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FROM: DUE: 05/24/02

EDO CONTROL: G20020282
DOC DT: 05/07/02
FINAL REPLY:

Ralph E. Beedle
Nuclear Energy Institute (NEI)

TO:

Chairman Meserve

FOR SIGNATURE OF : ** GRN ** CRC NO: 02-0341

Travers, EDO

DESC:

Risk-Informed, Performance-Based Regulatory Framework for Power Reactors (White Paper - NEI 02-02)

ROUTING:

Travers
Paperiello
Kane
Norry
Craig
Burns/Cyr
Thadani, RES

DATE: 05/13/02

ASSIGNED TO: NRR

CONTACT: Collins

SPECIAL INSTRUCTIONS OR REMARKS:

NRR to acknowledge receipt with Travers' signature.
(Due: 5/24/02)
Review and provide recommended approach to EDO.
RES to coordinate with NRR. (Due: 7/8/02)

Template: SECY-017

E-RIDS: SECY01

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Date Printed: May 10, 2002 11:07

PAPER NUMBER:	LTR-02-0341	**LOGGING DATE:**	05/10/2002
ACTION OFFICE:	EDO		

AUTHOR: Ralph Beedle

AFFILIATION: NEI

ADDRESSEE: Richard Meserve

SUBJECT: Forwards White Paper, NEI-02-02, A Risk-Informed, Performance-Based Regulatory Framework for Power Reactors....

ACTION: Appropriate

DISTRIBUTION: RF, Encls to: EDO

LETTER DATE: 05/07/2002

ACKNOWLEDGED No

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NEI

NUCLEAR ENERGY INSTITUTE

Ralph E. Beedle
SENIOR VICE PRESIDENT AND
CHIEF NUCLEAR OFFICER,
NUCLEAR GENERATION

May 7, 2002

The Honorable Richard A. Meserve
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Chairman Meserve:

The enclosed industry White Paper, NEI 02-02, *A Risk-Informed, Performance-Based Regulatory Framework for Power Reactors*, was produced with the objective of starting discussion on a new and improved regulatory framework that would be applicable to all types of power reactor technologies. The paper is intended to be a catalyst for discussion.

We have gained significant experience in designing, operating, and regulating power reactors over the past 40 years. The NRC's transition to a risk-informed, performance-based regulatory regime and the advent of new non-light-water reactor designs provide the opportunity for improving the current regulatory framework. This paper builds on the concepts and success of the new reactor oversight process and incorporates insights from 40 years of operating experience, risk analyses, and new technologies. Through such developments, we can continue the progression towards a safer, more efficient and effective regulatory environment.

This paper proposes a more holistic approach than Option 3, *Risk-Informing NRC Technical Requirements*. It introduces a risk-informed regulatory regime that is not focused on one type of reactor design and incorporates the significant advances made in risk-analyses and technologies since the existing regulations were introduced. This neutral technology proposal calls for the development and issuance of a completely new Part to Title 10 for power reactors.

Through public discussion and input, we believe a new and improved regulatory regime will emerge. As such, following the example of the successful development and implementation of the new reactor oversight process, we hope that this paper can become the basis for a public workshop and an Advanced Notice of Proposed Rulemaking (ANPR) on the issues described in the White Paper. Our intent is that through public input, the NRC will be able to construct a new regulatory framework that will take us well into the 21st Century.

1776 I STREET, NW SUITE 400 WASHINGTON, DC 20006-3708 PHONE 202.739.8088 FAX 202.785.1898

We look forward to discussing the paper with you and members of your staff. If you or your staff have any questions, please contact Steve Floyd (202-739-8078) or me.

Sincerely,

Ralph E. Beedle

Enclosure

c: The Honorable Greta Joy Dicus, Commissioner, NRC
The Honorable Nils J. Diaz, Commissioner, NRC
The Honorable Edward McGaffigan Jr., Commissioner, NRC
The Honorable Jeffrey S. Merrifield, Commissioner, NRC
Dr. William D. Travers, Executive Director for Operations, NRC

CHAIRMAN REC'D

02 MAY -7 PM 4:31

NEI 02-02

Nuclear Energy Institute

A Risk-Informed, Performance-Based Regulatory Framework For Power Reactors

May 2002

ACKNOWLEDGMENTS

This report has been prepared by the NEI New Plant Regulatory Framework Task Force, and the NEI Risk-Informed Regulatory Working Group

NOTICE

NEI 02-02

A RISK-INFORMED, PERFORMANCE-BASED REGULATORY FRAMEWORK FOR POWER REACTORS

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A RISK-INFORMED, PERFORMANCE-BASED REGULATORY FRAMEWORK FOR POWER REACTORS

EXECUTIVE SUMMARY

In May 2001, a new vision for the nuclear industry, Vision 2020, was presented to the industry and the public. The vision supports an energy policy that would add 50,000 megawatts of nuclear generation by 2020.

In response to industry feedback on Vision 2020, NEI formed the *New Plant Regulatory Framework Task Force*. This task force was charged with developing a new and optional risk-informed, performance-based regulatory framework for commercial nuclear power reactors, focusing mainly on technical and operational requirements.

This white paper describes the new regulatory framework. It includes principles, baseline criteria, a complete set of proposed regulations, and the foundations for the new framework.

The development of a new framework is an essential step in achieving the 50,000 MW capacity goal of Vision 2020. Such action is required to maintain the nuclear generating capacity at the same percentage it is today—generating 20 percent of the nation's electricity supply. This is a fundamental tenet in achieving a national energy strategy that is based on secure, independent and diverse energy supplies.

This white paper includes a complete set of regulations for a new Part to Title 10 of the Code of Federal Regulations (CFR), Part 53. This new part is intended to be an alternative to 10 CFR Part 50 for commercial nuclear power reactors, and, as such would be optional. Proposed rule language is included as Appendix A to this white paper. Subsequent steps beyond this white paper will include the public rulemaking processes for the issuance of the new Part 53, the development of new or revised detailed regulatory guidance, the development of new or revised NRC standard review plans, and development of generic industry implementation guidance, as needed.

The intent is to provide the same standards of protection for the public and environment as current regulations, while providing for a more cost effective, efficient and safety-focused means of licensing and regulating commercial nuclear power reactors.

The framework balances an increased focus on those matters that have safety significance with increased licensee regulatory flexibility. Prescriptive and deterministic requirements are replaced by risk-informed, performance-based criteria. These criteria provide reasonable assurance that the safety significant functions will be satisfied, and that the assumptions and insights from the risk assessments are maintained, thereby providing adequate protection of public health and safety.

The approach blends the latest risk-informed technology and insights with operating experience, historic regulatory requirements, and new technical information to produce the new risk-informed, performance-based regulations.

These new regulations will be available for use by all prospective licensees and reactor system designers, regardless of reactor design. The new part would be applicable to all types of reactor designs: light-water reactors, gas reactors, liquid metal, etc. As a result, the regulatory requirements are prescribed at a higher level with specific implementation criteria and guidance being provided in regulatory guides and standard review plans.

It is not the intent to preclude other power reactor entities from using the new Part 53, although this proposed new part to Title 10 is focused predominantly on new plants. The new Part 53 is organized so that a Part 50 license holder could adopt the risk-informed, Part 53 operational programs in place of the counterpart programs in Part 50, via a license amendment.

The alternative Part 53 will provide potential licensees and nuclear reactor suppliers with an option of using the Part 50-52 process or a Part 53-52 process for the approval and issuance of new designs and power reactor licenses. The proposed framework is structured and written to allow an applicant for a combined construction and operating license (COL) to combine a Part 50/52 certified design with Part 53 operational requirements in the Part 52 combined construction and operating license process. In addition, the framework does not preclude the use of a design that is approved under Part 50 from being combined with Part 53 operational requirements in a license application.

The framework's foundation is based on the Reactor Oversight Process (ROP) cornerstones. It uses an integrated, risk-informed decisionmaking process for determining the safety-significance of equipment. The framework establishes performance criteria tied to public health and safety objectives as opposed to prescriptive implementation criteria, as the vehicle to assess licensee regulatory effectiveness.

The decision to develop a completely new part rather than just amend or develop alternative Part 50 requirements is based on reducing regulatory complexity and reducing the potential for misinterpretation. Increased complexity results in a higher resource burden in implementation and increased probability of misinterpretation. In such a complex regime the safety focus becomes diffuse as resources that could be better employed on safety-significant matters are expended in addressing interpretation issues coming from an unnecessarily complex regulatory process. An example of the benefit of moving to a full risk-informed, performance-based regulatory regime is reflected in the new NRC reactor oversight process.

The new regulatory framework is performance-based. In addition, it is intended to apply in a logical and consistent manner to all types of reactors. As a result, the new Part is not as prescriptive as Part 50. For example, the majority of the technical requirements for Part 53 are enveloped in the language and criteria of the proposed §53.20 *Initiating Events and Prevention*, §53.21, *Mitigation*, §53.22, *Functional Barriers to Radionuclide*

Release, and §53.30, *Operational Requirements*. These four regulations are spelled out in eight pages and envelope the majority of requirements listed in: §50.36, *Technical Specifications*, §50.44, *Standards for combustible gas control system in light-water-cooled power reactors,* §50.46, *Emergency Core Cooling Systems*, §50.48, *Fire Protection*, §50.49, *Environmental Qualification of Electric Equipment Important to Safety for Nuclear Power Plants*, §50.62 *Requirements for Reduction of Risk from Anticipated Transients Without Scram (ATWS) Events for Light-Water-Cooled Nuclear Power Plants*, §50.63, *Loss of All Alternating Current Power, §50.65, Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants*, and the associated Appendices A, J, K, R and S to 10 CFR 50, consisting of approximately 90 pages.

The proposed framework includes requirements for a graded approach to emergency planning and preparedness based on the risk to the public. In some cases a simple hazards plan for communicating with local authorities and agencies may be all that is required. In addition, the reporting and notification requirements would be based on insights from risk-informed evaluations.

The new part places significant emphasis on probabilistic risk-informed concepts, approaches and evaluations. As such, any prospective licensee or reactor system supplier would be required to develop and maintain a high quality, full scope risk-assessment, encompassing internal, external and low power/shutdown events. Equipment is categorized as being either safety-significant or industrial through a risk-informed, decision-making process that incorporates the use of expert panel solicitation. This type of equipment categorization process has been proven in the implementation of specific risk-informed improvements to Part 50.

The second major step is the development of a set of supporting regulatory guides. These guides would be risk-informed and would directly support the new rule. The new guides may be developed by the NRC, or be industry standards or guidance documents that are adopted by the NRC as regulatory guides. A list of the new guides is under development and possible sources of expertise to develop them are being explored. Standard Review Plans (SRP) provides guidance to NRC reviewers and applicants on the information required in an application for a license. The source of these new plans is undetermined but is ultimately the responsibility of the NRC.

In developing this white paper a number of general and policy issues were identified. These include such issues as:

- The need to replace the traditional full level "Appendix B" quality assurance program with a more focused performance-based approach;
- The inclusion of probability numbers and criteria in the regulations;
- The degree of selective implementation that should be allowed;
- Duration of a commercial power reactor operating license; and
- How to treat defense-in-depth in a risk-informed, performance-based regime.

A complete list of the issues identified is provided in Appendix C.

Following the issuance of this white paper, it is envisioned that the NRC would give serious consideration to publishing an Advanced Notice of Public Rulemaking that would request feedback on the concepts, baseline criteria, principles and issues that are raised by the white paper. The issuance of such a notice would provide the starting point for a full and open discussion on the need and content of a completely new set of risk-informed, performance-based requirements for commercial nuclear power reactors.

In the last ten years, the NRC has been moving incrementally towards an improved, risk-informed performance-based regulatory regime. Policy statements and new or amended rules have been introduced as part of a long-term plan to improve Part 50. The NRC has already addressed use of PRA in licensing actions with the NRC Policy Statement and implementation guidance such as Regulatory Guide 1.174. The proposed framework takes advantage of the existing initiatives and the industry/NRC experience with the ROP. The use of this combination of existing, proven concepts and innovative approaches to regulatory requirements should result in timely approval of a much more logical and cost effective framework for licensing.

A RISK-INFORMED, PERFORMANCE-BASED REGULATORY FRAMEWORK FOR POWER REACTORS

INTRODUCTION

Purpose

The purpose of this white paper is to describe the industry view of what a risk-informed, performance-based regulatory process should be for future generations of commercial nuclear power reactors, in terms of both design and operational requirements. It describes the way the new regulations should fit into the overall regulatory process, including the role of regulatory guides, the standard review plan, and regulatory oversight. It is intended to provide the industry's input into the development of a NRC Advanced Notice of Proposed Rulemaking that would seek formal feedback from stakeholders on a series of issues associated with the development of risk-informed, performance-based, technology neutral regulations for new commercial nuclear power reactors.

The white paper directly supports one of the performance objectives of the NRC strategic plan: making NRC activities and decisions more effective, efficient, and realistic. The intent is to enhance the efficiency and effectiveness of the regulatory process for commercial nuclear power plants while enhancing safety. The proposed framework provides for increased regulatory flexibility to allow and encourage the inclusion of new technical information and operating experience into the regulations. As a result, resources can be better focused on those matters that have safety significance.

Background

The 1954 Atomic Energy Act (AEA) is the foundation of the US Nuclear Regulatory Commission's regulations for commercial nuclear power plants. The Nuclear Regulatory Commission (NRC) has established its regulatory requirements for commercial nuclear power plants to ensure that "no undue risk to public health and safety" results from licensed uses of the nuclear power plants. The existing regulatory requirements were developed using prototype testing experience and programs, expert judgment, deterministic engineering analyses, and commercial nuclear power plant operating experience. The process considered factors such as engineering margin and the principle of defense-in-depth.

The objective of NRC regulations is to provide reasonable assurance of protection of public health and safety. In developing most of the regulations, accident probabilities were not quantified. The NRC did not evaluate accident or event probabilities in a systematic way, even generically, until 1975, when the Reactor Safety Study (WASH-

1400) was published. Following the WASH 1400 study, several other NRC and independent studies, e.g., the Kemeny Commission and Rogovin reports on the accident at Three Mile Island, and the 1993 NRC Regulatory Review Group Report have recommended that safety could be enhanced if industry and NRC resources could be better focused solely on safety-significant matters. One way of improving licensee and regulatory focus is through a risk-informed approach that combines the insights of probabilistic risk assessments, operating experience and technical knowledge and design in determining safety significance.

In 1988, NRC requested all plant licensees to complete Individual Plant Examinations (IPEs) to verify plant safety and to identify accident vulnerabilities. Through this activity, industry and NRC personnel gained a better understanding of safety contributors and priorities. Based on these insights, many licensees voluntarily implemented modifications to plant equipment, procedures and practices.

1995 Policy Statement

In 1995, following the success of the IPE activity, the Commission formalized its commitment to risk-informed regulation through the issuance of a policy statement, *Probabilistic Risk Assessment Policy Statement* (60 FR 42622, August 16, 1995). Following the policy statement, the NRC initiated steps in 1998 to adopt a risk-informed, performance-based reactor oversight process (ROP) with the following objective: improve the oversight process through a better NRC oversight focus on safety-significant matters while providing licensees with a higher degree of regulatory flexibility. This new oversight regime focuses inspection resources based on the safety significance of plant events and conditions, and on licensee performance against a predetermined set of performance indicators. The successful industrywide implementation of this program, beginning in 2000, has demonstrated that the NRC can continue to fulfill its public health and safety mission using risk-informed, performance-based concepts. The program has improved the regulatory focus on those matters that could impact safety.

The result of implementing only a few risk-informed regulatory activities and numerous voluntary licensee initiated risk-informed improvements has been a dramatic improvement in safety and economic performance. Nuclear power plants have attained an unsurpassed level of safety performance while becoming the lowest cost baseline generating option in the U.S. Nuclear generators have increased electricity production by 20%, yet plant safety systems challenges have been reduced by a factor of three, and the number of safety significant events has been reduced by a factor of ten. The expansion of the risk-informed, performance-based concept to other regulations, where practical, presents an opportunity for achieving further improvements in safety performance while increasing the efficiency of the regulatory process.

SECTION A

DESCRIPTION AND RATIONALE

A.1 A Risk-Informed Performance-Based Regulatory Process

A risk-informed, performance-based regulatory regime provides for an increased focus on safety, while providing the licensee increased regulatory flexibility in meeting the regulations. This new regime has been slowly evolving since 1988 when the NRC issued its generic letter 88-20 on Individual Plant Examination (IPE) with the intent of developing: (1) a better appreciation of severe accident behavior, (2) a better understanding of the most likely severe accident sequences that could occur at its plant, (3) a more quantitative understanding of the overall probabilities of core damage and fission product releases, and (4) if necessary, the basis for modifying, where appropriate, hardware and procedures that would help prevent or mitigate severe accidents.

A risk-informed, performance-based regulatory process is one where the emphasis is on safety-significant equipment and activities; where prescriptiveness is replaced with performance monitoring and corrective action; where a requirement describes what is to be achieved, not how it is to be achieved; and where a licensee is afforded the flexibility in determining how a requirement will be implemented. Such an approach has, and if pursued, will continue to engender innovation that will result in further enhancements in safety performance.

Advances in technology and analytical techniques now enable complex PRA and accident evaluations to be performed from a desktop environment. Analyses that took days at the time of the Kemeny and Rogovin reports can now be accomplished in minutes. Improvements in performance-monitoring techniques and data analyses have improved the potential for the earlier identification of potential deficiencies. These improvements have reduced the cycle time for evaluating and correcting potential deficiencies before they present a challenge to a plant's safety systems. With development of improved technologies and analytical techniques, risk analyses can be performed in a time frame that enables risk-insights to be incorporated into the operational decisionmaking process. Licensees are better positioned to make better safety determinations as detailed risk analyses and performance assessments can be evaluated and action taken within a practical and cost-beneficial schedule.

New Framework Founded on Reactor Oversight Principles

The proposed alternative regulatory framework builds on the cornerstones of safety in the Reactor Oversight Process (ROP), thus ensuring regulatory consistency between the regulations, and the new oversight and enforcement processes. Linking requirements to the ROP framework provides a clear relationship between the requirements and the cornerstone objectives that were developed to ensure the NRC's public health and safety mission is fulfilled. The tie between the ROP and the regulations ensures that compliance and safety are directly linked.

The regulatory framework described in this white paper provides a generic process and a set of top-tier regulations that specify safety objectives, but permit flexibility in how the objectives are achieved. This is important as the next generation of commercial nuclear power reactors may include a variety of plant designs of varying nuclear technologies. As such, a prescriptive regulatory approach that is directly linked to one specific reactor technology is not an appropriate framework for future power reactors. Setting top tier safety performance objectives is a more efficient approach that avoids having to promulgate a different set of regulations tailored to each reactor technology design.

The risk-informed, performance-based proposals contained in this white paper, when implemented, support the attainment of the NRC's strategic goal of conducting an effective regulatory program that provides for the safe use of nuclear materials for civilian purposes in a manner that protects the public and the environment. The white paper directly supports a performance objective of the NRC Strategic Plan: making NRC activities and decisions more effective, efficient, and realistic.

In a risk-informed, performance-based framework, licensee implementation methods and programs are expected to go beyond the safety requirements prescribed in the regulations. The incentive for such action is associated with increased operational margin and investment protection.

Strategic Areas and Cornerstones

The proposed regulatory framework consists of four strategic areas: reactor safety, radiation safety, safeguards, and administrative. The most significant improvements are being made in the reactor safety and radiation safety areas. Each strategic area is divided into specific cornerstones as follows:

Reactor Safety

- Initiating Events
- Mitigation
- Functional Barriers to Radionuclide Release
- Emergency Preparedness

Radiation Safety

- Public Radiation Safety
- Occupational Radiation Safety

The radiation safety strategic area reflects a performance-based approach that provides for flexibility in implementation consistent with performance and skill of the craft. The proposals include an update of the public radiation safety requirements to achieve consistency with the current radiation safety concepts and standards.

Safeguards

- Physical Protection

At present there are no anticipated changes to the Safeguards strategic area beyond that being contemplated in response to the events of September 11, 2001.

Administrative

This white paper adds a fourth strategic area, administrative, covering the administrative regulations for areas, such as, licensing process, change control, NRC reports, financial and legal requirements.

The majority of regulations in this strategic area are similar to those included in Part 50. Changes are being made to the reporting requirements, content of the FSAR, quality assurance, and financial assurance for decommissioning.

