair of the NRC, the Honorable Shirley Ann Jackson, from the ACRS, R. L. Seale, December 16, 1997.

[ACRS, May 1987] ACRS Comments on an Implementation Plan for the Safety Goal Policy (May 1987).

[Baranowsky] P. W. Baranowsky, *Evaluation of Station Blackout Accidents at Nuclear Power Plants: Technical Findings Related to Unresolved Safety Issues A-44, Draft Report for Comment*, USNRC Report NUREG-1032 (1985).

[Brattle and Campbell] R. E. Brattle and D. J. Campbell, *Reliability of Emergency a-c Power Systems at Nuclear Power Plants,* USNRC Report NUREG/CR-2989 (1983).

[Clinton Power Station SALP, 1995]

[Cunningham] M. Cunningham, PRA Research Program Supporting Risk-Based Regulation, Presentation to USNRC's Nuclear Safety Research Review Committee (19 May 1995).

[DOE 1995] U.S. Department of Energy, "Report of Department of Energy Working Group on External Regulation," December 1995, DOE/US-0001.

[DOE Advisory Committee] Advisory Committee on External Regulation of DOE Nuclear Safety, "Improving Regulation of Safety at DOE Nuclear Facilities," December 1995.

[ERI/SKI 99-401] Sewell, R. T. and M. Khatib-Rahbar, Energy Research, Inc., and H. Erikson, Swedish Nuclear Power Inspectorate (SKI), *Implementation of a Risk-Based Performance Monitoring System for Nuclear Power Plants: Phase II – Type-D Indicators*, February 1999, ERI/SKI 99-401.

[FR, 1986] Federal Register, Vol.51, No.162, August 21,1986, (p.30028).

[Golay, 1988] M.W.Golay, V.P.Manno, C.Vlahoplus,Jr.: "Nonprescriptive Nuclear Safety Regulation: The example of Loss of Offsite Power", *Nuclear Safety,* vol 29 No.1, January-March 1988.

[Golay, *et al*] M.W. Golay, J. D. Dulik, F.A. Felder, and S.M. Utton, *Project on Integrated Models, Data Bases and Practices for Risk-Informed, Performance-Based Regulation of Nuclear Power Plants: Final Report*, MIT-ANP-TR-060, December 1998.

[Hoyle] John C. Hoyle, Secretary "Staff Requirements - COMSECY-96-053 - Oversight Of The Department Of Energy (DSI 2)," Memorandum to L. Callan, K. Cyr and R. Scroggins, March 28, 1997.

[Inside NRC] "DOE Hedges on Giving NRC Regulatory Authority over DOE Complex," *Inside NRC*, Vol. 20, No. 11, May 25, 1998.

[Jackson] Shirley A. Jackson, Chairman, U.S. Nuclear Regulatory Commission, "The NRC and the DOE: An Evolving Regulatory Relationship," 10th Annual Weapons Complex Decision-Maker's Forum, October 13, 1998.

[Lockheed Martin] Lockheed Martin Energy Research Corporation, "Position Paper on External Regulation of Department of Energy Nuclear and Radiological Facilities," June 1998.

[NEI 1998] A New Regulatory Oversight Process: Towards Risk-Informed Performance-Based Assessment, Inspection and Enforcement, NEI, September 10, 1998.

[NEI Dec. 14, 1998] *Industry Comments on Proposed Rulemaking to 10 CFR 50.65, Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants*, letter to the Secretary of the NRC, December 14, 1998.

[NRC NUREG/CR-6407] *Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety* NRC Report Number: NUREG/CR-6407, INEL-95/0551

[NRC NUREG/CR-5392] *Elements of an Approach to Performance-Based Regulatory Oversight*, January 1999.

[NRC RG 1.174] NRC, "Regulatory Guide 1.174: "An Approach for Using Probabilistic Risk Assessment In Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis", July 1998.