Cornerstone Objectives

The framework establishes specific objectives for each of the cornerstones. Through the cornerstone concepts, the same degree of defense-in-depth for the adequate protection of public health is maintained for plants licensed under this new Part to 10 CFR compared with plants licensed under 10 CFR Part 50. For this new set of power reactor requirements, an initiating event would have to occur, followed by failures in mitigation, a failure in the functional barriers to radionuclide release, and a failure of the emergency plan before public health and safety would be endangered.

Initiating Events Objective is to limit the frequency of those events that upset plant stability and challenge critical safety functions, during shutdown as well as power operations. When such an event occurs in conjunction with equipment and human failures, a reactor accident may occur. Licensees can reduce the likelihood of a reactor accident by maintaining a low frequency of these initiating events combined with improved design, more focused operator qualification programs, and rigorous configuration controls. Such events include reactor trips due to turbine trip, loss of feedwater, loss of offsite power, and other reactor transients.

Mitigation Objective is to ensure the design or the availability, reliability, and capability of systems that mitigate initiating events satisfy the design assumptions for the prevention of reactor accidents. Licensees reduce the likelihood of reactor accidents through design or by enhancing the availability and reliability of mitigating systems. Mitigation systems might include systems associated with safety injection, residual heat removal, and the associated support functions and systems, such as emergency electrical power capabilities. This cornerstone encompasses both operating and shutdown events.

Functional Barriers to Radionuclide Release Objective is to ensure that physical barriers protect the public from radionuclide releases caused by accidents. Licensees can reduce the effects of reactor accidents or events if they do occur by maintaining the functional requirements of the barriers. Functional barriers may include, fuel coating, fuel cladding, reactor system boundaries and, where needed, tertiary functional barriers to provide additional radionuclide confinement.

Emergency Preparedness Objective is to ensure that actions required by the emergency plan would provide adequate protection of the public health and safety during a radiological emergency. Drills and training provide reasonable assurance that the licensee can effectively protect the public health and safety in the event of a radiological emergency.

Public Radiation Safety Objective is to ensure adequate protection of public health and safety from exposure to radioactive material released into the public domain as a result of routine civilian power reactor operations. These releases include routine gaseous and liquid radioactive effluent discharges, the inadvertent release of solid contaminated materials, and the offsite transport and disposal of radioactive materials and wastes. Licensees can maintain public protection by meeting the applicable regulatory limits and the constraint on radiological effluents.

Occupational Radiation Safety Objective is to ensure adequate protection of worker health and safety from exposure to radiation from radioactive material during routine power reactor operations. Licensees can maintain occupational worker protection by meeting applicable regulatory limits and implement a program to keep worker doses as low as reasonably achievable.

Physical Protection Objective is to provide assurance that the physical protection systems and processes can protect against the design basis threat of radiological sabotage. The threat could come from either external or internal threats. Licensees can maintain adequate protection against threats of sabotage based on an effective design and security program that relies on a risk-informed, defense-in-depth approach for the physical protection of the power plant facility.

Administrative Objective is to provide guidance and assurance that the administrative and legal elements of the licensing and regulatory process for power reactors are consistent with the requirements of the Atomic Energy Act and the Administrative Procedures Act, are as efficient as possible, and provide appropriate and accurate information to all stakeholders.

A.2 The Need for a New Regulatory Framework

Today's reactor regulatory process for commercial power reactors is based largely on the same concepts and principles as it was 35 years ago: deterministic design-basis events. As operating experience has increased, new insights and information have been transformed into new prescriptive requirements. These new requirements have been layered on top of existing regulations without an overall comparison of the safety benefit against the resources required to implement the requirements. Each new requirement has an accompanying detailed and prescriptive regulatory guidance. The resource effort required to change these existing requirements and guidance documents asphyxiates innovation and hamstrings attempts to incorporate more efficient and effective requirements and implementation activities.

Improving Safety, Enhancing Regulatory Efficiency

The current regulations have provided for an adequate level of protection of public health and safety. Yet, operating experience and risk analyses insights have revealed that the process could be significantly enhanced by increasing regulatory focus and attention on some requirements, while other requirements could be significantly reduced or eliminated. The adoption of a complete risk-informed, performance-based approach would enhance the protection of public health and safety through increased licensee and NRC attention and focus on safety significant matters, while increasing regulatory efficiencies and reducing unnecessary regulatory burden.

In a competitive generating market, plant safety must continue to be of paramount importance. Nearly 30 years after PRAs were first used to evaluate reactor designs and operations, tools and processes are available that would allow the NRC to provide licensees additional flexibility in the manner in which they can implement the regulations, while at the same time improving the protection of public health and safety. Failure to take advantage of, and incorporate new, more efficient and improved technologies and processes into the regulatory process will stifle safety innovations and performance improvements rendering commercial nuclear generation uncompetitive.

Consistent Regulatory Process

In 2001, the NRC completed the transition to a risk-informed, performance-based ROP. Having successfully made this transition, similar changes are needed to the administrative, operational and technical regulations and the associated implementing guidance to assure and improve regulatory consistency, efficiency and predictability. Yet, progress in risk-informing other elements within the regulatory process is sporadic. The efforts to risk-inform power reactor regulations are being hindered by several factors:

- Current plants are already designed, built and are operating to existing regulations, and imposing a complete set of risk-informed changes to the extent described in these proposals may be difficult and costly,

- The regulations are interwoven in a fashion that makes targeted changes difficult, and
- Changing the regulatory regime to more risk-informed, performance-based regulatory regime after 30+ years of success presents significant cultural issues, which can be resolved only through an acceptance of the new paradigm by licensee and NRC personnel.

Neutral Reactor Technology Regulation

The existing regulatory process is based on "light water reactor" technologies. The advent of new non-light water reactor designs provides additional incentive and need for an improved and updated regulatory framework. The new framework needs to be flexible enough to encompass varying reactor designs and reactor technologies while incorporating insights from 30+ years of reactor operating experience, and take into account advances in analytical techniques and technologies.

A.3 Principles and Baseline Criteria

Principles

The principles of a risk-informed, performance-based regulatory framework are:

(1) Stakeholder input and recommendations shall be an integral part of the new regulatory framework development.
(2) The framework shall satisfy the NRC's mission of "adequate protection of public health and safety" and satisfy the current safety goals.
(3) The framework shall take advantage of the 30+ years of licensing and operating experience as well as risk-informed insights, building on risk-informed regulatory activities that have been implemented.
(4) The new framework shall focus on safety significant issues and eliminate requirements in current regulations that do not address nuclear safety
(5) Risk-informed analyses and decisionmaking shall be based on best-estimate data, model and assumptions.
(6) Design and operational requirements shall be influenced through performance-based monitoring and corrective action.
(7) The framework shall provide for defense-in-depth through requirements and processes that include design, construction, regulatory oversight and operational activities. Additional defense-in-depth shall be provided through the application of deterministic design and operational features for events that have a high degree of uncertainty with significant consequences to public health and safety.
(8) The new framework shall provide at least the same degree of protection of the public and the environment for new plants as for current plants.
(9) Additional requirements shall be imposed only when backfit criteria are satisfied.

(10) The framework shall be flexible enough to accommodate new reactor designs and existing levels of design certifications.
(11) The framework must result in a more efficient and effective regulatory review and approval of designs, license applications and regulatory oversight of plant operations consistent with the safety significance of the issue, improving regulatory consistency and predictability.

Baseline Criteria

These criteria are based on the safety concepts and philosophies described in the NRC Safety Goal Policy Statement with additional margin.

General Approach

(1) Replace the existing Part 50 regulations and associated appendices to make them performance-based, risk-informed requirements. The requirements become high-level generic requirements that can be applied to varying LWR and non-LWR activities and designs. Detailed implementation appendices from 10 CFR 50 become detailed implementation guidelines. Deterministic requirements are retained, where it is not possible to develop risk-informed, performance-based requirements.
(2) The proposed framework is modeled after the NRC's new Reactor Oversight Process (ROP). The oversight framework focuses industry and regulatory attention on equipment and activities that are the most important to the protection of public health and safety. The new set of requirements is consistent with the cornerstone objectives of the oversight process.
(3) Administrative requirements are included, divided into specific sections: Administrative, Programmatic, and Licensing.

Basic Requirements

(1) Each application for a license shall include a risk assessment, consisting of not less than a probabilistic risk assessment of internal events and bounding realistic safety assessments of shutdown and plant protected events[1].
(2) The design shall be evaluated to provide reasonable assurance that the mean frequency of a radionuclide release satisfies the objectives in the NRC safety goal policy statement.
(3) Each application for a license shall conduct a risk-informed SSC categorization to identify safety-significant SSCs.
(4) Risk and performance monitoring programs shall be implemented to provide reasonable assurance that the required functions will be satisfied and that functional capability assumptions of the risk assessment are met. Where

[1] An event is a set of occurrences of individual or combined component actuations, failures, errors, or natural phenomena occurrences, each of which results in the same plant system change of state.

performance monitoring is impractical, configuration controls and condition monitoring shall be established.

Specific Requirements

(I) *Initiating Events[2] and Prevention*

(a) In applying for a design approval, a design certification or a license application, the applicant shall identify the set of plant internal initiating events (PIEs) that have a mean frequency of occurrence greater 10^{-7}/yr.

These PIEs are divided into the following categories:

(1) Anticipated Operating Occurrences (AOOs) are internal initiating events that have a mean frequency of occurrence of 10^{-2}/yr or greater.
(2) Plant Design Bases Events (PDBEs) are internal initiating events (power and low power/shutdown) that have a mean frequency of occurrence between 10^{-2}/yr to 10^{-5}/yr.
(3) Emergency Preparedness Bases Events (EPBEs) are the internal initiating events that have a mean frequency of occurrence between 10^{-5}/yr to 10^{-7}/yr.

(b) A set of Plant Protected Design Events (PPEs) shall be identified that are the most severe natural phenomena events, such as earthquakes, fires, tornadoes, hurricanes, floods, tsunami, and seiches, that have been historically reported for the site and surrounding area plus other non-plant events, such as internal fires that could reasonably endanger the safe shutdown capability.

(c) Plant design and operational programs shall include features to limit event frequency and magnitude.

(d) Initiating event functions and preventative functions shall be monitored to provide reasonable assurance that functional capability assumptions of the risk assessment are met, where performance monitoring is practical. If performance monitoring is impractical, configuration controls and condition monitoring shall be established to provide reasonable assurance that functional capability assumptions of the risk assessment are met.

[2] *An initiating event* is any event that perturbs the steady state operation of the plant, if operating, or the steady state operation of the decay heat removal systems during shutdown operations such that a transient is initiated in the plant. Initiating events trigger sequences of events that challenge plant control and safety systems.

(II) *Mitigation*

(a) The design shall incorporate features and measures that assure the following criteria are satisfied:

(1) For light water reactors, equipment programs and processes shall be designed to mitigate AOOs, PDBEs and PPEs defined in Section (I), *Initiating Events and Prevention,* such that the total mean core damage frequency to include internal and external events does not exceed 10^{-4} /yr,

(2) For non light water reactors (gas, liquid metal, heavy water,...) [*will be determined through pilot licensing activities for these reactors]*

(b) For plant protected events, safety-significant structures, systems, and components shall be designed to withstand the effects of natural phenomena such as earthquakes, fires, tornadoes, hurricanes, floods, tsunami, and seiches without loss of capability to perform their safety functions. The plant protected event design bases shall reflect appropriate consideration of the most severe events for the listed natural phenomena that have been historically reported for the site and surrounding area, with sufficient margin for the limited accuracy, quantity, and period of time in which the historical data have been accumulated. In addition, appropriate consideration is given to other combinations of effects that are evaluated and identified through licensee safety assessments. Non-plant events (such as internal fires and physical insurgency) that could threaten the safe shutdown capability of the plant are evaluated as part of the evaluations of Plant Protected Design Events.

(c) Where practical, mitigation features shall be monitored to provide reasonable assurance that the functional capability, availability and reliability assumptions of the risk assessment are met. Where performance monitoring is impractical, configuration controls and condition monitoring shall be established to provide reasonable assurance that functional capability assumptions of the risk assessment are met.

(III) *Functional Barriers to Radionuclide Release*

The design shall incorporate sufficient functional barriers to a radionuclide release such that:

(a) A radionuclide release from each AOO shall not exceed the limits prescribed in §53.33.

(b) A radionuclide release from each PDBE or PPE shall not exceed the limits described in §53.35,

(c) The total mean frequency of a large radionuclide release[3] from all initiating events, defined in Section (I) above , shall be less than 10^{-5} /yr, and

[3] *Large release* – the release of volatile radionuclides into the environment that could result in a prompt fatality to a member of the general public.

(d) Where practical, mitigation features shall be monitored to provide reasonable assurance that the functional capability, availability and reliability assumptions of the risk assessment are met. Where performance monitoring is impractical, configuration controls and condition monitoring shall be established to provide reasonable assurance that functional capability assumptions of the risk assessment are met.

(IV) ***Emergency Preparedness***

(a) Each power reactor licensee shall establish an onsite emergency response capability. Local authorities shall be provided with an offsite hazards emergency summary. Arrangements shall be made for onsite response from state and local agencies, as determined by the licensee.

(b) Each licensee shall confirm that a graded offsite emergency response capability exists if any initiating event, defined in Section (I) above, results in a total effective dose in excess of 10 mSv (1 rem) total effective dose equivalent (TEDE) at the exclusion area boundary at a mean frequency of greater than 10^{-6}/yr. after considering available mitigation. The offsite response plan shall be consistent with the risk to public health and safety from the event.

Figure A-1 provides a pictorial representation of the reactor safety strategic area.

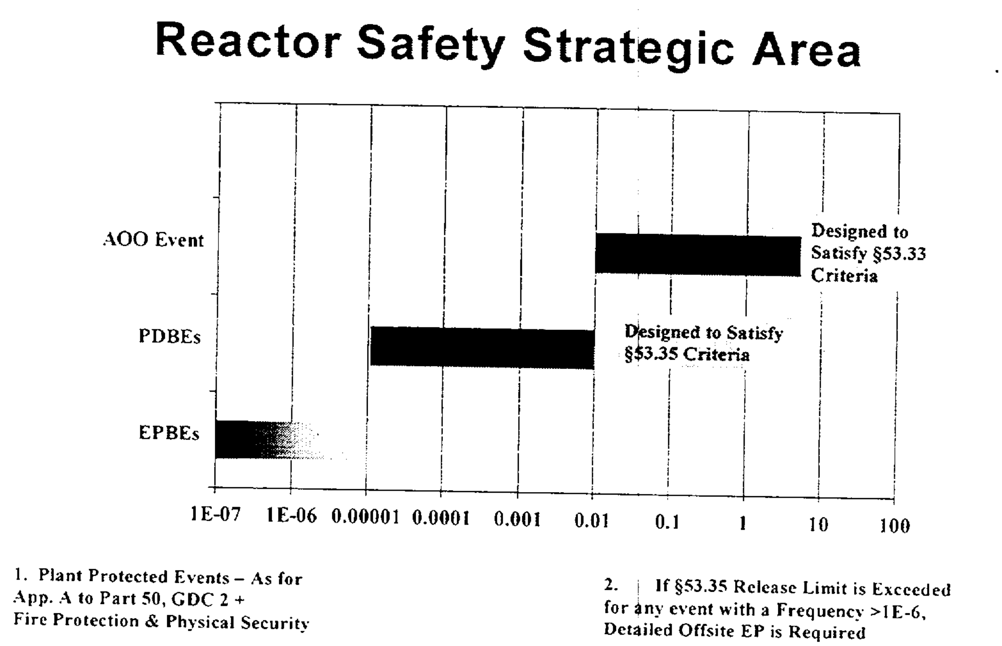

Figure A-1

(V) ***Radiation Safety***

The existing limits are applied in an experience- and performance-based manner.

(VI) ***Safeguards***

No change to criteria.

(VII) ***Defense-in-Depth***

Defense-in-depth is achieved through a combination of process, probabilistic insights, the application of deterministic design and operational features. It is based on the cornerstones established in the reactor oversight process that encompass processes that include the design, construction, regulatory oversight and operational activities. Additional defense-in-depth is provided by the application of deterministic design and operational features that compensate for events that have a high degree of uncertainty with significant consequences to public health and safety.

Figure A-2 depicts the application of defense-in-depth for Part 53. It is a series of iterative steps. The first step is to complete the initial design. The second step is to perform a risk assessment of the design that includes a probabilistic risk assessment (PRA). Having completed the PRA the design is modified, as necessary, to meet risk acceptance criteria defined in the regulations (§53.20. §53.21,and §53.22) and in internal industry and licensee guidelines. This comparison and modifications to the design would take into consideration cost-beneficial risk insights. These changes are, in turn, reflected in the PRA.

Next, the defense-in-depth opportunities are considered to compensate for unacceptable risk uncertainty. Any additional necessary defense-in-depth is achieved through a combination of probabilistic insights and the application of deterministic design features and operational processes. It is based on the cornerstones established in the reactor oversight process that encompass design, construction, regulatory oversight and operational activities.

There are four discrete defense-in-depth options. The strategy favors risk management or performance monitoring during operations or construction, where appropriate, in lieu of additional design features, which provide safety margin, redundancy, or diversity. As the uncertainty often cannot be quantified, the effectiveness of the defense-in-depth measure need not strictly be quantified, but it must be demonstrated to effectively reduce the unacceptable uncertainty in safety function performance.

Performance monitoring can include SSC operability, performance, or condition monitoring; human performance monitoring; or safety function availability and reliability. Other risk management activities can include equipment configuration management, risk-informed corrective action programs, program effectiveness assessments, and risk-informed maintenance.

Finally, the design specific PRA is amended to reflect all changes in design and operations resulting from the defense-in-depth evaluation. This iterative process is continued until the deterministic design and operational requirements are considered to be satisfactory. At which point the design can be finalized.

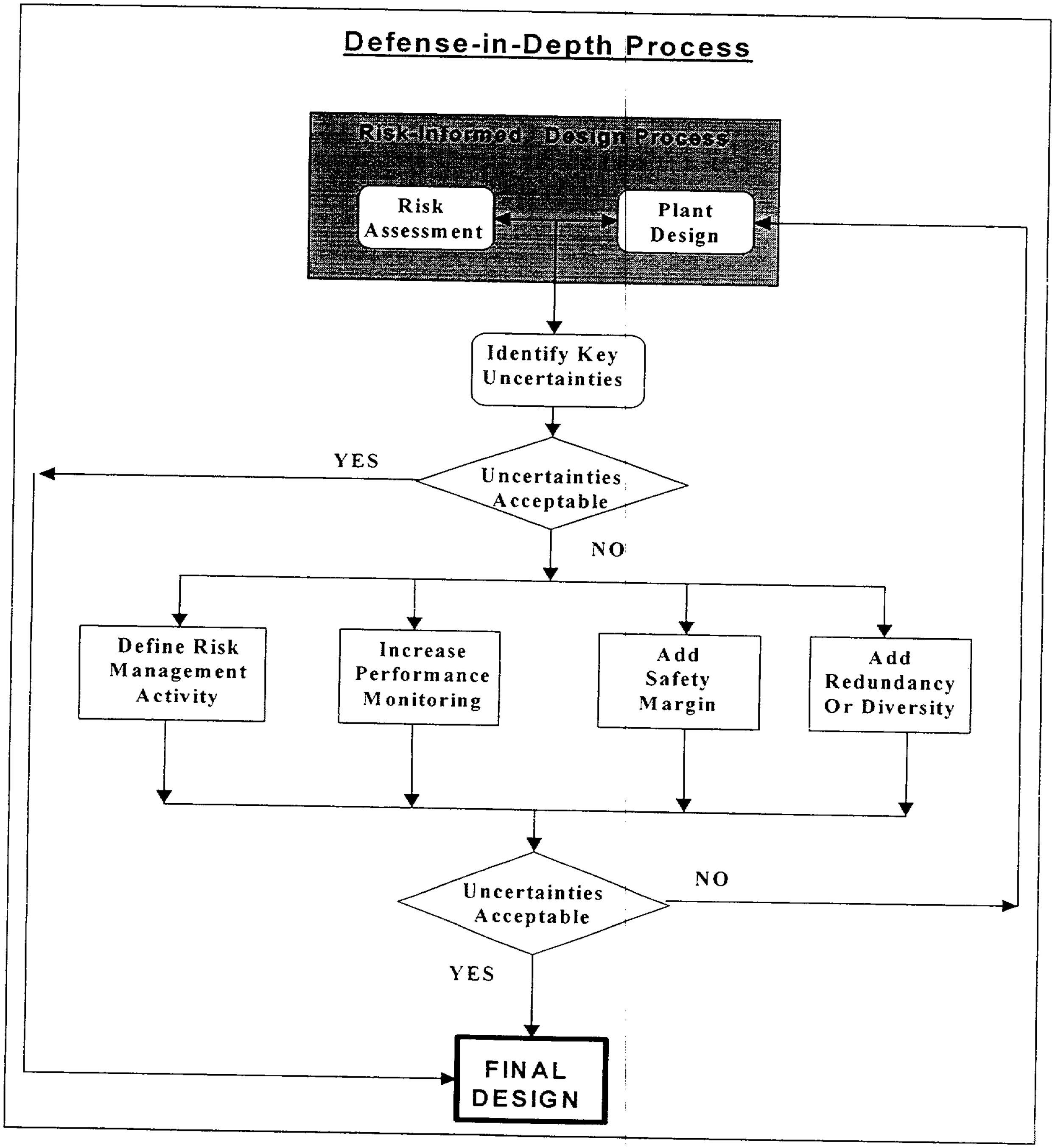

Figure A-2

A.4 Benefits of a New, Risk-Informed, Performance-Based Regulatory Framework

Safety Benefits

The anticipated safety benefits from adopting a complete risk-informed, performance-based regulatory process include:

- Improved operator focus on events that are more probable and are of safety significance,
- Enhanced training programs for operators, craftsmen, and support personnel that focus on the more likely, safety significant events and associated tasks,
- Reduced chance of inadvertent malfunctions from testing the equipment under unnecessarily harsh conditions, and a reduction in maintenance resources to repair defects caused by such testing,
- Reduced testing and maintenance of low safety-significant equipment, reduces the potential for operator or maintenance errors, which impact equipment reliability,
- Reduced number of unnecessary operational and thermal transients caused by overly conservative Technical Specifications that result in power reductions or shutdowns,
- Improved automatic and operator generated emergency core cooling system (ECCS) equipment loading sequences that are linked to the more probable, more safety-significant events, improving long term equipment reliability and availability, e.g., emergency diesel generator reliability and availability, and lower occupational worker exposures through the reduction in unnecessary testing and surveillance requirements,
- Increased ECCS effectiveness for the more probable, safety-significant events,
- More realistic and reliable set points and performance criteria for annunciators and valves, and
- Simplified designs and equipment layout that will reduce the burden on operators during transient events.

Economic Benefits

A complete and detailed cost-benefit analysis has yet to be completed. Preliminary estimates for adopting a complete risk-informed, performance-based approach regulating power reactors, based on the anticipated benefits for the existing fleet of nuclear power reactors indicate substantial cost-benefit in the operational phase in excess of $5 million/unit/yr. Such estimates include revenue enhancements as well as cost savings. The preliminary estimates for design and construction are more significant, with provisional estimates being in excess of several hundred million dollars per unit.

SECTION B

FRAMEWORK ELEMENTS

B.1 Introduction

A regulatory framework for a new generation of commercial nuclear power plants must meet several objectives. The major objectives are: 1) flexibility to address several potential reactor types/designs, 2) consideration of the lessons learned from 30+ years of experience in licensing light water reactors, 3) inclusion of risk information to assure proper safety focus, 4) support NRC Mission of adequate protection of public health and safety, and 5) support NRC strategic objectives. The proposed framework discussed in this section will accomplish these objectives.

Figure B-1 shows the proposed hierarchy of the regulatory framework. This represents a structured approach to determining the relative scope of NRC policies and safety goals, regulations, regulatory guides, Standard Review Plans, and Standard Format and Content Guidance. A major objective of this framework is to provide regulatory stability for the regulator and licensees while continuing to support the NRC mission of assuring adequate protection of public health and safety.

The content of the elements of the framework is based on a combination of 30+ years of deterministic licensing experience and more recent insights from risk-informed analyses of reactor design and operation. Content of the elements is also affected by the need for flexibility in addressing a number of future reactor designs. For example, the concept of fission product barriers is addressed *functionally* in the regulations (Proposed 10 CFR 53.22). Specific requirements to fulfill the functional requirements for barriers would be included in design specific regulatory guides or in the SAR. This approach contrasts with the current very specific requirements of 10 CFR 50, Appendix A, GDCs 55, 56, and 57 for light water reactor containment penetrations. Another example is the functional requirement in the regulations for maintaining the fuel cladding (primary barrier) integrity function during normal operational occurrences. Currently, GDC 10 requires maintaining specific fuel design limits during transients. Such specific requirements would be included in design specific regulatory guides or specific applications in the new framework. The new regulations would list specific limits that are applicable during specific events, such as Anticipated Operational Occurrences.

The framework is based on the cornerstones of the Reactor Oversight Program implemented industrywide in 2000. This program has been tested over several years with considerable stakeholder input and is the basis for NRC's assurance that adequate protection of public health and safety is maintained. The requirements outlined in the new framework should support a performance based regulatory process, i.e., the requirements specify what performance should be and not how to accomplish the performance.

New Regulatory Architecture

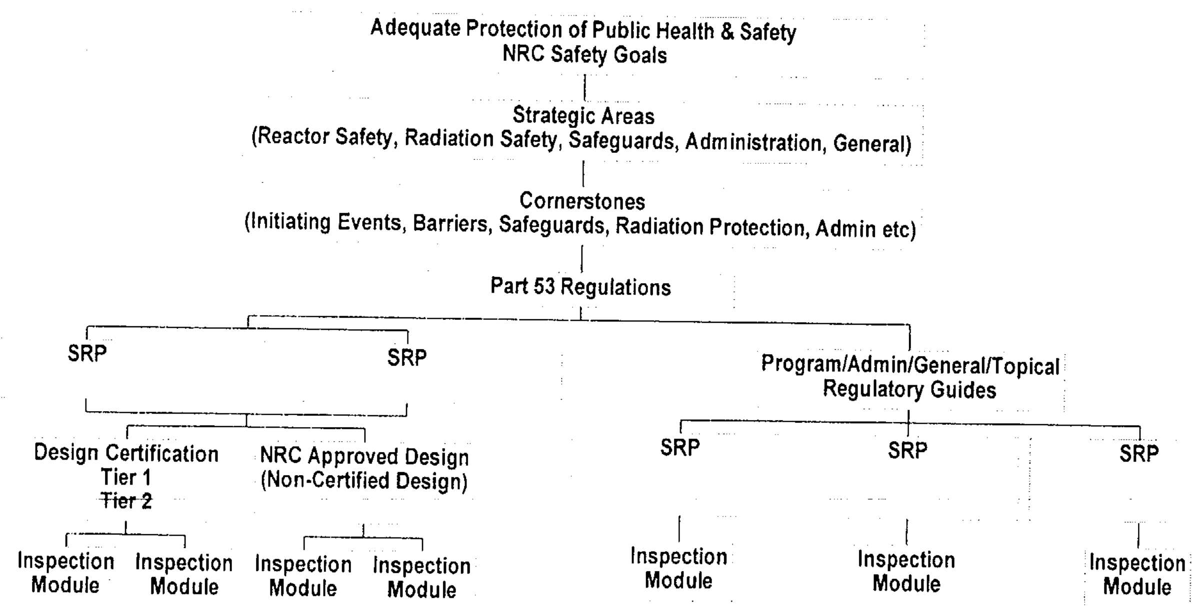

Fig B-1

B.2 Requirements/Regulations

A fundamental part of the framework is the Regulation or Requirements element. The proposed framework is designed to fit into Title 10 of the Code of Federal Regulations. A new Part 53 contains optional requirements for an applicant choosing a risk-informed licensing process. Applicants would retain the option of licensing under the existing 10 CFR Part 50. Part 53 is intended to be a complete replacement for the current Part 50 such that some of the administrative process sections of Part 53 duplicate those in Part 50. The requirements are generic to accommodate all reactor types and will support the Commission's mission and safety goals.

The proposed Part 53 is organized to facilitate selective implementation by licensees. The new rule is divided into subparts A (General Provisions, including QA), B (Reactor Safety, including design and construction), C (Operational Provisions, including operational requirements, radiation protection, emergency preparedness, and security) and D (Administrative Provisions). It is anticipated that some licensing scenarios will exist, requiring a combination of Part 50 and Part 53 processes. For example, a licensee seeking a COL with a design certified under Part 50 may want to take advantage of the risk-informed operational requirements of Part 53. The proposed organization of Part 53 will facilitate the combined process.

Since the level of detail is decreased in the new Part 53 relative to Part 50, the need for subsequent rulemaking to revise the regulations to account for future developments and experience should be drastically reduced. This regulatory approach is appropriate for a mature industry with many years of operating experience and with the risk assessment tools that are now available. Adjustments to the basis for these requirements can be made by changing the supporting Regulatory Guides and Standard Review Plans.

B.3 Regulatory Guides

Regulatory guides have traditionally provided "an acceptable means of meeting regulations". In practice, the use of regulatory guides has been inconsistently applied to various issues at various levels of detail. An objective of the new framework is to provide a set of principles for the level of detail and a "need threshold" for regulatory guides. Part of the framework would tie each regulatory guide to a specific regulation or regulations. The regulations should serve as the basis for defining the set of regulatory guides. Regulatory guides should be limited to providing an acceptable means of demonstrating compliance with the regulations and should focus on acceptance criteria with methodology being a subsidiary part of the guidance.

One principle of the new framework is to provide flexibility to address a number of new reactor types. Regulatory guides should be organized into divisions corresponding to reactor types. A common division would address generic issues, e.g., environmental qualification and fire protection.

It is illustrative to look at examples of how existing Regulatory Guides would be modified to meet the criteria for Regulatory Guides in the new framework. One such example is Regulatory Guide 1.105, Revision 3, 12/99, "Setpoints for Safety-Related Instrumentation". This Regulatory Guide endorses Part 1 of Instrument Society of America (ISA) standard ISA-S67.04-1994. The discussion in the regulatory guide indicates that the impetus for its existence is that "Operating experience indicates that setpoints for safety-related instrumentation may allow plants to operate outside the Limiting Conditions for Operation specified in Technical Specifications". This is a valid basis for development of a guide in the current framework. Should this guide exist in the new framework?

Regulatory Guide 1.105 is linked to Regulations 10 CFR 50, App. A, GDC 13, GDC 20, and 10 CFR 50.36. Since similar regulations would exist in the new framework, this regulatory guide meets the criterion of directly supporting a regulation. The regulatory guide currently applies to safety-related instrumentation and would only apply to safety-significant instrumentation under the new framework. It would probably apply to all reactor designs.

Section C.1 of the regulatory guide states that "Section 4 of ISA-S67.04-1994 specifies the methods, but not the criterion, for combining uncertainties in determining a trip setpoint and its allowable values". The regulatory guide adds acceptance criteria to the provisions of the standard. Under the new framework, the regulatory guide should specify the acceptance criterion and allow the licensee to specify the means of meeting the criteria. The language of the regulatory guide may indicate NRC acceptance of the methodology as a separate section of the guide.

The application of Regulatory Guide 1.189, "Fire Protection for Operating Nuclear Power Plants", is an example of a current regulatory guide that would not fit into the new framework. This guide serves a purpose in the current regulatory system of documenting, in an organized manner, the extensive set of requirements and guidance published by the NRC for current operating plants. It is too prescriptive, however, for the objectives proposed for the new framework.

An example of this excessive detail is found in section 1.1.f.iv of the regulatory position. The section is presenting "an acceptable means" of providing a qualified and trained staff to address fire protection. The specific paragraph identifies 5 as the minimum number of personnel for the on-shift fire brigade. In a performance-based regulatory regime, the regulations should set limits or define functional requirements. The regulatory guide provides specific guidance on the boundaries for implementation, and may provide examples of implementation. In the case of the on-shift fire brigade, the design may allow for fewer or a larger number of on-shift firefighters depending on the design features. Regulatory guidance should specify the functional requirements the licensee must meet and the method of meeting them should be left up to the licensee.

B.4 Standard Review Plans and Standard Format and Content Guide

In the current regulatory framework, the Standard Format and Content Guide provides application guidance to Applicants for a Combined Construction Permit and Operating License (COL). Standard Review Plans specify review procedures for NRC Staff. Although these documents do not have the same status as regulations, they do have a significant effect on the licensing process and, ultimately, on the final design, construction, and operation of new plants. A goal of the new framework is to structure these documents such that they are consistent with the risk-informed, performance-based objectives of the framework. These documents are necessary to provide the common ground for reviewers and applicants and must be developed within the total framework.

The Standard Format and Content Guide and the Standard Review Plans should be tied to regulations and regulatory guides. Much of the current content of these documents is based on historical information requirements that are no longer needed in the risk-informed, performance-based environment. Development of 10 CFR 53 and its supporting Regulatory Guides should take into account the need to create a new Standard Format and Content guidance document.

SECTION C

REGULATORY STRUCTURE

C.1 Introduction

This section describes the regulation element of the new regulatory framework, 10 CFR 53, and the basis for concluding it will provide an adequate basis for licensing new plants. As discussed earlier, 10 CFR 53 is proposed as an optional alternate to 10 CFR 50 for licensing new plants. Part 53 is risk-informed and, therefore, based on risk insights complemented by deterministic requirements as a means of assurance of public health and safety. The role of Part 53 relative to other elements of the framework is discussed in Section B.

Appendix B provides the basis for each section of Part 53 that is a significant departure from the counterpart section of Part 50. The subsections of Appendix B are numbered to correspond to the assigned regulation number as defined in Appendix A. Each subsection includes a general discussion of the subject relative to the same subject in Part 50 and a detailed discussion of each item (numbered B53.XX.xx). The discussions in those subsections compare the new regulatory treatment to that of Part 50 since Part 50 has and will continue to provide an adequate regulatory basis for licensing. If it can be shown that the proposed Part 53 section provides equivalent requirements, then it is also adequate.

This section recognizes that the scope of licenses to be covered in Part 53 is different than that of Part 50. It applies only to Power Reactors and it also applies to designs different from Light Water Reactors. The new part is also written to recognize the licensing processes of 10 CFR 52 (Early Site Permits, Certified Designs, and Combined Operating Licenses). Where possible, sections were combined to make the total Part less cumbersome.

There are some detailed aspects of Part 50 that are not directly addressed in Part 53 as discussed in Section C.2. This is driven primarily by the concept that the regulation will provide a comprehensive, high-level set of requirements and that much of the detailed requirements will be incorporated into Regulatory Guides and Standard Review Plans. For example, the requirements corresponding to 10 CFR 50, Appendix K would be addressed in two places. 10 CFR 53.20 and 21 provide the general requirements related to initiating events and mitigation for all events including loss of coolant accidents. Regulatory Guides for each reactor type to be licensed under Part 53 would provide specific, acceptable approaches for analyses and system designs to assure the regulations are met.

Section C.3 provides a summary of the basis for determination that the new Part 53 provides an adequate basis for licensing new reactors.

C.2 Material Relocated from Regulations

As stated in Section B and illustrated in the preceding subsections, a considerable amount of detailed information that is currently in 10 CFR 50 would not be duplicated in 10 CFR 53. Section A discusses the new framework and the basis for locating requirements in the regulation vs. the license application. This section lists the major technical subjects that are included in Part 50 but not addressed in detail in Part 53 and explains the basis for the new regulatory framework for each area.

List of Regulations Relocated to Other Locations

The following is a list of Part 50 regulations that would be significantly changed in the proposed Part 53. Table C-1 provides a cross-reference from Part 50 to Part 53. Significantly changed means that the details in the Part 50 regulation would be relocated to regulatory guidance documents or that the Part 50 regulation is not needed in a risk-informed framework. A brief discussion of the proposed disposition of the regulation is included.

(a) §50.36, Technical Specifications. The new regulation includes Technical Specifications in §53.30 but the level of detail is reduced. A required configuration control program would replace much of what is included in current Technical Specifications.

(b) §50.44, Standards for Combustible Gas Control System. This regulation would be eliminated consistent with the recent rule change. Requirements for hydrogen control for specific reactor types would be a part of the application for those plants.

(c) §50.46 and Appendix K, Acceptance Criteria for Emergency Core Cooling Systems. Regulatory requirements for all safety-significant, mitigation systems are included in 10 CFR 53.21. Specific system requirements will be included in the license application or regulatory guides.

(d) §50.55a, Codes and Standards. 10 CFR 50.55a consists of several pages of conditions for operating licenses and COLs related to the ASME Code, Sections III and XI, and IEEE Standards 279 and 603. These conditions either fully or conditionally endorse the standards for various classes of facilities. Under the proposed Part 53 (10 CFR 53.74), a requirement is placed on applicants for an operating license to identify all industry codes and standards utilized in the design, construction, and operation of the facility as part of the application.

(e) §50.60, Acceptance Criteria for fracture prevention measures, §50.61, (Appendices G and H) Fracture Toughness Requirements for Protection Against Pressurized Thermal Shock Events, Appendix J, Primary Reactor Containment Leakage Testing, Appendix S, Earthquake Engineering Criteria, §50.62, Requirements for Reduction of Risk from Anticipated Transients Without Scram (ATWS) Events, §50.63, Loss of All Alternating Current Power, and §50.66, Requirements for Thermal Annealing of the Reactor Pressure Vessel. These are detailed regulatory requirements for Light Water Reactors. Under the new framework, the detailed requirements would be specified in the license application and ultimately approved by the Staff. Regulatory requirements to address these and similar issues would be inherent in the requirements of 10 CFR 53.20, 21, and 22.

(f) 10 CFR Part 50, Appendix A, General Design Criteria. The requirements of Appendix A that would apply to any reactor design are addressed in §53.21 and §53.22. Requirements that are specific to particular designs would be included in the license applications for those plants and in regulatory guidance.

(g) Appendix E, Emergency Planning and Preparedness and §50.47 requirements are combined and included as risk-informed emergency preparedness requirements in §53.40.

(h) Appendix I, Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion "As Low as Reasonably Achievable;" §50.34a, Design Objectives for Equipment to Control Releases for Radioactive Material in Effluents; §50.36a, Technical Specification on Effluents from Nuclear Power Reactors; and 10 CFR 50, have been revised and relocated to §53.33. Radiation protection requirements from 10 CFR 20 that apply to power reactors licensed under Part 53 are included in § 53.33 and §53.34.

(i) 10 CFR 50, Appendix R, Fire Protection Program. Fire protection regulatory requirements are addressed in §53.21. The regulation covers overall requirements and the detailed requirements would be addressed in regulatory guidance.

C.3 Regulatory Adequacy of Part 53

Section C and Appendix B include a comparison of the proposed Part 53 to the existing Part 50. The comparison results in a regulatory analysis that relies on the fact that Part 50 provides an adequate means of licensing commercial power reactors. The proposed optional replacement regulation is shown to also provide an adequate basis for licensing. It would also support a more efficient licensing process since it focuses on commercial power reactors and takes advantage of modern safety assessment tools to ensure adequate protection of public health and safety.

The differences between the proposed Part 53 and Part 50 are, in general, the result of the following factors:

(a) Framework Principles 3, 4 and 5, which state that the framework shall be risk-informed and performance-based.

(b) Framework Principle 10 which states that the framework must be flexible enough to accommodate new reactor designs and existing levels of design certifications.
(c) Framework Principle 11, which addresses the need for a more efficient and effective regulatory review process.
(d) Proposed Part 53 applies only to commercial power reactors and, therefore, does not include counterpart regulations to those in Part 50 for research and other facilities.

Appendix B presents a comparison of the sections of the new rule that would be changed most significantly relative to their Part 50 counterpart sections. The description in each section of this comparison explains the adequacy of that part of the proposed new rule and the basis for any changes. A detailed regulatory analysis of the proposed rule will be developed prior to the publication of the NOPR.

C.4 Part 50-Part 52-Part 53 Interface

This discussion relates to scenarios 1 and 2 of figure C-2 below. It is intended to give a preliminary indication on the conforming changes that may need to be made to Part 52 at the time of issuance of the new Part 53.

(a) The primary benefit of using Part 53 for these cases is the ability to define "safety-significant" SSCs in lieu of current requirements for "safety-related" programs. Based on a preliminary review of Tier 1, the certified designs could use the §53.15 QA program if Part 52 is modified to allow the option of adopting Part 53 requirements instead of the currently required Part 50, Appendix B.

(b) §53.30(e), Assessment Program and §53.30(f), Technical Specifications would be available for these scenarios if Part 52 were modified to allow these as alternates to §50.65, Maintenance Rule and §50.36, Technical Specifications. This does not appear to be limited by the Tier 1 information.