[NRC RG 1.177] USNRC, *Regulatory Guide 1.177 (Draft Guide DG-1065) An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications (Predecisional)*, Draft, (Mar. 2, 1998)

[NRC SECY-99-007] "Recommendations for Reactor Oversight Process Improvements," January 8, 1999.

[NRC SECY-98-080] "Status Report of the Nuclear Regulatory Commission Task Force on Oversight of the U. S. Department of Energy, in Response to COMSECY-96-053-DSI 2 (REPORT NO. 3)," SECY-98-080, April 14, 1998.

[NRC SECY-98-185] "Proposed Rulemaking - Revised Requirements For The Domestic Licensing of Special Nuclear Material," July 30, 1998.

[NRC SECY-98-138] "Risk-informed, Performance-based and Risk-informed, Less-prescriptive Regulation in the Office of Nuclear Material Safety and Safeguards," June 11, 1998.

[NRC SECY-98-139] "Trial Use of Application-Specific Regulatory Guide and Standard Review Plan for Risk-Informed Inservice Inspection of Piping," June 11, 1998.

[NRC SECY-97-137] "Proposed Resolution to Petition for Rulemaking Filed by the Nuclear Energy Institute," June 30, 1997.

[NRC SECY-93-0298] USNRC, *Elimination of Requirements Marginal to Safety*, SECY-93-0298, USNRC (Feb. 1993).

[NRC Dec. 1994] USNRC, *Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities*, USNRC Proposed Policy Statement, Fed. Register (Dec. 1994).

[NRC Nov. 1992] USNRC, *Program for Elimination of Requirements Marginal to Safety*, Proposed USNRC Rule, Fed. Register 57(227):55157-55161 (Nov. 1992)

[NRC Aug. 1986] USNRC, Safety Goals for the Operations of Nuclear Power Plants: Policy Statement, Fed. Register, 51(149) (Aug. 1986).

[NUREG/BR-0216] NRC, NUREG-BR0216, Radioactive Waste: Production, Storage, Disposal, July 1996.

[NUREG/CR-6372] Lawrence Livermore National Laboratory, Recommendations for Probabilistic Seismic Hazard Analysis: Guidance on Uncertainty and Use of Experts, Main Report, Report Number: NUREG/CR-6372; UCRL-ID-122160 Vol. 1.

[NRC White Paper] *White Paper on Risk-Informed and Performance-Based Regulation,* Nuclear Regulatory Commission Staff White Paper, June 22, 1998.

[Predecisonal Draft Document] ORNL, "REDC Pilot Project Report," *Predecisional Draft Document* http://x10capserv.ornl.gov/nrc_doe/pilot.html), July 1, 1998.

[Savage, 1995] Savage, David, ed., The Scientific and Regulatory Basis for the Geological Disposal of Radioactive Waste, New York: John Wiley & Sons, 1995.

[Seale 1997] R.L.Seale, "Treatment of Uncertainties versus point values in the PRA-Related Decision-making Process", ACRS, Letter to the NRC, Dec. 16th, 1997.

[Seale 1997a] R.L.Seale, "Impact of probabilistic risk assessment rersults and insights on the regulatory system", ACRS, Letter to the NRC, Dec. 16th, 1997.

[Serpan, 1997] C.Z.Serpan,Jr, Michael E.Mayfield, J.Muscara: "US Nuclear Regulatory Commission research fro primary system integrity regulations", *Nuclear Engineering and Design*, 171, 1-14, 1997.

[Sorenson, *et al*] J.N.Sorensen, G.E.Apostolakis et al: "*On the role of defense in depth in risk-informed regulation*", to be presented at PSA'99.

[WASH-1400] USNRC, *Reactor Safety Study: An Assessment of Accident Risk in U.S. Commercial Nuclear Power Plants*, USNRC, NUREG-75/014 (WASH-1400), 1975.

[Weapons Complex Monitor, Feb. 1999] Weapons Complex Monitor, February 22, 1999.

[Weapons Complex Montior, Mar. 1999] Weapons Complex Monitor, March 22, 1999.