(c) §53.30(h) would be available for these scenarios after modification of Part 52 to allow use of this section in place of Part 50. The Tier 1 information does require ASME Section III for some components, but the development of ASME code cases addressing the treatment of low safety-significant (industrial) structures, systems and components could address the Tier 1 requirement.

(d) §53.31 could be used in these scenarios if Part 52 were modified.

(e) §53.33, §53.34 and §53.35 could be used in these scenarios after modification of Part 52. This information is not specified in the Tier 1 documents.

Part 52-Part 53 Relationship

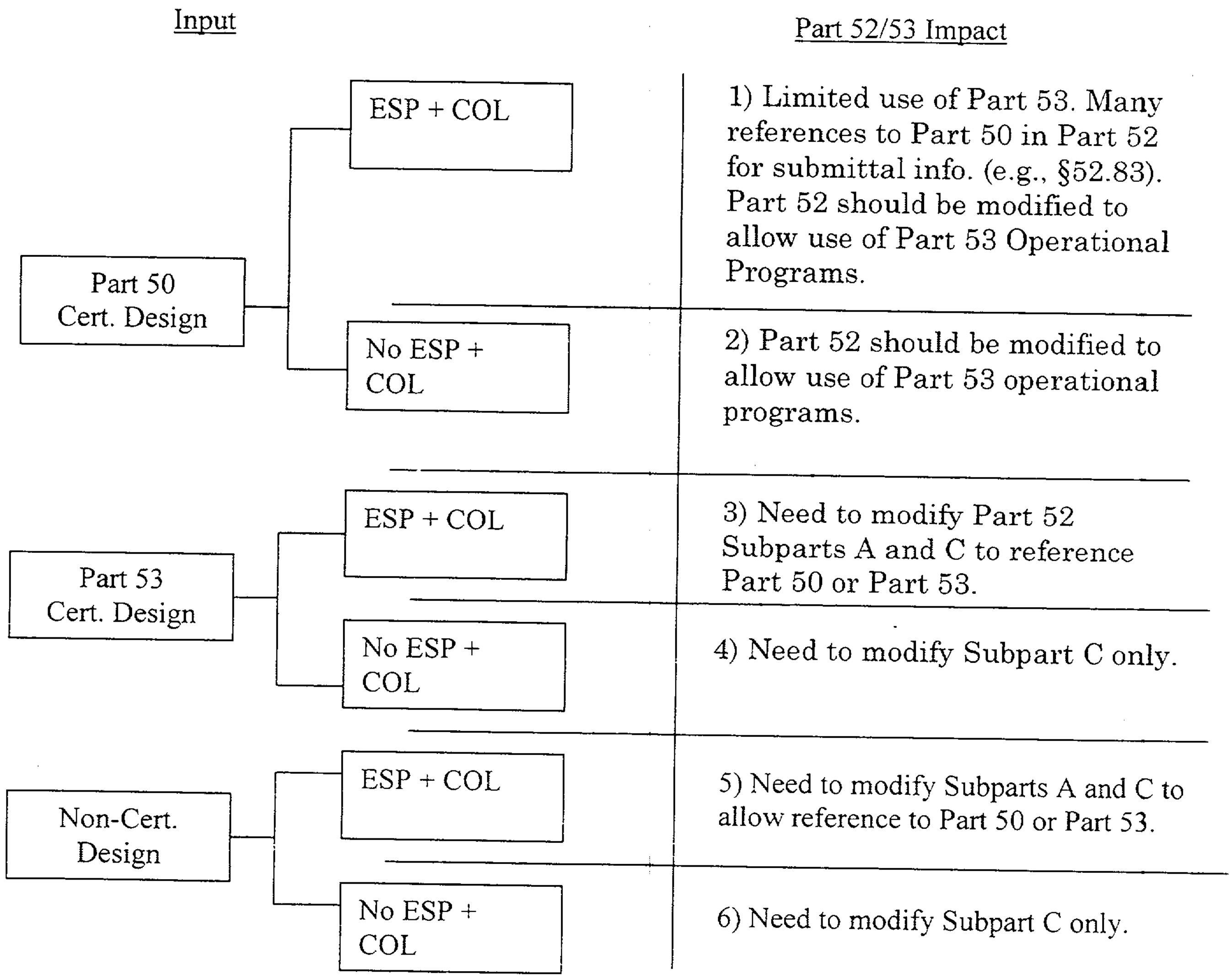

Figure C-2

(f) §53.30(e), Assessment Program and §53.30(f), Technical Specifications would be available for these scenarios if Part 52 were modified to allow these as alternates to §50.65, Maintenance Rule and §50.36, Technical Specifications. This does not appear to be limited by the Tier 1 information.

(g) §53.30(h) would be available for these scenarios after modification of Part 52 to allow use of this section in place of Part 50. The Tier 1 information does require ASME Section III for some components, but the development of ASME code cases addressing the treatment of low safety-significant (industrial) structures, systems and components could address the Tier 1 requirement.

(h) §53.31 could be used in these scenarios if Part 52 were modified.

(i) §53.33, §53.34 and §53.35 could be used in these scenarios after modification of Part 52. This information is not specified in the Tier 1 documents.

(j) §CFR 53.40 could be adopted in these scenarios after Part 52 is modified.

Part 50-Part 53 Cross Reference

10 CFR 50 Section	10 CR 53 Section	Notes
50.1, Basis, purpose and procedures applicable	53.1, Scope	
50.2, Definitions	53.2, Definitions.	
50.3, Interpretations	53.3, Interpretations	
50.4, Written communications	53.4, Written communications.	
50.5, Deliberate misconduct	53.5, Deliberate misconduct.	
50.7, Employee protection	53.7, Employee protection.	
50.8, Information collection requirements: OMB approval	53.8, Information collection requirements: OBM approval	
50.9, Completeness and accuracy of information	53.9, Completeness and accuracy of information	
50.10, License required	53.60, License required	
50.11, Exception and exemptions from licensing requirements	53.61, Exceptions and exemptions from licensing requirements	
50.12, Specific exemptions	53.62, Specific exemptions	
50.13, Attacks and destructive acts by enemies of the United States; and defense activities	53.63, Attacks and destructive acts by enemies of the United States; and defense activities	
50.20, Two classes of licenses	N/A	Only power reactors
50.21, ~~Class 104 licenses;~~	N/A	Only power reactors
50.22, Class 103 license;	53.65, Power reactor license	
50.23, Construction permits	N/A	CP Only
50.30, Filing of applications for licenses; oath & affirmation	53.70, Filing of applications for licenses; oath or affirmation	
50.31, Combining applications	53.71, Combining applications.	
50.32, Elimination of repetition	53.72, Elimination of repetition.	
50.33, Contents of applications; general information	53.73, Contents of applications; general information	
50.33a, Information requested by the Attorney	N/A	CP only

Part 50-Part 53 Cross Reference

10 CFR 50 Section	10 CR 53 Section	Notes
General for anti-trust		
50.34, Contents applications; technical information	53.74, Contents application; technical information.	
50.34a, Design objectives for equipment to control releases of radioactive material in effluents	53.74, Contents application; technical information.	
50.35, Issuance of construction permits	N/A	CP Only
50.36, Technical Specifications	53.30, Operational requirements	
50.36a, Technical Specifications on effluents for nuclear power reactors	N/A	Not a Tech. Spec. item in new Framework
50.36b, Environmental conditions	N/A	Not a Tech. Spec. item in new Framework
50.37, Agreement limiting access to restricted data.	53.50, Agreement limiting access to restricted data	
50.38, Ineligibility of certain applicants	53.51, Ineligibility of certain applicants.	
50.39, Public Inspection of applications	53.52, Public inspection of applicants.	
50.40, Common standards	53.86, Common standards.	
50.41, Additional standards for class 104 licenses	N/A	Power Reactors only
50.42, Additional standards for Class 103 licenses	53.86, Common standards	
50.43, Additional standards and provisions affecting class 103 licenses for commercial power	53.86, Common standards	
50.44, Standards for combustible gas control system in light-water-cooled power reactors	N/A	Below the level of detail in new FW.

Part 50-Part 53 Cross Reference

10 CFR 50 Section	10 CR 53 Section	Notes
50.45, Standards for construction permits	N/A	CP only
50.46, Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors	53.21, Mitigation	Detail in RGs
50.47, Emergency plans	53.40, Emergency preparedness	
50.48, Fire Protection	53.21, Mitigation	Detail in RGs
50.49, Environmental qualification of electric equipment important to safety for nuclear power plants	53.21, Mitigation	Detail in RGs
50.50, Issuance of licenses and construction permits	53.87, Issuance of combined licenses.	
50.51, Continuation of license	N/A	Replaced by aging mgt. Program in 53.30
50.52, Combining licenses	53.85, Combining licenses	
50.53, Jurisdictional limitations	53.55, Jurisdictional limitations.	
50.54, Conditions of licenses	53.83, License conditions	
50.55, ~~Conditions of construction permits~~	N/A	CP only
50.55a, Codes and Standards	53.74, Contents of applications; technical information	Specific Stds. In OL Appl.
50.56, Conversion of construction permits to license, or amendment of license	N/A	CP only
50.57, Issuance of operating license	53.87, Issuance of combined licenses	Only OL issuance anticipated in Part 53
50.58, Hearings and report of Advisory Committee on Reactor Safeguards	53.53, Hearings and report of Advisory Committee on Reactor Safeguards	
50.59, Changes, tests and experiments	53.31, Changes, tests, and experiments	

Part 50-Part 53 Cross Reference

10 CFR 50 Section	10 CR 53 Section	Notes
50.60, Acceptance criteria for fracture prevention measures for light-water nuclear power reactors for normal op	53.22, Functional barriers to radionuclide release	Detail in RGs
50.61, Fracture toughness requirements for protection against pressurized thermal shock events	53.22, Functional barriers to radionuclide release	Detail in RGs
50.62, Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water nuclear power plants	53.20, Initiating events and prevention	Detail in RGs
50.63, Loss of all alternating current power	53.20, Initiating events and prevention	Detail in RGs
50.64, Limitations on the use of highly enriched uranium (HEU) in domestic non-power reactors	N/A	Power Reactors only
50.65, Requirements for monitoring the maintenance at nuclear power plants. (Effected July 10, 1996)	53.30, Operational requirements	Detail in RGs
50.66, Requirements for thermal annealing of the reactor pressure vessel	53.22, Functional barriers to radionuclide release	Detail in RGs
50.67, Accident source term	53.35, Source term	
50.68, Criticality accident requirements	53.20, Initiating events and prevention	Detail in RGs
50.70, Inspections	53.54, Inspections	
50.71, Maintenance of records, making of reports	53.90, Documentation updates requirements	
50.72, Immediate notification requirements for operating nuclear power reactors	53.91, Notifications	
50.73, License events report system	53.92, Reporting requirements.	
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APPENDIX A
10 CFR PART 53
DOMESTIC LICENSING OF POWER REACTORS

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10 CFR PART 53

DOMESTIC LICENSING OF POWER REACTORS

SUBPART A – General Provisions

§53.1 Scope

The regulations in this part are promulgated by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended (68 Stat. 919), and Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242), to provide for the licensing of commercial nuclear power reactor utilization facilities. This part provides an alternative to the provisions in Part 50 of this chapter, and a plant may be licensed and regulated under Part 53 or Part 50 at the election of the applicant or licensee of a commercial nuclear power utilization facility. This Part also provides the provision to allow Part 50 or Part 52 licensees or applicants to selectively implement specific requirements of this Part provided that an integrated, risk-informed categorization process of the structures, systems and components has been performed per the requirements of §53.10 of this Part. While the term "applicant" is used in this Part, the requirements are applicable to holders of a combined construction and operating license issued under Part 52 or a holder of a Part 50 operating license for operating a nuclear power facility.

This Part also gives notice to all persons who knowingly provide to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of §53.5.

§53.2 Definitions

Anticipated operational occurrences are normal and abnormal events that are expected to occur during the life of an individual license. These are events that occur at a mean frequency of 10^{-2}/yr, or greater

Commercial nuclear power reactor is any nuclear power reactor that is used for the purposes of generating electricity or manufacturing a commercial commodity for sale to the general public, private companies, or government departments.

Core damage frequency (CDF), means the expected number of core damage events per unit of time. *(ASME PRA Standard)*

Defense-in-depth is achieved through the regulatory framework structure and processes that include the design, construction, regulatory oversight and operational activities. Additional defense-in-depth is provided by the application of deterministic design and operational features that compensate for events that have a high degree of uncertainty with significant consequences to public health and safety.

Defense-in-depth is a process and design property of a power plant unit characterized by the attainment and maintenance of protection of public health and safety through a combination of design and operational processes that prevent or mitigate accidents based on probabilistic insights and studies, and enhanced, as necessary, by deterministic design and operational features that compensate for low frequency events, if any, that have a high degree of uncertainty with significant consequences to public health and safety.

Design bases, means that information which identifies the safety-significant functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be (1) restraints derived from generally accepted "state of the art" practices for achieving functional goals, or (2) requirements derived from analysis (based on calculation and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals. *(10 CFR 50.2)*

Decommission, means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:
(1) Release of the property for unrestricted use and termination of the license; or
(2) Release of the property under restricted conditions and termination of the license. *(Part50)*

Design bases functions are the safety-significant functions performed by systems, structures and components (SSCs) that are (1) required by, or otherwise necessary to comply with, regulations, license conditions, orders, or technical specifications, or (2) credited in licensee safety analyses to meet NRC requirements.
(NEI 97-04, Rev. 1)

Dependency means, requirement external to an item and upon which its function depends
(ASME PRA Standard)

Emergency Planning Zones, means, geographic areas adjacent to a facility that have been determined by analysis to meet criteria specified in 10 CFR 53.40 requiring offsite emergency response planning to prepare for potential accident plume exposure or ingestion exposure.

Emergency Preparedness Bases Events are events with a frequency of less than 10^{-5}/yr but greater than 10^{-7}/yr.

Equipment diversity, means the use of a different type of equipment to achieve the same functional requirement.

Evaluation is defined as an analysis (traditional or computer calculations), a review of test data, a qualitative engineering evaluation, or a review of operational experience, or any combination of these elements. *(Industry UFSAR s)*

Exempt Wholesale Generator, means any person determined by the Federal Energy Regulatory Commission to be engaged directly, or indirectly through one or more affiliates and exclusively in the business of owning or operating, or both owning and operating, all or part of one or more eligible facilities and selling electric energy at wholesale.

Facility, means a single power reactor of unlimited thermal capacity or any number of identical power reactors whose combined thermal capacity does not exceed XXXX MW.

An initiating event is any event that perturbs the steady state operation of the plant, if operating, or the steady state operation of the decay heat removal systems during shutdown operations such that a transient is initiated in the plant. Initiating events trigger sequences of events that challenge plant control and safety systems.

Large release, means the rapid, unmitigated release of volatile radionuclides into the environment that could result in a prompt fatality to a member of the general public, without taking into account offsite emergency preparedness, environmental and meteorological effects.

Large release frequency (LRF) means expected number of large releases per unit of time *(Based on ASME PRA Standard)*

Major decommissioning activity, means any activity that results in permanent removal of major radioactive components, permanently modifies the structure of the containment, or results in dismantling components for shipment containing greater than class C waste in accordance with §61.55 of this chapter. *(Part 50)*

Performance-based, means an approach that establishes performance and results as the primary basis for regulatory decision-making. It incorporates the following attributes: (1) measurable (or calculable) parameters exist to monitor system, including facility performance; (2) objective criteria to assess performance are established based on risk insights, deterministic analyses and/or performance history; (3) licensee flexibility to determine how to meet the established performance; and (4) a defense-in-depth framework exists in which the failure to meet a performance criterion will not in and of itself constitute or result in an immediate safety-significant concern. *(Based on NRC Risk-Informed, Performance-Based Policy Statement)*

Plant design bases events are internal initiating events that have a mean frequency of occurrence between 10^{-2}/yr to 10^{-5}/yr.

Power plant unit is a single self-contained nuclear power reactor and associated electrical generating systems.

Probabilistic risk assessment (PRA) is a qualitative and quantitative assessment of the risk associated with plant operation and maintenance that is measured in terms of frequency of occurrence of risk metrics, such as core damage or a radioactive material release and its effects on the health of the public *(ASME PRA Standard)*

Quality assurance comprises all the planned and systematic actions necessary to provide reasonable assurance that a safety-significant structure, system, or component will perform its safety significant function.

Redundant, means the duplication of a structure, system, train, or component to provide an alternative functional capability in the event of a failure of the original structure, system, train or component

Risk, encompasses what can happen (scenario), its likelihood (probability), and its level of damage (consequences). *(NUMARC 93-01, Rev 2)*

Risk-Informed is an approach whereby operating experience and engineering judgment are used to complement probabilistic safety (risk) analyses to focus licensee and regulatory attention and decisionmaking process on issues commensurate with their importance to public health and safety.

Safety-Significant structures, systems and components are those structures, systems and components that are significant contributors to safety as identified through a risk-informed integrated decisionmaking process that combines risk assessment insights, operating experience and new technical information using expert panel evaluations.

Severe accident is an accident that involves extensive release of radionuclides beyond the primary barrier into the reactor systems, the tertiary confinement area, or the environment.

Site, means a single geographical location of one or more nuclear facilities

Train, means a collection of equipment that is configured and operated to serve some specific plant safety function and may be a sub-set of a system. The licensee can utilize the FSAR or PRA analysis to better define the intended configuration and function(s). (Based on NUMARC 93-01, Rev 2)

Utilization facility means any nuclear reactor other than one designed or used primarily for the formation of plutonium or U - 233.

§53.3 Interpretations

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§53.4 Written communications

(a) Address requirements. The signed original of all paper correspondence, reports, applications, and other written communications from the applicant or licensee to the Nuclear Regulatory Commission concerning the regulations in this part or individual license conditions must be addressed to the U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D. C. 20555. Electronic filings of such information should be submitted in accordance with the electronic information exchange (EIE) process or the CD ROM Submittal Procedure.

(b) Distribution requirements. Copies of all correspondence, reports, and other written communications concerning the regulations in this part or individual license conditions must be either submitted to the Nuclear Regulatory Commission at the locations and in the quantities set forth below (addresses for the NRC Regional Offices are listed in Appendix D of part 20 of this chapter or electronically in accordance with the EIE process or the CD ROM Submittal Procedure.

(c) Applications for amendment of permits and licenses, reports, and other communications. All written communications (including responses to generic letters, bulletins, information notices, inspection reports, and miscellaneous requests for additional information), that are required of holders of operating licenses or COLs issued pursuant to this part, must be submitted as follows, except as otherwise specified in paragraphs (b)(2) through (b)(7) of this section: the signed original to the Nuclear Regulatory Commission, Document Control Desk, Washington, D.C. 20555, one copy to the appropriate Regional Office, and one copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility.

(d) Applications for permits and licenses, and amendments to applications. Written applications for COLs, applications for operating licenses, and amendments to either type of application may be made by sending 37 copies and the signed original to the Nuclear Regulatory Commission, Document Control Desk, Washington, D. C. 20555, one copy to the appropriate Regional Office, and one copy to the appropriate Resident Inspector.

(e) Acceptance Review Application. Written communications required for an application for determination of suitability for docketing pursuant to 53.70(a)(6) must be submitted as follows: the signed original and 13 copies to the Nuclear Regulatory Commission, Document Control Desk, Washington, D. C. 20555 and one copy to the appropriate Regional Office.

(f) Security Plan and related submittals. Written communications, as defined in paragraphs (b)(4)(i) through (iv) of this section must be submitted as follows: the signed original and three copies to the Nuclear Regulatory Commission, Document Control Desk, Washington, D. C. 20555 and two copies to the appropriate Regional Office;

(1) Physical Security Plan pursuant to §53.74;
(2) Safeguards contingency plan pursuant to §53.74;
(3) Change to security plan, guard training and qualification plan, or safeguards contingency plan made without prior Commission approval pursuant to §53.83;
(4) Application for amendment of physical security plan, guard training and qualification plan, or safeguards contingency plan pursuant to §53.77.

(g) Emergency Plan and related submittals. Written submittals as defined in paragraphs (b)(5)(i) through (iii) in this section, must be submitted as follows: the signed original to the Nuclear Regulatory Commission, Document Control Desk, Washington, D. C. 20555, two copies to the appropriate Regional Office, and one copy to the appropriate resident inspector if one has been assigned to the site of the facility.

(1) Emergency Plan pursuant to §53.74;
(2) Change to an Emergency Plan pursuant to §53.83;

(3) Emergency implementing procedures pursuant to §53.40.

(h) Updated FSAR. A written update to the Final Safety Analysis Report (FSAR) or replacement pages, pursuant to §53.90 must be submitted as follows: the signed original and 10 copies to the Nuclear Regulatory Commission, Document Control Desk, Washington, D. C. 20555, one copy to the appropriate Regional Office, and one copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility.

(1) Quality Assurance related written submittals. A written change to the Safety Analysis Report quality assurance program description pursuant to §53.15 or §53.30 must be submitted as follows: the signed original to the Nuclear Regulatory Commission, Document Control Desk,
Washington, D. C. 20555, one copy to the appropriate Regional Office, and one copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility.
(2) Certification of permanent cessation of operations
(3) Certification of permanent fuel removal
(4) Form of communications. All written submittal copies submitted to meet the requirements set forth in paragraph (b) of this section must be typewritten, printed or otherwise reproduced in permanent form on unglazed paper. Exceptions to these requirements may be granted for the submittal of micrographic or photographic forms.
(5) Delivery of communications. Written or CD ROM communications may be delivered to the Document Control Desk at 11555 Rockville Pike, Rockville, Maryland between the hours of 8:15a.m. and 4:00 p.m. Eastern Time. If a submittal due date falls on Saturday, Sunday, or a Federal holiday, the next Federal working day becomes the official due date.

§53.5 Deliberate misconduct

(a) Any licensee, applicant for a license, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any safety-significant components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or
(2) Deliberately submit to the NRC, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

§53.7 Employee protection

(a) Discrimination by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in paragraph (a) introductory text of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) introductory text or under these requirements if the employee has identified the alleged illegality to the employer;

(iii)Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv)Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) introductory text.

(2) Assisting or participating in, or is about to assist or participate in, these activities.

(3) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(4) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraph (a), (d), or (e) of this section by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant may be grounds for –

(1) Denial, revocation, or suspension of the license.
(2) Imposition of a civil penalty on the licensee or applicant.
(3) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each licensee and each applicant for a license shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in 10 CFR 19.11(c). This form must be posted at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(2) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in Appendix D to Part 20 of this chapter or by calling the NRC Information and Records Management Branch at (301) 415 - 7230.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

53.8 Information collection requirements: OMB approval

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 USC 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number XXXXXX.

(b) The approved information collection requirements contained in this part appear in §§53.20, 53.21, 53.30, 53.31, 53.40, 53.70, 53.73, 53.74, 53.75, 53.76, 53.77, 53.78, 53.83, 53.90, 53.91, 53.92, 53.95.

(c) This Part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) (*Will be determined at a later date*)

53.9 Completeness and accuracy of information

(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the licensee shall be complete and accurate in all material respects.

(b) Each applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having, for the regulated activity, a significant implication for public health and safety or common defense and security. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification shall be provided to the Administrator of the appropriate Regional Office within two working days of identifying the information. This requirement is not applicable to information, which is already required to be provided to the Commission by other reporting or updating requirements.

Safety classification of structures, systems and components

§53.10 Risk-informed classification of structures, systems and components

An applicant or licensee who elects to implement any section of this Part shall categorize the structures, systems and components (SSCs) into one of two categories: Safety-significant SSCs and Industrial SSCs. The categorization process must:

(a) Use a plant-specific Probabilistic Risk Assessment (PRA) to determine the relative importance of modeled SSC functions in terms of core damage frequency and large release frequency. This calculation must be performed with an evaluation model that includes internal initiating events at full power operations. External initiating events and low power and shutdown modes of operation must also be considered, either as part of this PRA or as part of the integrated decision-making process described in paragraph (b) of this Section.

(b) Use an integrated decision-making process to determine the safety significance of functions performed by the SSCs. The categorization of these functions as either safety significant or industrial must include:

(1) Results and insights from the PRA, including those from importance evaluations.
(2) Determination of SSC function importance using an acceptable process for addressing initiating events and plant operating modes not modeled in the PRA.
(3) Defense-in-depth for events that have a high degree of uncertainty with significant consequences to public health and safety.
(4) Maintenance of sufficient safety margins.
(5) Documentation, in terms of (1) through (4) above, of the basis for determining that a function is safety-significant.

(c) Include a means for monitoring the performance or condition of those SSCs that, when degraded, can affect the results of the categorization process, and a means for taking actions, as necessary, such that the bases for an SSC's categorization continues to be satisfied.

(d) Include a provision for timely updates of the risk assessment and categorization documentation to provide reasonable assurance that the actual design, operational practices, and operational experience of the plant are correctly reflected in the bases for categorization.

Assurance

53.15 Quality Assurance

Introduction.

Every applicant for a combined construction permit and operating license or a holder of an operating license shall include in its safety analysis report a summary of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility.

These requirements apply to safety-significant structures, systems and components and activities that could affect safety-significant functions. These activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system that provide a means to control the quality of the safety-significant material, structure, component, or system to predetermined requirements.

(a) Organization

The applicant for a combined license or holder of an operating license shall be responsible for the establishment and execution of the quality assurance program. The applicant or licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility therefore. The authority and duties of persons and organizations performing activities affecting the safety-significant functions of structures, systems, and components shall be documented. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of, (1) assuring that an appropriate quality assurance program is established and effectively executed, and (2) verifying, such as by checking, auditing, inspection, and testing, that activities affecting the safety-significant functions have been correctly performed.

Personnel performing quality assurance functions may be from the organization being reviewed but shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. These personnel shall report to a management level such that this required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms provided that the persons and organizations assigned the quality assurance functions have this required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location shall have direct access to such levels of management as may be necessary to perform this function.

(b) Quality Assurance Program

The applicant shall establish, a quality assurance program. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions. The applicant shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations.

The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety and the experience and skill of the craft. Activities affecting quality shall be accomplished under suitably controlled conditions. The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The applicant shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program, which they are executing.

A licensee may make changes to its quality program description without prior NRC review and approval providing the resulting change complies with the requirements of this section.

(c) Design Control

Measures shall be established by the applicant to assure that applicable regulatory requirements and the design basis, as defined in §53.2, and as specified in the license application, for the safety-significant structures, systems, and components are correctly translated into specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-significant functions.

Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualifications testing of a prototype structure, system or component under the design basis conditions. Design changes, including field changes, shall be subject to design control measures and be approved by the organization that performed the original design unless the applicant designates another responsible organization.

(d) Procurement Document Control

Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements that are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require suppliers, contractors or subcontractors to provide a quality assurance program that is consistent with the pertinent provisions of this section, or that is certified as satisfying a nationally recognized consensus standard by an approved and nationally recognized quality registrar.

(e) Instructions, Procedures, and Drawings

Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances, the experience and skill of the craft, and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important safety-significant activities have been satisfactorily accomplished.

(f) Document Control

Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.

(g) Control of Purchased Material, Equipment, and Services

Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the facility prior to its use in operations. This documentary evidence shall be retained at the facility or other licensee designated location, and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment. The effectiveness of the control of quality by contractors and subcontractors shall be assessed at intervals consistent with the importance, complexity, performance, and quantity of the product or services.

(h) Identification and Control of Materials, Parts, and Components

Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item.

(i) Control of Special Processes

Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

(j) Inspection

A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Such inspection shall be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed shall be performed for each work operation, as appropriate and where necessary, to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both. If mandatory inspection hold points that require witnessing or inspecting by the licensee's designated representative and beyond which work shall not proceed without the consent of the licensee's representative is required. The specific hold points shall be indicated in appropriate documents.

(k) Test Control

A test program shall be established for safety-significant structures, systems, and components. The test program shall include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during the facility operations to provide reasonable assurance that the safety-significant functions will be satisfied. Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied.

(l) Control of Measuring and Test Equipment

Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

(m) Handling, Storage and Shipping

Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided.

(n) Inspection, Test, and Operating Status

Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear facility. These measures shall provide for the identification of items, which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures shall also be established for indicating the operating status of structures, systems, and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.

(o) Nonconforming Materials, Parts, or Components

Measures shall be established to control materials, parts, or components that do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

(p). Corrective Action

Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

(q) Quality Assurance Records

Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

(r) Audits and Assessments

A comprehensive system of audits and assessments shall be carried out based on performance to verify compliance with aspects of the quality assurance program and to determine the effectiveness of the program. These audits and assessments shall be performed by line organizations, licensee management or personnel, or independent internal, or external organizations or groups in accordance with the written procedures or checklists.

The type, frequency, and degree of specificity of assessments shall be determined by the safety significance and performance history of the SSCs or work activity being evaluated. Licensee management is responsible for overseeing the assessment program. Personnel performing assessments and audits shall be qualified through training, work experience, or certification. Lead auditors shall not have direct responsibilities in the area or organization being audited.

Audit and assessment results shall be documented and reviewed by management having responsibility in the area audited.

(s) Change Control Process

A licensee may make changes to the QA program description referenced or included in the FSAR, or to the procedures and processes for implementing the requirements of this section, if the requirements of this section continue to be met. The licensee (or applicant) shall prepare a written basis for this determination.

SUBPART B – Reactor Safety – Design and Construction

53.20 Initiating events and prevention

(a) *Identification of Event Frequency*: Each applicant for a license under this part shall analyze the proposed plant to determine the mean frequency of occurrence of the following event classes. The analysis performed will be submitted as part of the application per 10 CFR 53.74 and maintained per 10 CFR 53.90.

(1) *Anticipated Operating Occurrences (AOO)* are internal initiating events with a mean frequency greater than 10^{-2} per year.

(2) *Plant Design Basis Events (PDBE)* are internal initiating events that have a mean frequency of occurrence less than 10^{-2} per year but greater than 10^{-5} per year.

(3) *Plant Protected Design Events (PPE)* are the most severe natural phenomena events, such as earthquakes, fires, tornadoes, hurricanes, floods, tsunami, and seiches, that have been historically reported for the site and surrounding area, plus the set of non-plant events such as internal fires and physical insurgency that could reasonably endanger the safe shutdown capability and security of the plant.

(4) *Emergency Preparedness Bases Events (EPBE)* are internal events that have a mean frequency of occurrence less than 10^{-5}/year but greater than 10^{-7}/year.

(b) *Monitoring Event Frequency & Magnitude*: The frequency and magnitude of initiating event frequencies shall be periodically reassessed to assure that those values remain within the categories determined in the original analysis. Changes to magnitude and frequency shall be processed in accordance with 10 CFR 53.31.

(c) *Prevention Design.* Each facility licensed under this part shall be evaluated to determine those SSCs that are relied upon to limit event frequency and magnitude (prevention). These SSCs shall be identified in the SAR and shall be designed with the appropriate margins to assure that their contribution to event prevention is maintained.

(1) *Specific Design Features.* The following design features shall be incorporated into all facilities licensed under this part.

(i) *Reactivity Control.* Reactivity control methods and systems, fuel storage systems and reactor designs shall include consideration of the potential for inadvertent criticality and power stability. Specific design characteristics to address these issues will vary according to reactor type and shall be specified in the application.

(ii) *Reactor inherent protection.* The reactor core and associated systems shall be designed such that, during normal power operations, the net effect of the prompt inherent nuclear feedback characteristics tends to compensate for a rapid increase in reactivity.

(iii) *Reactor design.* The reactor design shall include sufficient margin to assure that the fuel design limits specified in the application are not exceeded during normal operation including Anticipated Operational Occurrences (AOO).

(iv) *Reactor power oscillations.* The reactor core and associated cooling, control and protection systems shall be designed such that power oscillations which can result in conditions exceeding fuel design limits specified in the application are either not possible or can be reliably and readily detected and suppressed.

53.21 Mitigation

(a)(1) The plant design shall incorporate the necessary equipment and programs to mitigate the initiating events defined in Section 53.20 as determined by a risk assessment and accompanying safety analyses. The risk assessment shall consist of not less than a probabilistic risk assessment of internal events, bounding realistic safety assessments of shutdown and plant protected events, and shall demonstrate that the following criteria are met:

(i) For light water reactors, equipment systems and programs shall be designed to provide a mitigation capability for all design bases events such that the mean core damage frequency is less than 10^{-4} /year.

(ii) For gas reactors, equipment, systems and programs shall be designed to provide a mitigation and prevention capability such that the [ ] will not be exceeded. [*Specific criteria will be developed and based on pilot licensing activities for new gas reactors*]

(2) *Requirements for safety-significant structures, systems and components:* The design of safety-significant SSCs shall meet the appropriate industry standards and applicable sections of this Part for safety-significant structures, systems and components, as specified in the safety analyses report.

(3) The design shall include the necessary redundancy, diversity, testability, power supplies, and supporting systems to assure that the safety-significant functions used in the risk assessment required by paragraph (a)(1) remain valid.

(4) Safety-significant SSCs shall be designed and located, consistent with other design constraints, to provide reasonable assurance that the plant can achieve and maintain a safe shutdown.

(b) *Fire Protection*

(1) *Fire Protection Plan.* Each applicant under this Part shall submit, as part of the application, a fire protection plan for the facility. The plan shall include the following elements.
(2) *Program.* The plan shall identify the fire protection policy for the facility and the organization, equipment and procedures required to implement the policy.
(3) *Fire Hazards Analysis.* Each plan shall include a fire hazards risk assessment, which evaluates fire hazards and the potential for such hazards to prevent the plant from achieving and maintaining a safe shutdown.
(4) *Detection.* The facility shall include the equipment and procedures necessary to ensure detection of fires that could prevent achieving and maintaining safe shutdown of the plant.
(5) *Suppression.* Fire suppression shall be provided to assure that SSCs necessary to shutdown the plant and maintain it in a safe shutdown condition can perform those functions.

(c) *Environmental and Dynamic Effects.*

(1) *Protection against natural phenomena.* Safety-significant structures, systems, and components whose safety-significant functions would be impacted by natural phenomena shall be designed to withstand, or be protected from the affects of natural phenomena, such as earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches without loss of capability to perform their safety functions. The design and protective features shall reflect the most severe natural phenomena that have been historically reported for the site and surrounding area, with sufficient margin for uncertainty related to the limited accuracy, quantity, and period of time in which the data have been accumulated. The applicant shall determine that the equipment will operate under design bases conditions based on design, testing, analyses, or operating experience data, or a combination thereof.
(2) *Environmental conditions.* Safety-significant structures, systems, and components shall be designed to accommodate the affects of, and to be compatible with the service conditions credited in the risk assessment. As appropriate, service conditions include the effects of temperature, humidity, chemicals, toxic gases, radiation, and submergence.

An applicant or licensee shall determine through testing, analyses, or operating experience, or any combination thereof that safety-significant structures, systems and components that could be affected by environmental service conditions are capable of performing the safety-significant functions.

Safety-significant structures, systems, and components need to be protected from dynamic effects, including the effects of missiles, pipe whipping, and discharging fluids resulting from a PDBE or PPE event that could preclude a safety-significant function from being met as determined by an evaluation.

(d) *Reactor Protection System.* A system shall be included in the plant design to initiate a timely safe shutdown of the reactor in the event of AOOs, PDBEs, and PPEs that could result in NRC-approved fuel design limits specified in the application being exceeded.

(1) *Design.* The system design shall include, consistent with the needs identified in the FSAR, appropriate redundancy, diversity, reliability, timeliness of automatic initiation, power sources, and quality.

(2) System independence. The system design shall include the appropriate level of system independence described in the FSAR. Factors to be evaluated should include effects of natural phenomena, normal operation, accident conditions, maintenance and testing.

(e) *Monitoring.* Where practical, mitigation features shall be monitored to provide reasonable assurance that the functional capability, availability and reliability assumptions of the risk assessment are met. Where performance monitoring is impractical, configuration controls and condition monitoring shall be established to provide reasonable assurance that functional capability assumptions of the risk assessment are met.

53.22 Functional barriers to radionuclide release

The design shall incorporate sufficient capability, capacity, and functional barriers to a radionuclide release such that:

(a) A radionuclide release from each AOO shall not exceed the limits prescribed in §53.33.

(b) A radionuclide release from each PDBE or PPE shall not exceed the limits described in §53.35.

(c) The total mean frequency of a large radionuclide release[4] from all events defined in §53.21 shall be less than 10^{-5}/yr. Where practical, the safety-significant functional barriers shall be monitored to provide reasonable assurance that functional capability assumptions of the risk assessment are met.

(d) Where performance monitoring is impractical configuration controls shall be established to provide reasonable assurance that the functional capability assumptions of the risk assessment are met.

[4] *Large release* – the release of volatile radionuclides into the environment that could result in a prompt fatality to a member of the general public.

SUBPART C – Operational Provisions

Operations

53.30 Operational Requirements

(a) *Introduction.* Each holder, or applicant for a power reactor license under this Part shall establish and implement operational programs[5] described in this paragraph. The purpose of these programs is to establish work controls and practices that when implemented provide reasonable assurance that the safety-significant structures, systems and components are capable of performing their safety-significant functions. These programs shall be referenced or described in the safety analyses report.

Each licensee is responsible for managing the programs and monitoring the effectiveness of such programs.

(b) *Scope.* The requirements of this section shall be applied to activities that could affect safety-significant functions and the associated safety-significant structures, systems and components. The requirements of this section apply to activities that occur after the Commission issues its 10 CFR 52.103(g) finding, an operating license or, a license amendment.

(c) *Training Program.*

(1) A licensee shall establish, implement, and maintain a training program derived from a systematic approach to training as defined in 10 CFR 55.4. As applicable, the training program shall provide for the training and qualification of the following categories of nuclear facility personnel:
(i) Non-licensed operator.
(ii) Shift supervisor.
(iii) Shift technical advisor.
(iv) Instrument and control technician.
(v) Electrical maintenance personnel.
(vi) Mechanical maintenance personnel.
(vii) Radiological protection technician.
(viii) Chemistry technician.
(ix) Engineering support personnel.

(2) The training program shall incorporate the instructional requirements necessary to provide qualified personnel to operate and maintain the facility in a safe manner in all applicable modes of operation. The training program shall be consistent with the

[5] These programs, when implemented, collectively encompass and include the functions and activities of a traditional quality assurance program.

facility license, the technical specifications and applicable regulations. The training program shall be evaluated periodically and revised, as appropriate, to reflect industry experience, equipment modifications, changes to procedures and programs, and amendments to applicable regulations.

(3) Records must be maintained by the licensee to maintain program integrity and kept available for NRC inspection to verify the adequacy of the program.

(d) Operator staffing requirements. Operator staffing requirements shall be commensurate with the NRC approved designed operational assumptions and actions that are necessary to safely operate and, when necessary, safely shutdown the plant to assure adequate protection of public health and safety.

(e) Monitoring and Configuration Risk Management Program

(1) Where practical, the licensee shall establish performance criteria for safety-significant equipment functions. The performance criteria, when satisfied, shall be sufficient to provide reasonable assurance that the safety-significant function will be met. If performance monitoring is not practical, the licensee shall develop a condition monitoring and evaluation program.

(2) Performance and condition monitoring activities shall be evaluated at least once per refueling cycle, taking into account, where practical, industrywide operating experience. As necessary, adjustments shall be made to licensee programs and activities with the objective of providing adequate assurance that the safety functions will be performed, yet minimizing the unavailability of structures, systems, and components from quality assurance activities. In monitoring the effectiveness of a licensee's programs, an assessment of the total plant equipment that is out of service should be taken into account to determine the overall effect on performance of safety functions. This assessment will provide an indication that the plant remains within the risk configuration limits of the plant Tech Specs are not exceeded.

(3) Before performing maintenance, surveillance and other testing activities on safety-significant SSCs, the licensee shall assess and manage the increase in risk that may result from the proposed activities.

(4) Surveillance testing, calibration, or inspection shall be performed on safety-significant SSCs to provide reasonable assurance that: the functional capability, availability and reliability assumptions of the risk assessment are met; plant operations and activities will be within safety limits: and the limiting conditions for operation will be met.

(f) *Technical Specifications*

(1) Each applicant for an Operating License or COL under this part shall include in the application proposed technical specifications in accordance with the requirements of this section. A summary statement of the bases or reasons for such specifications shall be included in the application, but shall not become part of the technical specifications.

(2) Each Operating License or COL issued under this part will include technical specifications. The technical specifications will be derived from the analyses and evaluations, including the risk assessment included in the Safety Analysis Report, and amendments thereto, submitted pursuant to §53.74.

(3) Technical Specifications will include items in the following categories:

(i) *Safety Limits*. Safety Limits are maximum or minimum values of important process variables that are found to be necessary to reasonably protect the integrity of fission product barriers. If any Safety Limit is exceeded, the reactor must be shut down.

(ii) *Limiting Safety System Settings*. Limiting Safety System Settings are setpoints for automatic protective functions related to the Safety Limits specified in paragraph (3)(i) of this Section. These settings must be chosen so that automatic protective action will correct the abnormal situation before the safety limit is exceeded. If, during normal operation, it is determined that the automatic protective function does not function as required, the licensee shall take appropriate action which may include shutting down the reactor. The licensee shall take appropriate action as defined in the license that may include shutting down the reactor.

(iii) *Risk Configuration Limits*. Risk configuration limits are the values of elapsed time during which predetermined values of small increases in core damage frequency or large release frequency may be allowed to exist without shutting down the plant or taking other appropriate action.

(iv) Should the limits defined in para. (iii) of this section be exceeded, immediate action is to be taken to place the plant on a safe shutdown condition in a controlled manner.

The licensee shall notify the Commission, review the matter, and record the results of the review, including the cause of the condition and the basis for corrective action taken to preclude recurrence. In such cases, the plant shall remain in a shutdown condition until the Commission has reviewed and accepted the licensee's corrective action plan.

(g) *Plant Shutdowns*. In the event of an Operating Basis Earthquake, the plant shall be placed in a safe shutdown condition. The Commission shall be notified immediately, in accordance with section 53.91. Prior to resuming power operations a damage survey shall be performed and the Commission shall be informed of the bases that provide reasonable assurance that the safety-significant functions will be satisfied.

(h) *Aging management program*. Each applicant shall submit an aging managing program description as part of each application for a license under this part. The program shall include the identification of safety-significant SSCs subject to degradation from aging mechanisms, the aging mechanisms affecting each of those SSCs, initial expected service life of those SSCs and the schedule for periodic updates of the program to address new information. Each licensee shall establish a program as approved by the NRC. Documentation of the evaluation and actions taken to assure safety-significant SSCs will fulfill their safety-significant functions shall be maintained for the life of the plant.

In the development of the selection of equipment, a determination shall be made on the expected service life of safety-significant components, taking into consideration the effects of design service conditions, and operational transient and accident component and structural loads. The licensee shall monitor the performance of such equipment, and may adjust the expected service life through analyses, refurbishment or replacement to provide reasonable assurance that the safety significant functions will be met.

53.31 Changes, Tests, and Experiments

(a) Definitions for purposes of this section:

(1) *Change* means a modification or addition to, or removal from, the facility or procedures that affect a safety significant function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

(2) *Departure from a method of evaluation described in the PRA section of the FSAR (as updated) used in establishing the design bases or in the safety analysis* means:
(i) Changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or
(ii) Changing from a method described in the FSAR to another method unless that method has been approved by the NRC for the intended application.

(3) *Facility as described in the FSAR (as updated)* means:
(i) The safety-significant structures, systems, and components (SSC) that are described in the FSAR (as updated),
(ii) The design and performance requirements for safety-significant SSCs described in the FSAR (as updated), and
(iii)The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs that demonstrate the safety-significant intended function(s) will be accomplished.

(4) *Final Safety Analysis Report (as updated)* means the Final Safety Analysis Report submitted in accordance with §53.74 as amended and supplemented and as updated per the requirements of §53.90.

(5) *Initiating events* are those events defined in §53.20

(6) *Procedures as described in the FSAR (as updated)* means those procedures that contain information described in the FSAR (as updated) such as how structures, systems and components are operated and controlled.

(7) *Tests or Experiments not described in the FSAR (as updated)* means any activity where any safety-significant structure, system, or component is utilized or controlled

in a manner, which is outside the bounds of the PSA/IDP section of the FSAR that would significantly increase the risk to public health and safety.

(b)(1) A licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) without obtaining a license amendment pursuant to §53.77 only if:

(i) a change to the technical specifications incorporated in the license is not required, and

(ii) the change, test or experiment does not meet any of the criteria in paragraph (b)(2) of this section.

(2) A licensee shall obtain a license amendment pursuant to §53.77 prior to implementing a proposed change, test or experiment if the change test or experiment would:

(i) Result in the creation of a new Initiating Event as defined in §53.20;

(ii) Result in the change to the frequency of an Initiating Event such that it would be classified in a category of higher frequency;

(iii)Result in an increase in Core Damage Frequency (CDF) of greater than 10^{-6} /year,

(iv)Result in a change to a radionuclide barrier design basis limit, or;

(v) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analysis.

(3) In implementing this paragraph, the FSAR (as updated) is considered to include FSAR changes resulting from evaluations performed pursuant to this section and analyses performed pursuant to §53.77 since submittal of the last update of the FSAR pursuant to §53.90.

(4) The provisions of this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(c) The licensee shall maintain records of changes in the facility, of changes to procedures, and of tests and experiments made pursuant to paragraph (b) of this section. These records must include a written evaluation, which provides the bases for the determination that the change, test, or experiment does not require a license amendment pursuant to (b)(2) of this section.

(1) The licensee shall submit as specified in §53.4, a report containing a brief description of any changes tests, or experiments, including a summary evaluation of each. A report must be submitted at intervals not to exceed 24 months.

(2) The records of changes in the facility must be maintained until termination of a license issued pursuant to this part. Records of changes in procedures and records of tests and experiments must be maintained for a period of 5 years.

Radiation Protection

Definitions and units of radiation dose and radioactivity for the purposes of this part are contained in §20.1003, §20.1004, and §20.1005.

53.33 Public Radiation Safety

(a) Dose limits for individual members of the public.

Each licensee shall conduct operations so that the dose limits for individual members of the public in §20.1301 are not exceeded.

(b) Constraint on radiological effluents released to the environment.

(1) Each licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve levels of radioactive material in effluents released to unrestricted areas and doses to members of the public that are as low as is reasonably achievable (ALARA). To implement this requirement, a constraint on radiological effluents released to the environment, excluding Radon-222 and its daughters, shall be established by the licensee, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of [value to be determined] mrem per year from these effluents. If a licensee exceeds this dose constraint, the licensee shall report the exceedance and promptly take appropriate corrective action to ensure against recurrence.

(2) The constraint on radiological effluents in (b)(i) of this section shall provide numerical guidance for design objectives and limiting conditions of operations as required in this section. The numerical guidance and associated design objectives and limiting conditions of operations are not to be construed as radiation protection standards.

(c) Design objectives for equipment to control releases of radioactive material in effluents.

(1) An application for a permit to construct a nuclear power reactor shall include a description of the preliminary design of equipment to be installed to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations, including anticipated operational occurrences. The application shall also identify the design objectives, and the means to be employed, for keeping levels of radioactive material in effluents to unrestricted areas as low as is reasonably achievable. The term "as low as is reasonably achievable" as used in this part means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety and

other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest. The constraint set out in (b)(i) of this section provides numerical guidance for use in developing design objectives for equipment to control releases of radioactive material in effluents.

(2) Each application for a permit to construct a nuclear power reactor shall include:

(i) A description of the preliminary design of equipment to be installed pursuant to paragraph (c)(i) of this section;
(ii) An estimate of the quantity of each of the principal radionuclides expected to be released annually to unrestricted areas in effluents produced during normal reactor operations, and expected resultant exposures to members of the public; and
(iii)A general description of the provisions for packaging, storage, and shipment offsite of solid waste containing radioactive materials resulting from treatment of gaseous and liquid effluents and from other sources.

(3) Each application for a license to operate a nuclear power reactor shall include (1) a description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, pursuant to paragraph (c)(i) of this section; and (2) a revised estimate of the information required in paragraph (c)(ii)(2) of this section if the expected releases and exposures differ significantly from the estimates submitted in the application for a COLs.

(d) Programs, manuals, and procedures.

The following programs shall be established, implemented, and maintained:

(1) Radiological effluents monitoring and control program

(i) A radiological effluents monitoring and control program shall be provided to assure compliance with the limits in §20.1301. The program shall include limiting conditions of operation for maintaining releases of radioactive material in radiological effluents, and resultant doses to members of the public, as low as reasonably achievable and shall include remedial actions to be taken whenever the limiting conditions of operation are exceeded. The constraint set out in §53.33(b)(i) provides numerical guidance for use in developing limiting conditions of operation required in this section.
(ii) In establishing and implementing the operating procedures for the radiological effluent monitoring and control program, the licensee shall be guided by the following considerations: Experience with the design, construction, and operation of nuclear power reactors indicates that compliance with the limiting conditions of operation required by this section will keep average annual releases of radioactive material in effluents and resultant doses to members of the public at small percentages of the dose limits specified in §20.1301 and in the license. At the same time, the licensee is permitted the flexibility of operation, compatible

with considerations of health and safety, to assure that the public is provided a dependable source of power even under unusual conditions which may temporarily result in releases higher than such small percentages, but still within the limits specified in §20.1301 of this chapter and in the license. It is expected that in using this flexibility under unusual conditions, the licensee will exert its best efforts to keep levels of radioactive material in effluents, and resultant doses to members of the public, as low as is reasonably achievable.

(2) Radiological environmental monitoring program

A radiological environmental monitoring program shall be provided to monitor radiation and radionuclides in the environs of the plant. The program shall provide for representative measurements of radioactivity in the highest potential exposure pathways and verification of the accuracy of the radiological effluent monitoring program and modeling of exposure pathways. The program will also provide for a land use census to ensure changes in the use of areas at or beyond the site boundary are identified and that modifications to the monitoring program are made if required by the census results.

(3) Offsite Dose Calculation Manual

An offsite dose calculation manual (ODCM) shall be provided that contains the methodology and parameters used in the calculation of offsite doses resulting from radiological effluents, in the calculation of radiological effluent monitoring alarm/trip setpoints, and in the conduct of the radiological environmental monitoring program. The ODCM shall also contain the radiological effluents control and radiological environmental monitoring programs, described in paragraph (d)(iii) and (d)(iv) of this section, and descriptions of the information that should be included in the annual radiological effluent release and annual radiological environmental reports, described in paragraph (e) of this section.

(4) Process Control Program

A process control program shall be provided to ensure that processing and packaging of solid radioactive waste will be accomplished in such a way as to assure compliance 10 CFR parts 20, 61, and 71, State regulations, radioactive waste disposal site requirements, and other requirements governing disposal of solid radioactive waste.

(e) Reports

The following annual reports covering the operation of the plant in the previous calendar year shall be submitted before May 1 of each year. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may require the licensee to take action, as the Commission deems appropriate.

(1) Annual radiological effluent report

An annual radiological effluent report shall include a summary of quantities of radioactivity in effluents and solid waste released from the plant and other information required by the Commission to estimate maximum annual radiation doses to the public resulting from effluent releases. Changes made during the calendar year to the radiological effluent monitoring and control program and the offsite dose calculation manual shall be described in the report.

(2) Annual radiological environmental monitoring report

An annual radiological environmental report shall include summaries, interpretations, and analysis of trends of the results of the radiological environmental monitoring program and the land use census for the reporting period. Changes made during the calendar year to the radiological environmental monitoring program shall be described in the report.

(f) Monitoring for radiological releases.

Means shall be provided for monitoring the reactor containment atmosphere, spaces containing components for recirculation of loss-of-coolant accident fluids, effluent discharge paths, and the plant environs for radioactivity that may be released from normal operations, including anticipated operational occurrences, and from postulated accidents.

(g) Disposal of licensed material.

Disposal of licensed material shall be in accordance with Subpart K to 10 CFR Part 20.

53.34 Occupational Radiation Safety

(a) Occupational dose limits.

Each licensee shall conduct operations so that the occupational radiation dose limits for adults in §20.1201, minors in §20.1207, and an embryo/fetus in §20.1208 are not exceeded.

(b) Maintaining occupational doses as low as reasonably achievable.

The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses that are as low as is reasonably achievable.

(c) Radiation Protection Programs.

Each licensee shall develop, document, and implement a radiation protection program to ensure compliance with (a) and (b) of this section and to include the following:

(1) Surveys and monitoring shall be conducted as necessary to comply with regulations in this part and reasonable under the circumstances to evaluate radiological hazards.
(2) Instruments, equipment, and personnel monitoring devices used to conduct surveys and monitoring shall be calibrated and maintained to assure suitable accurate and precise measurements.
(3) Access to high and very high radiation areas shall be controlled to prevent inadvertent or unauthorized access.
(4) Respiratory protection equipment and controls shall be used as necessary to restrict intakes of radioactive material, consistent with maintaining the total effective dose equivalent as low as reasonably achievable.
(5) Licensed radioactive material shall be secured or monitored to prevent unauthorized removal or access.

(6) Radiation, high radiation, very high radiation, airborne radioactivity, and radioactive materials areas shall be posted and radioactive materials labeled with a conspicuous sign or clearly visible label, including additional information, as appropriate, to make individuals aware of the radiological hazard.
(7) Procedures consistent with §20.1906 are established for receiving and opening packages containing radioactive material.
(8) Records of radiation protection programs, surveys, and individual monitoring results shall be maintained.
(9) Notifications and reports shall be made in accordance with Subpart M to 10 CFR 20.
(10) The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

53.35 Source term

(a) Applicants shall submit as part of the application an evaluation of the potential magnitude and mix of the radionuclides that could be released from the fuel. This information shall be expressed as fractions of the fission product inventory in the fuel, the physical and chemical form of the potential release, and the timing of the release of such nuclides from the reactor. The evaluations should be based upon the events defined in Section 53.20.
(b) The evaluation shall determine that the combination of the design and the operating assumptions included in the design are sufficient to satisfy the following criteria:
    (1) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated radionuclide release, would not receive a radiation dose in excess of 0.25 Sv (25 rem)[6] total effective dose equivalent (TEDE).
    (2) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated radionuclide

[6] The use of 0.25 Sv (25 rem) TEDE is not intended to imply that this value constitutes an acceptable limit for emergency doses to the public under accident conditions. Rather, this 0.25 Sv (25 rem) TEDE value is a reference value for establishing the design bases and subsequent changes to the design bases.

release (during the entire period of its passage), would not receive a radiation dose in excess of 0.25 Sv (25 rem) total effective dose equivalent (TEDE).

(3) Adequate radiation protection is provided to permit access to and occupancy of the control room under accident conditions without personnel receiving radiation exposures in excess of 0.05 Sv (5 rem) total effective dose equivalent (TEDE) for the duration of the accident.

Emergency Preparedness

53.40 Emergency Preparedness

Each applicant for an Operating License or COL under this part shall submit as part of the application an analysis of the frequency and consequences of Emergency Planning Basis Events (EPBE). The set of EPBEs to be evaluated shall be developed based on the facility's risk assessment and will include events with an initiating event mean frequency greater than 10^{-7}/year and less than 10^{-5}/year. The results of the analysis will determine the extent and nature of offsite and onsite emergency planning requirements as described in (a) and (b) of this section. NRC shall review and disposition, as necessary, the FEMA findings relative to offsite emergency response plans of affected States and Local entities for reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency in those instances where the analysis shows that §53.40(b) requires detailed plans.

(a) On-site Plan and Facilities

Each applicant for an Operating License or COL shall submit for approval, as part of the application, an onsite emergency plan addressing the response requirements for EPBEs identified in the plant risk assessment. The plan will specify:

(1) On-shift licensee responsibilities for emergency response including adequate staffing by functional area, staff augmentation capability, and the interfaces between licensee organizations,
(2) On-site emergency facilities and equipment.
(3) Emergency classification and action level scheme for EPBEs, if any, that would require offsite emergency planning per 10 CFR 53.40(b).
(4) Means for controlling radiological exposures for emergency workers,
(5) Arrangements for medical services for contaminated individuals,
(6) General plans for recovery and reentry,
(7) Plans for periodic exercises,
(8) Worker training programs.

(b) Offsite Planning Requirements

(1) If the analysis required by this section shows that there is a greater than 10^{-6}/year mean frequency that radiation exposure at the exclusion area boundary (EAB) from an EPBE is greater than 10 mSv. (1 rem) total effective dose equivalent (TEDE), the

following offsite planning requirements shall apply in addition to the requirements specified in §53.40(a).

(i) *Notification Criteria.*

(A) Procedures shall be established for notification, by the licensee, of State and local response organizations, and for notification of emergency personnel by all organizations of information related to a plant radiological emergency. Procedures for notification of the populace within the plume exposure pathway planning zone (offsite response area) shall also be established. The plume exposure pathway planning zone shall be defined in the license application and based on an analysis of the need for protective actions for members of the public following an EPBE.

(B) Procedures shall be established describing how information will be made available to the public on a periodic basis regarding their initial actions in response to a notification of a radiological emergency and how the news media will be used to disseminate information after an emergency.

(ii) *Communication and Interface with State and Local Agencies.*

(A) Primary responsibilities for emergency response by the nuclear facility licensee and by State and local organizations within the Emergency Planning Zones shall be identified. The application shall identify the organizations required to support emergency response activities, and demonstrate that the responsible organizations are adequately staffed to respond and to augment the initial response on a continuous basis.

(B) Applicants shall demonstrate that arrangements for requesting and effectively using assistance resources have been made.

(C) Adequate methods, systems and equipment for assessing and monitoring actual or potential offsite consequences shall be provided.

(D) Protective actions shall be established consistent with EPA Protective Action Guidelines. These protective actions shall be disseminated to responsible State and local organizations in the Emergency Planning Zones.

(E) Periodic exercises shall be conducted to evaluate major portions of emergency response capabilities.

(iii) If the analysis per §53.20 shows there are no EPBEs resulting in greater than 10^{-6} /year probability that offsite doses will exceed 10 mSv. (1 rem) at the EAB, then the following offsite planning requirements apply in addition to the requirements specified in §53.40(a).

(A) Procedures shall be established for notifying appropriate State and local entities of the activation of onsite emergency response plans.

(B) Responsibilities and means of coordinating licensee and offsite responders shall be identified for offsite response to onsite emergencies.

(C) Training plans shall be established for offsite agency personnel required to respond in an emergency.

(D) The means of communication to offsite responders shall be specified.
(E) Exercises shall be conducted on an appropriate periodic basis to assure communications and coordination are adequate.

(c) Update and Change Control Provisions

(1) *Plan Maintenance.* Each Licensee shall maintain the emergency plan required by §53.40(a) and (b) and update them on a periodic basis as required. Provisions shall be made to assure that updates are communicated to affected State and local entities.

(2) *Review of Changes.* An emergency plan required by this section may be changed by the licensee without prior Commission approval if the net effect of the change does not result in a decrease in effectiveness of the plans. Measures of effectiveness (such as offsite notification times, staff augmentation times, and public alert and notification times) shall be established in the plans to provide a means of determining the need for Commission approval. A licensee may make a change to a plan that decreases effectiveness if the same provision has been approved for another facility and is applicable. The Commission shall be notified of the change. Licensees must notify the Commission of major plan changes that would impact local area or public protection by submitting a copy of plan updates in accordance with §53.4.

(d) A license may be issued under this part, absent compliance with paragraph (b) of this section, if an applicant shows:

(1) An inability to comply with the requirements of paragraph (b) of this section is wholly or substantially the result of non-participation of state and/or local governments.
(2) A sustained, good faith effort to secure and retain the participation of the pertinent state and/or local governmental authorities, including the furnishing of copies of the emergency plan.
(3) The emergency plan provides reasonable assurance that public health and safety is not endangered by operation of the facility. The NRC will evaluate the applicant's plan against the requirements normally applied to a state or local plan with allowance made both for;
(i) Those elements for which state and/or local non-participation makes compliance infeasible and,
(ii) The applicant's measures designed to compensate for any deficiencies resulting from state and/or local non-participation.

Physical Security

§53.45 Security

(a) Applicants must submit the security plan, safeguards contingency plan and safeguards information protection plan information as required by 10 CFR 73 to the NRC as part of an application.

(b) The safeguards contingency plan shall include plans for dealing with threats, thefts, and radiological sabotage, as defined in Part 73 of this chapter, relating to the special nuclear material and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for such a license shall include the first four categories of information contained in the applicant's safeguards contingency plan. The fifth category of information, Procedures, does not have to be submitted for approval.

(c) The licensee shall prepare and maintain safeguards contingency plan procedures in accordance with appendix C of part 73 of this chapter for effecting the actions and decisions contained in the Responsibility Matrix of the safeguards contingency plan. A licensee may make a change to the security plan; the guard training and qualification plan, prepared pursuant to §53.74(m) or part 73 of this chapter; without prior approval of the Commission if, following the change, these plans satisfy the requirements of Part 73 of this chapter.

(d) The licensee shall maintain records of changes to the plans made without prior Commission approval for a period of three years from the date of the change, and shall submit, as specified in §53.4, a report containing a description of each change at periodic intervals consistent with updates to the FSAR.

(e) As necessary, based on an assessment by the licensee against performance indicators, an assessment or audit shall be performed.

SUBPART D Administrative Provisions

General

53.50 Agreement limiting access to restricted data

As part of its application and in any event before the receipt of Restricted data or classified national security information or the issuance of a license, the applicant shall agree in writing that it will not permit any individual to have access to or any facility to possess Restricted data or classified national security information until the individual and/or facility has been approved for such access under the provisions of 10 CFR Parts 25 and/or Part 95. The agreement of the applicant in this regard shall be deemed part of the license, whether so stated therein or not.

53.51 Ineligibility of certain applicants

Any person who is a citizen, national or agent of a foreign country, or any corporation, or other entity which the Commission knows or has reason to believe is owned, controlled or dominated by an alien, a foreign corporation, or a foreign government, shall be ineligible to apply for and obtain a license.

53.52 Public inspection of applications

Applications and documents submitted to the Commission in connection with applications may be made available for public inspection in accordance with the provisions of the regulations contained in part 2 of this chapter.

53.53 Hearings and report of the Advisory Committee on Reactor Safeguards

(a) Each application for a standard design certified under 10 CFR 52 shall be referred to the Advisory Committee on Reactor Safeguards (ACRS) for a review and report. The portion of each application for an Operating License, Combined Operating License or early Site Permit not already reviewed by the ACRS as part of a standard design application shall be referred to the ACRS for a review and report.

(b) Each application for a standard design certified under 10 CFR 52 shall be referred to the Advisory Committee on Reactor Safeguards (ACRS) for a review and report. The portion of each application for an Operating License, Combined Operating License or early Site Permit not already reviewed by the ACRS as part of a standard design application shall be referred to the ACRS for a review and report. Any report shall be made part of the record of the application and available to the public, except to the extent that security classification prevents disclosure.

53.54 Inspections

(a) Each licensee shall permit inspection, by duly authorized representatives of the Commission, of the records, premises, activities, and of licensed materials in possession or use, related to the license or COL as may be necessary to effectuate the purposes of the Act, including section 105 of the Act.

(b)(1) Each licensee shall upon request by the Director, Office of Nuclear Reactor Regulation, provide rent-free office space for the exclusive use of the Commission inspection personnel. Each licensee shall furnish heat, air conditioning, light, electrical outlets and janitorial services. The office shall be convenient to and have full access to the facility and shall provide the inspector both visual and acoustic privacy.

(2) For a site with a single reactor, the space provided shall be adequate to accommodate a full time inspector, a part time secretary, and transient NRC personnel and will be generally commensurate with other office facilities at the site. For sites with multiple reactors, additional space may be requested to accommodate additional full time inspectors. The Commission will furnish all furniture, supplies and communication equipment.

(3) The licensee shall afford any NRC resident inspector assigned to that site, or other NRC inspectors identified by the Regional Administrator as likely to inspect the facility, immediate unfettered access, equivalent to access provided regular plant employees, following proper identification and compliance with applicable access control measures for security, radiological protection and personal safety.

53.55 Jurisdictional limitations

No license under this part shall be deemed to have been issued for activities, which are not under or within the jurisdiction of the United States.

Requirement of License, Exceptions

53.60 License required

(a) Except as provided in §50.11 and §53.61, no person within the United States shall transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, or use any power reactor facility except as authorized by a license issued by the Commission.

(b) No person shall begin power reactor construction activities beyond those permitted by Part 52 of this chapter until a Combined Operating License (COL) has been issued.

(c) Notwithstanding the provisions of paragraph (b) of this section, and subject to paragraph (d) of this section, no person shall effect commencement of construction of a facility subject to the provisions of §51.20(b) of this chapter on a site on which the facility is to be operated that would adversely affect the environment to the extent that would invalidate the conclusions of the environmental impact statement for the site. As used in this paragraph, the term "construction" means any clearing of land, excavation or other substantial action that would adversely affect the environment of a site, but does not mean:

(1) Changes desirable for the temporary use of the land for public recreational uses, necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site or to the protection of environmental values; and

(2) Procurement or manufacture of components of the facility.

(d)(1) The Director of Nuclear Reactor Regulation may authorize a COL applicant, which is subject to §51.20(b) of this chapter, to conduct the following activities:

(i) Preparation of the site for construction of the facility (including such activities as clearing, grading, construction of temporary access roads and borrow areas); (ii) installation of temporary construction support facilities (including such items as warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and construction support buildings);

(ii) Excavation for facility structures;

(iii) Construction of service facilities (including such facilities as roadways, paving, railroad spurs, fencing, exterior utility and lighting systems, transmission lines and sanitary sewerage treatment facilities); and

(iv) the construction of structures, systems, and components, which do not prevent or mitigate the consequences of postulated events that could cause undue risk to the health and safety of the public. No such authorization shall be granted unless the NRC staff has completed a final environmental impact statement on the issuance of a siting permit or a COL as required by Subpart A of Part 51 of this chapter.

(2) Such an authorization shall be granted only after the presiding officer in the proceeding on the COL application has:

(i) Made all the findings required by §51.104(b) and §51.105 of this chapter to be made prior to issuance of the COL for the facility, and (ii) has determined that, based upon the available information, and

(ii) Reviewed and determined that there is reasonable assurance that the proposed site is a suitable location for a reactor of the general size and type proposed from the standpoint of radiological health and safety considerations under the Act, and the rules and regulations promulgated by the Commission pursuant thereto.

(3)(i) The Director of Nuclear Reactor Regulation may authorize an applicant for a COL for a facility under this part to conduct, in addition to the activities described in paragraph (d)(1) of this section, the installation of structural foundations, including any necessary subsurface preparation, for structures, systems and components which prevent or mitigate the consequences of postulated events that could cause undue risk to the health and safety of the public.

(4) Any activities undertaken pursuant to an authorization granted under this Section shall be entirely at the risk of the applicant and the authorization shall have no bearing on the issuance of a COL with respect to the requirements of the Act, and rules, regulations, or orders promulgated thereto.

53.61 Exceptions and exemptions from licensing requirements

Nothing in this part shall be deemed to require a license for:

(a) The manufacture, production, or acquisition by the Department of Defense of any power reactor or utilization facility authorized pursuant to section 91 of the Act, or the use of such facility by the Department of Defense or by a person under contract with and for the account of the Department of Defense;

(b) The manufacture, production or acquisition by the Department of Defense of any power reactor or utilization facility or the use of such a facility for:

(1)(i) The processing, fabrication, or refining of special nuclear material or the separation of special nuclear material, or the separation of special nuclear material from other substances by a prime contractor of the Department under a prime contract for;

(A) The performance of work for the Department at a United States government-owned or controlled site;

(B) Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or

(C) The use or operation of a power reactor facility in a United States owned vehicle or vessel; or

(ii) By a prime contractor or subcontractor of the Commission or the Department under a prime contract or subcontract when the Commission determines that the exemption of the contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety;

(2)(i) The construction or operation of a power reactor or utilization facility for the Department at a United States government-owned or controlled site, including the transportation of the power reactor or utilization facility to or from such site and the performance of contract services during temporary interruptions of such transportation; or the construction or operation of a power reactor or utilization facility for the Department in the performance of research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof; or the use or operation of a power reactor or utilization facility for the

Department in a United States government-owned vehicle or vessel; provided that such activities are conducted by a prime contractor of the Department under a prime contract with the Department.

(ii) The construction or operation of a power reactor or utilization facility by a prime contractor or subcontractor of the Commission or the Department under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that under the terms of the contract or subcontract, there is reasonable assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

53.62 Specific exemptions

(a) The Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the regulations of this part, which are:

(1) Authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security.

(2) The Commission will not consider granting an exemption unless special circumstances are present. Special circumstances are present whenever –

(i) Application of the regulation in the particular circumstances conflicts with other rules or requirements of the Commission; or

(ii) Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule; or

(iii) Compliance would result in undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted, or that are significantly in excess of those incurred by others similarly situated; or

(iv) The exemption would result in benefit to the public health and safety that compensates for any decrease in safety that may result from the grant of the exemption; or

(v) The exemption would provide only temporary relief from the applicable regulation and the licensee or applicant has made good faith efforts to comply with the regulation; or

(vi) There is present any other material circumstance not considered when the regulation was adopted for which it would be in the public interest to grant an exemption. If such condition is relied on exclusively for satisfying paragraph (a)(2) of this section, the exemption may not be granted until the Executive Director for Operations has consulted with the Commission.

(b) Any person may request an exemption permitting the conduct of activities prior to the issuance of a Combined Operating License (COL) prohibited by §53.60. The

Commission may grant such an exemption upon considering and balancing the following factors:

(1) Whether conduct of the proposed activities will give rise to a significant adverse impact on the environment and the nature and extent of such impact, if any;
(2) Whether redress of any adverse environment impact from conduct of the proposed activities can reasonably be effected should such redress be necessary;
(3) Whether conduct of the proposed activities would foreclose subsequent adoption of alternatives; and
(4) The effect of delay in conducting such activities on the public interest, including the power needs to be used by the proposed facility, the availability of alternative sources, if any, to meet those needs in a timely basis and delay costs to the applicant and to consumers.

Issuance of such an exemption shall not be deemed to constitute a commitment to issue an Early Site Permit (ESP) or a COL.

53.63 Attacks and destructive acts by enemies of the United States; and defense activities

An applicant for a license to construct and operate a power reactor facility, or for an amendment to such license, is not required to provide design features or other measures for the specific purpose of protection against the effects of (a) attacks and destructive acts, including sabotage, directed against the facility by an enemy of the United States, whether by a foreign government or other person, or (b) use or deployment of weapons incident to U.S. defense activities.

Classification and Description of Licenses

53.65 Power Reactor License

A class 103 license will be issued, to an applicant who qualifies, for any one or more of the following: To transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, or use a power reactor facility for industrial or commercial purposes. In the case of a power reactor facility which is useful in the conduct of research and development activities of the types specified in section 31 of the Act, such facility is deemed to be for industrial or commercial purposes if the facility is to be used so that more than 50% of the annual cost of owning and operating the facility is devoted to: the production of energy for sale or commercial distribution, or to the sale of services, other than research and development or education or training.

License Applications, Transfers, Suspensions and Amendments: Form, Contents, Ineligibility of Certain Applicants

53.70 Filing of applications for licenses; oath or affirmation.

(a) *Serving of applications.*
(1) Each filing of an application for a license under this part must be submitted to the U. S. Nuclear Regulatory Commission in accordance with §53.4.
(2) An additional 10 copies of the general information and 30 copies of the safety analysis report, or part thereof or amendment thereto, must be retained by the applicant for distribution in accordance with the written instructions of the Director, Office of Nuclear Reactor Regulation.
(3) Each applicant shall, upon notification by the Atomic Safety and Licensing Board appointed to conduct a public hearing required by the Atomic Energy Act, update the application and serve the updated copies of the application or parts of it, eliminating all superseded information, together with an index of the updated application, as directed by the Atomic Safety and Licensing Board. In addition, at that time the applicant shall serve a copy of the updated application on the Atomic Safety and Licensing Appeal Panel. Any subsequent amendment to the application must be served on those served copies of the application and must be submitted to the U. S. Nuclear Regulatory Commission as specified in §53.4.
(4) The applicant must make a copy of the updated application available at the public hearing for the use of any other parties to the proceeding, and shall certify that the updated copies of the application contain the current contents of the application submitted in accordance with the requirements of this part.
(5) At the time of filing of an application, the Commission will make available at the NRC Web site, http://www.nrc.gov, a copy of the application, subsequent amendments, and other records pertinent to the facility for public inspection and copying.

(b) *Oath or affirmation.* Each application for a license or amendment of an application must be executed in a signed original by the applicant or duly authorized officer thereof under oath or affirmation.

(c) *Application for operating licenses.* The holder of a COL for a power reactor shall, at the time of submission of the final safety analysis report, file an application for an operating license or an amendment to an application for a COL, as appropriate. The application or amendment shall state the name of the applicant, the name, location and power level of the facility and the time when the facility is expected to be ready for operation, and may incorporate by reference any pertinent information submitted in accordance with §53.73 with the application for a COL.

(d) *Filing fees.* Each application for a production facility license shall be accompanied by the fee prescribed by Part 170 of this chapter. No fee will be required to accompany an application for renewal, amendment or termination of a license except as provided in

§170.21 of this chapter.

(e) *Environmental Report.* An application for a license for a facility whose construction or operation may be determined by the Commission to have a significant impact on the environment shall be accompanied by any Environmental Report required pursuant to Subpart A of Part 51 of this chapter.

53.71 Combining applications

An applicant may combine in one his several applications for different kinds of licenses under the regulations in this chapter.

53.72 Elimination of repetition

In the application, the applicant may incorporate by reference information contained in previous applications, statements or reports filed with the Commission: Provided, that such references are clear and specific.

53.73 Contents of applications; general information

Each application shall state:

(a) Name of applicant;
(b) Address of applicant;
(c) Description of business or occupation of applicant;
(d) (1) If applicant is an individual, state citizenship.
 (2) If applicant is a partnership, state name, citizenship and address of each partner and the principal location where the partnership does business.
 (3) If applicant is a corporation or an unincorporated association, state:
  (i) The state where it is incorporated or organized and the principal location where it does business;
  (ii) The names, addresses and citizenship of its directors and of its principal officers;
  (iii)Whether it is owned, controlled, or dominated by an alien, a foreign corporation, or foreign government, and if so, give details.

 (4) If the applicant is acting as agent or representative of another person in filing the application, identify the principal and furnish information required under this paragraph with respect to such principal.

(d) The class of license applied for, the use to which the facility will be put, and a list of other licenses, except operator's licenses, issued or applied for in connection with the proposed facility.

(e) Except for an electric utility applicant for a license to operate a power reactor facility of the type described in 10 CFR 53. 65, information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with regulations in this chapter, the activities for which the permit or license is sought. As applicable, the following should be provided:

(1) If the application is for a Combined Operating License (COL), the applicant shall submit information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs. The applicant shall submit estimates of the total construction costs of the facility and related fuel cycle costs, and shall indicate the source(s) of funds to cover these costs. The applicant shall also submit information to demonstrate that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operating costs. The applicant shall submit estimates of the estimated operating costs for the first five years of operation of the facility and the sources of funds to cover those costs.

(2) Each application for a COL submitted by a newly formed entity organized for the primary purpose of constructing and operating a facility must include information showing:

(i) The legal and financial relationship it has or proposes to have with its stockholders or owners;
(ii) Its financial ability to meet any contractual obligation to the entity which they have incurred or proposed to incur; and
(iii)Any other information considered necessary by the Commission to enable it to determine the applicant's financial qualification.

(3) The Commission may request an established entity or a newly formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility.

(f) An applicant for a COL shall submit radiological emergency response plans of State and local governmental entities in the United States that are wholly or partially within the Plume Exposure Pathway Planning Zone (offsite response area). The offsite response area shall be determined as part of the license application as required by §53.40.
(g) The earliest and latest dates for completion of facility construction.
(h) A list of the names and addresses of such regulatory agencies as may have jurisdiction over the rates and services incident to the proposed activity, and a list of trade and news publications which circulate in the area where the proposed activity will be conducted and which are considered appropriate to give reasonable notice of the application to those municipalities, private utilities, public bodies, and cooperatives, which might have a potential interest in the facility.
(i) If the application contains Restricted Data or other defense information, it shall be prepared in such manner that all Restricted Data and other defense information are separated from the unclassified information.

(j) Information in the form of a report, as described in §53.95, indicating how reasonable assurance will be provided that funds will be available to decommission the facility.

53.74 Contents of applications; technical information

This section includes the technical information requirements for a number of licensing approaches currently recognized in 10 CFR 50 and 10 CFR 52. The technical information required will vary according to the approach used and the objective of the license application.

(a) *Applicability.* Table 53.74 – 1 defines the applicability of information required in the following sections according to the type of application.

(b) *Safety Analysis.* A preliminary or final safety analysis report shall be submitted as part of an application per Table 53.74 – 1. The PSAR or FSAR shall address the issues presented in the version of the NRC's Standard Format and Content Guide in existence 24 months prior to submittal of the application. Items (c) through (o) of this section shall be included in the application as required by Table 53.74 – 1.

(c) *Assessment of Offsite Consequences.* Each application for a license or permit shall include a preliminary or final assessment (in accordance with Table 53.74 – 1) of the offsite consequences of the events defined by §53.20. The analysis of the site, reactor, and safety features shall be performed in accordance with acceptable industry standards and must determine that the limits of §53.35 are satisfied.

(d) *Technical Assessment.* A technical assessment of the facility shall be included in the application and must address the information required by the revision of the NRC's Standard Review Plan in effect 24 months prior to submittal. The assessment shall include a description of the site and facility design. It shall include the design bases and design criteria and an analysis of how those are met with sufficient detail to allow an evaluation by the Staff that adequate protection of public health and safety will be assured. If specific sections of the Standard Review Plan are not applicable, the assessment shall include the basis and justification for an exemption to those sections of the review plan.

(e) *Licensee Organization.* A plan for the applicant's organization, training of personnel, responsibilities, personnel qualification requirements, and conduct of operations shall be included in the application as applicable per Table 53.74 – 1.

(f) *Preoperational Testing and Initial Operations.* Each COL applicant or holder of an operating license shall include the applicant's plans for preoperational testing and initial operations.

(g) *Quality Assurance Programs.* Each application shall include a description of the Quality Assurance Program for design, procurement, and construction or for operation as required by Table 53.74 – 1.

(h) *Emergency Plans.* Each application shall include the preliminary or final Emergency Plan for the facility as required by Table 53.74 – 1. The information contained shall meet the requirements of §53.40.

(i) *Technical Specifications.* Applications for an Operating License or COL shall include proposed Technical Specifications meeting the requirements of §53.30(l).

(j) *Research and Development Programs.* The application shall include plans for or results of Research and Development Programs, if any, needed to confirm resolve any safety issues for safety significant SSCs and the proposed dates for completion of such programs as specified in Table 53.74 – 1.

(k) *Environmental and Meteorological Monitoring Results.* Each application for an OL or COL shall include the results of meteorological and environmental monitoring required to be conducted during facility construction.

(l) *Operator Requalification Program.* Applications shall describe the plans for operator requalification as required by 10 CFR 55 and as specified in Table 53.74 – 1.

(m) *Security Plan Information.* As specified in Table 53.74 – 1, applications must include the security plan, safeguards contingency plan and safeguards information protection plan information as required by 10 CFR 73.

(n) *PRA Results.* PRA results and insights shall be included in applications as required by Table 53.74 – 1.

(o) *Codes and Standards.* The editions of nationally accepted codes and standards applicable to the design, inspection, testing and operation of safety significant SSCs shall be specified in applications per Table 53.74 – 1. Alternate methods to the standards, if proposed, should be specified in the applications.

Applicability Matrix for §53.74
Contents of Applications – Technical Information

Applic.	Prelim. Assesmt of Offsite Doses	Final Assesmt of Offsite Doses	Technical Assessmt per SRP*	Prelim. Plan for Licensee Orgnztn.	Final Licensee Organization		
50.34 Ref	(a)(1)(ii)	(b)(11)	(g)	(a)(6)	(b)(6)		
53.74 Ref	(c)	(c)	(d)	(e)	(e)		
ESP	x						
Des Cert			x				
COL	x	x	x		x		
OL		x	x		x		

Applic.	R & D Plans	R & D Results	Results of Environment Meteorological Monitoring	Operator Requalification Prog.	Security Plan Info
50.34 Ref	(a)(8)	(b)(5)	(b)(1)	(b)(8)	(c), (d), (e)
53.74 Ref	(j)	(j)	(k)	(l)	(m)
ESP					
Des Cert	x				
COL		x	x	x	x
OL		x	x	x	x

Applic.	Pre Op/Start Up Test	Design, Construction, Procurement, QA Program	Operations QA Program	Preliminary Emergency Plan	Final Emergency Plan	Proposed Tech Specs
50.34 Ref	(b)(6)	(a)(7)	(b)(6)	(a)(10)	(b)(6)	(b)(6)
53.74 Ref	(f)	(g)	(g)	(h)	(h)	(i)
ESP				x		
Des Cert		x				
COL	x	x	x		x	x
OL	x		x		x	x

Applic.	Preliminary PRA Results	Final PRA Results	PSAR	FSAR	Codes and Standards
50.34 Ref	N/A	n/a	(a)	(b)	n/a
53.74 Ref	(n)	(n)	(b)	(b)	(o)
ESP			x		
Des Cert	x			x	x
COL		x		x	x
OL		x		x	x

Fig. 53.74-1

53.75 Transfer of licenses

(a) No license issued under this part, or any right thereunder, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission shall give its consent in writing.

(b) An application for transfer of a license shall include as much of the information described in §53.73 and §53.74 of this Part with respect to the identity and technical and financial qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. The Commission may require additional information such as data respecting proposed safeguards against hazards from radioactive materials and the applicant's qualifications to protect against such hazards. The application shall include also a statement of the purposes for which the transfer of the license is requested, the nature of the transaction necessitating or making desirable the transfer of the license, and an agreement to limit access to Restricted Data pursuant to §53.50. The Commission may require any person who submits an application for a license pursuant to the provisions of this section to file a written consent from the existing licensee or a certified copy of an order or judgment of a court of competent jurisdiction attesting to the person's right (subject to the licensing requirements of the Act and these regulations) to possession of the facility involved.

(c) After appropriate notice to interested persons, including the existing licensee, and observance of such procedures as may be required by the Act or regulations or orders of the Commission, the Commission will approve an application for the transfer of a license, if the Commission determines:

(1) That the proposed transferee is qualified to be the holder of the license; and
(2) That transfer of the license is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

53.76 Termination of power reactor licenses

(a)(1) (i) When a licensee has determined to permanently cease operations, the licensee shall, within 30 days, submit a written certification to the NRC consistent with the requirements of §53.4(b)(8);
(ii) Once fuel has been permanently removed from the reactor, the licensee shall submit a written certification to the NRC that meets the requirements of 10 CFR 53.4(b)(9) and;

(2) Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel, or when a final legally effective order to permanently cease operations has come into effect, the 10 CFR 53 license no longer authorizes operation of the reactor or emplacement or retention of fuel in the reactor.
(3) Decommissioning will be completed within 60 years of permanent cessation of operations. Completion of decommissioning beyond 60 years will be approved by the Commission only when necessary to protect public health and safety. Factors that will be considered by the Commission in evaluating an alternative that provides for completion of decommissioning beyond 60 years of permanent cessation of operations include unavailability of waste disposal capacity and other site specific factors affecting the licensee's capability to carry out decommissioning, including presence of other nuclear facilities at the site.

(4)(i) Prior to or within 2 years following permanent cessation of operations, the licensee shall submit a post-shutdown decommissioning activities report (PSDAR) to the NRC, and a copy to the affected State(s). The report must include a description of the planned decommissioning activities along with a schedule for their accomplishment, an estimate of expected costs, and a discussion that provides the reasons for concluding that the environmental impacts associated with site-specific decommissioning activities will be bounded by appropriate previously issued environmental impact statements.

(ii) The NRC shall notice receipt of the PSDAR and make the PSDAR available for public comment. The NRC shall also schedule a public meeting in the vicinity of the licensee's facility upon receipt of the PSDAR. The NRC shall publish a notice in the Federal Register and in a forum, such as local newspapers, that is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

(5) Licensees shall not perform any major decommissioning activities, as defined in §53.2, until 90 days after the NRC has received the licensee's PSDAR submittal and until certifications of permanent cessation of operations and permanent removal of fuel from the reactor, as required under §53.76(a)(1), have been submitted.

(6) Licensees shall not perform any decommissioning activities, as defined in §53.2, that-

(i) Foreclose release of the site for possible unrestricted use;
(ii) Result in significant environmental impacts not previously reviewed; or
(iii)Result in there no longer being reasonable assurance that adequate funds will be available for decommissioning.

(7) In taking actions permitted under §53.31 following submittal of the PSDAR, the licensee shall notify the NRC, in writing and send a copy to the affected State(s), before performing any decommissioning activity inconsistent with, or making any significant schedule change from, those actions and schedules described in the PSDAR, including changes that significantly increase the decommissioning cost.

(8)(i) Decommissioning trust funds may be used by licensees if:

(A) The withdrawals are for expenses for legitimate decommissioning activities consistent with the definition of decommissioning in §53.2;
(B) The expenditure would not reduce the value of the decommissioning trust below an amount necessary to place and maintain the reactor in a safe storage condition if unforeseen conditions or expenses arise and;
(C) The withdrawals would not inhibit the ability of the licensee to complete funding of any shortfalls in the decommissioning trust needed to ensure the availability of funds to ultimately release the site and terminate the license.

(i) Initially, 3 percent of the generic amount specified in §53.95(a) may be used for decommissioning planning. For licensees that have submitted the certifications required under §53.76(a)(1) and commencing 90 days after the NRC has received the PSDAR, an additional 20 percent may be used. A site-specific decommissioning cost estimate must be submitted to the NRC prior to the licensee using any funding in excess of these amounts.

(ii) Within 2 years following permanent cessation of operations, if not already submitted, the licensee shall submit a site-specific decommissioning cost estimate.

(iii)For decommissioning activities that delay completion of decommissioning by including a period of storage or surveillance, the licensee shall provide a means of adjusting cost estimates and associated funding levels over the storage or surveillance period.

(9) All licensees must submit an application for termination of license. The application for termination of license must be accompanied or preceded by a license termination plan to be submitted for NRC approval.

(i) The license termination plan must be a supplement to the FSAR or equivalent and must be submitted at least two years before termination of the license date.

(ii) The license termination plan must include –

(A) A site characterization;
(B) Identification of remaining dismantlement activities;
(C) Plans for site remediation;
(D) Detailed plans for the final radiation survey;
(E) A description of the end use of the site, if restricted;
(F) An updated site specific estimate of remaining decommissioning costs; and
(G) A supplement to the environmental report, pursuant to §51.53, describing any new information or significant environmental change associated with the licensee's proposed termination activities.

(iii)The NRC shall notice receipt of the license termination plan and make the license termination plan available for public comment. The NRC shall also schedule a public meeting in the vicinity of the licensee's facility upon receipt of the license termination plan. The NRC shall publish a notice in the Federal Register and in a forum, such as local newspapers, which is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

(10) If the license termination plan demonstrates that the remainder of decommissioning activities will be performed in accordance with the regulations in this chapter, will not be inimical to the common defense and security or to the health and safety of the public, and will not have a significant effect on the quality of the environment and after notice to interested persons, the Commission shall approve the plan, by license amendment, subject to such conditions and limitations as it deems

appropriate and necessary and authorize implementation of the license termination plan.

(11) The Commission shall terminate the license if it determines that:

(i) The remaining dismantlement has been performed in accordance with the approved license termination plan, and
(ii) The terminal radiation survey and associated documentation demonstrates that the facility and site are suitable for release in accordance with the criteria for decommissioning in 10 CFR 20, subpart E.

(A) For a facility that has permanently ceased operation before the expiration of its license, the collection period for any shortfall of funds will be determined, upon application by the licensee, on a case-by-case basis taking into account the specific financial situation of each licensee.

53.77 Amendment to a license

(a) *Issuance of an Amendment*

(1) In determining whether an amendment to a license for a facility under this Part will be issued to the applicant, the Commission will be guided by the considerations, which govern the issuance of initial licenses to the extent applicable and appropriate. If the amendment involves a significant hazards consideration, the Commission will give notice of its proposed action (1) pursuant to section 2.105 of this part before acting thereon and (2) as soon as practicable after the application has been docketed.
(2) The Commission will be particularly sensitive to a license amendment request that involves irreversible consequences (such as one that permits a significant increase in the amount of effluents or radiation emitted by a nuclear facility).
(3) The Commission may make a final determination, pursuant to the procedures in section 53.28, that a proposed amendment to a license for a facility licensed under this part involves no significant hazards consideration, if operation of the facility in accordance with the proposed amendment would not:

(i) Involve a significant increase in the frequency of occurrence of any initiating event (as defined in §53.71) from that documented in the SAR (as updated);
(ii) Involve a significant increase in the offsite doses from any Initiating Event;
(iii)Create the possibility of a new or different kind of initiating event from any evaluated in the SAR (as updated); or
(iv) Result in a significant increase to the design basis limit for any fission product barrier.

53.78 Public notice and state consultations on license amendments

(a) *Notice for public comment.*

(1) At the time a licensee requests an amendment, it must provide to the Commission, in accordance with the distribution requirements specified in §53.4, its analysis about the issue of no significant hazards consideration using the standards in §53.77a(3)(i).

(2) (i) The Commission may publish in the Federal Register under §2.105 an individual notice of proposed action for an amendment for which it makes a proposed determination that no significant hazards consideration is involved, or, at least once every 30 days, publish a periodic Federal Register notice of proposed actions which identifies each amendment issued and each amendment proposed to be issued since the last such periodic notice, or it may publish both such notices.

(ii) For each amendment proposed to be issued, the notice will:

(A) contain the staff's proposed determination, under the standards in §53.77a,

(B) provide a brief description of the amendment and of the facility involved,

(C) solicit public comments on the proposed determination, and

(D) provide for a 30-day comment period.

(iii)The comment period will begin on the day after the date of the publication of the first notice, and, normally, the amendment will not be granted until after this comment period expires.

(3) The Commission may inform the public about the final disposition of an amendment request for which it has made a proposed determination of no significant hazards consideration either by issuing an individual notice of issuance under §2.106 of this chapter or by publishing such a notice in its periodic system of Federal Register notices. In either event, it will not make and will not publish a final determination on no significant hazards consideration, unless it receives a request for a hearing on that amendment request.

(4) Where the Commission makes a final determination that no significant hazards consideration is involved and that the amendment should be issued, the amendment will be effective upon issuance, even if adverse public comments have been received and even if an interested person meeting the provisions for intervention called for in §2.714 of this chapter has filed a request for hearing. The Commission need hold any required hearing only after it issues an amendment, unless it determines that a significant hazards consideration is involved in which case the Commission will provide an opportunity for a prior hearing.

(5) Where the Commission finds that an emergency situation exists, in that failure to act in a timely way would result in derating or shutdown of a nuclear facility, or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, it may issue a license amendment involving no significant hazards consideration without prior notice and opportunity for a hearing or

for public comment. In such a situation, the Commission will not publish a notice of proposed determination of no significant hazards consideration, but will publish a notice of issuance under §2.106 of this chapter, providing for opportunity for a hearing and for public comment after issuance. The Commission expects its licensees to apply for license amendments in timely fashion. It will decline to dispense with notice and comment on the determination of no significant hazards consideration if it determines that the licensee has abused the emergency provision by failing to make timely application for the amendment and thus itself creating the emergency. Whenever an emergency situation exists, a licensee requesting an amendment must explain why this emergency situation occurred and why it could not avoid this situation, and the Commission will assess the licensee's reasons for failing to file an application sufficiently in advance of that event.

(6) Where the Commission finds that exigent circumstances exist, in that a licensee and the Commission must act quickly and that time does not permit the Commission to publish a Federal Register notice allowing 30 days for prior public comment, and it also determines that the amendment involves no significant hazards considerations, it:

(i)(A) Will either issue a Federal Register notice providing notice of an opportunity for hearing and allowing at least two weeks from the date of the notice for prior public comment, or;

(B) Will use local media to provide reasonable notice to the public in the area surrounding a licensee's facility of the licensee's amendment and of its proposed determination as described in paragraph (a)(2) of this section, consulting with the licensee on the proposed media release and on the geographical area of its coverage;

(ii) Will provide for a reasonable opportunity for the public to comment, using its best efforts to make available to the public whatever means of communication it can for the public to respond quickly, and, in the case of telephone comments, have these comments recorded or transcribed as necessary and appropriate;

(iii) When it has issued a local media release, may inform the licensee of the public's comments, as necessary and appropriate;

(iv) Will publish a notice of issuance under §2.106;

(v) Will provide a hearing after issuance, if one has been requested by a person who satisfies the provisions for intervention called for in §2.714 of this chapter;

(vi) Will require the licensee to explain the exigency and why the licensee cannot avoid it, and use its normal public notice and comment procedures in paragraph (a)(2) of this section if it determines that the licensee has failed to use its best efforts to make a timely application for the amendment in order to create the exigency and to take advantage of this procedure.

(7) Where the Commission finds that significant hazards considerations are involved, it will issue a Federal Register notice providing an opportunity for a prior hearing even in an emergency situation, unless it finds an imminent danger to the health or safety

of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2

(a) *State consultation.*

(1) At the time a licensee requests an amendment, it must notify the State in which its facility is located of its request by providing that state with a copy of its application and its reasoned analysis about no significant hazards considerations and indicate on the application that it has done so. (The Commission will make available to the licensee the name of the appropriate State official designated to receive such amendments.

(2) The Commission will advise the State of its proposed determination about no significant hazards consideration normally by sending it a copy of the Federal Register notice.

(3) The Commission will make available to the State official designated to consult with it about its proposed determination the names of the Project Manager or other NRC personnel it designated to consult with the State. The Commission will consider any comments of that State official. If it does not hear from the State in a timely manner, it will consider that the State has no interest in its determination; nonetheless, to ensure the State is aware of the application, before it issues the amendment, it will make a good faith effort to telephone that official. (Inability to consult with a responsible State official following good faith attempts will not prevent the Commission from making effective a license amendment involving no significant hazards consideration.)

(4) The Commission will make a good faith attempt to consult with the State before it issues a license amendment involving no significant hazards consideration. If, however, it does not have time to use its normal consultation procedures because of an emergency situation, it will attempt to telephone the appropriate State official. (Inability to consult with a responsible State official following good faith attempts will not prevent the Commission from making effective a license amendment involving no significant hazards consideration, if the Commission deems it necessary in an emergency situation.)

(5) After the Commission issues the requested amendment, it will send a copy of its determination to the State.

(c) *Caveats about State consultation.*

(1) The State consultation procedures in paragraph (b) of this section do not give the State a right:

(i) To veto the Commission's proposed or final determination;
(ii) To a hearing on the determination before the amendment becomes effective; or

(iii) To insist upon a postponement of the determination or upon issuance of the amendment.

(2) These procedures do not alter present provisions of law that reserve to the Commission exclusive responsibility for setting and enforcing radiological health and safety requirements for nuclear facilities.

53.79 Revocation, suspension, modification of licenses for cause

A license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application for license or in the supplemental or other statement of fact required of the applicant; or because of conditions revealed by the application for license or statement of fact or any report, record, inspection, or other means, which would warrant the Commission to refuse to grant a license on an original application; or for failure to construct or operate a facility in accordance with the terms of the license, provided that failure to make timely completion of the proposed construction or alteration of a facility under a COL shall be governed by the provisions of §53.83; or for violation of, or failure to observe, any of the terms and provisions of the Act, regulations, license, permit, or order of the Commission.

53.80 Retaking possession of special nuclear material.

Upon revocation of a license, the Commission may immediately cause the retaking of possession of all nuclear material held by the licensee.

53.81 Commission order for operation after revocation

Whenever the Commission finds that the public convenience and necessity requires continued operation of a power reactor facility, the license for which has been revoked, the Commission may, after consultation with the appropriate federal or State regulatory agency having jurisdiction, order that possession be taken of such facility and that it be operated for a period of time as, in the judgment of the Commission, the public convenience and necessity may require, or until a license for operation of the facility shall become effective. Just compensation shall be paid for the use of the facility.

53.82 Suspension and operation in war or national emergency

(a) Whenever Congress declares that a state of war or national emergency exists, the Commission, if it finds it necessary to the common defense and security, may,

(1) Suspend any license it has issued;
(2) Cause the recapture of special nuclear material;
(3) Order the operation of any licensed facility or
(4) Order entry into any plant or facility in order to recapture special nuclear material or to operate the facility.

(b) Just compensation shall be paid for any damages caused by recapture of special nuclear material or by operation of the facility, pursuant to this section.

53.83 License conditions

Whether stated therein or not, the following shall be deemed conditions of each license issued under this part:

(a) No right to the special nuclear material shall be conferred by the licensee except as may be defined by the license.

(b) Neither the license, nor any right thereunder, nor any right to utilize or produce special nuclear material shall be transferred, assigned, or disposed of in any manner, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the act and give its consent in writing.

(c) The license shall be subject to suspension and to the rights of recapture of the material or control of the facility reserved to the Commission under section 108 of the Act in a state of war or national emergency declared by congress.

(d) The license shall be subject to revocation, suspension, modification, or amendment for cause as provided in the act and regulations, in accordance with the procedures provided by the act and regulations.

(e) The licensee shall at any time before expiration of the license, upon request of the Commission, submit, as specified in section 53.4, written statements to enable the Commission to determine whether or not the license should be modified, suspended or revoked. The NRC must prepare the reasons for each information request prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. The Executive Director must approve each such justification provided for an evaluation performed by the NRC staff for Operations or his or her designee prior to issuance of the request.

(f) The license shall be subject to the provisions of the Act now or hereafter in effect and to all rules, regulations, and orders of the Commission. The terms and conditions of the license shall be subject to amendment, revision, or modification, by reason of amendments of the Act or by reason of rules, regulations and orders issued in accordance with the terms of the Act.

(g) Each licensed facility shall be continuously staffed by licensed (per 10 CFR 55) reactor operators and senior reactor operators as described in the license application.

(h) Each licensee shall take reasonable steps to obtain insurance available at reasonable costs and on reasonable terms from private sources or to demonstrate to the satisfaction of the NRC that it possesses an equivalent amount of protection covering the licensees obligation, in the event of an accident at the licensee's reactor, to stabilize and decontaminate the reactor and the reactor station site at which the reactor experiencing the accident is located, provided that:

(1) The insurance required by this paragraph must have a minimum coverage limit for each reactor site of either $1.06 billion or whatever amount of insurance is generally available from private sources, whichever is less. The required insurance must clearly state that, as and to the extent provided in paragraph (h)(4) of this section, any proceeds must be payable first for stabilization of the reactor and next for decontamination of the reactor and the reactor station site. If a licensee's coverage falls below the required minimum, the licensee shall within 60 days take all reasonable steps to restore its coverage to the required minimum. The required insurance may, at the option of the licensee, be included within policies that also provide coverage for other risks, including, but not limited to, the risk of direct physical damage.

(2)(i) With respect to policies issued or annually renewed on or after XXXX,xx, 2005, the proceeds of such required insurance must be dedicated, as and to the extent provided in this paragraph, to reimbursement or payment on behalf of the insured of reasonable expenses incurred or estimated to be incurred by the licensee in taking action to fulfill the licensee's obligation, in the event of an accident at the licensee's reactor, to ensure that the reactor is in, or is returned to, and maintained in, a safe and stable condition and that radioactive contamination is removed or controlled such that personnel exposures are consistent with the occupational exposure limits in 10 CFR part 20. These actions must be consistent with any other obligation the licensee may have under this chapter and must be subject to paragraph (h)(4) of this section. As used in this section, an "accident" means an event that involves the release of radioactive material from its intended place of confinement within the reactor or on the reactor station site such that there is a present danger of release off site in amounts that would pose a threat to the public health and safety.

(ii) The stabilization and decontamination requirements set forth in paragraph (h)(4) of this section must apply uniformly to all insurance policies required under paragraph (h) of this section.

(3) The licensee shall report to the NRC on April 1 of each year the current levels of this insurance or financial security it maintains and the sources of this insurance or financial security

(4) In the event of an accident at the licensee's reactor, whenever the estimated costs of stabilizing the reactor and of decontaminating the reactor and the reactor site exceed $100 million, the proceeds of the insurance required by paragraph (h) of this section must be dedicated to and used, first, to ensure that the reactor is in, or is returned to,

and can be maintained in, a safe and stable condition so as to prevent any significant risk to the public health and safety and, second, to decontaminate the reactor and reactor site in accordance with the licensee's detailed cleanup plan as approved by order of the Director of the Office of Nuclear Reactor Regulation. The plan will include the details of actions to be completed and the requirements for communicating results of the actions to NRC.

(i) A licensee may take reasonable action that departs from a license condition, technical specification or configuration control requirement in an emergency when this action is immediately needed to protect public health and safety or to implement national security objectives in a national emergency. These actions may only be taken when equivalent actions allowed by the technical specifications, license conditions or configuration control requirements are not immediately apparent.

(j) Licensee action under paragraph *(i)* of this section shall be approved, as a minimum, by a licensed senior operator, or, at a nuclear power reactor facility for which the certifications required under §53.76 have been submitted, by either a licensed senior operator or a certified fuel handler, prior to taking the action.

(k) The licensee shall, within 2 years following permanent cessation of operation of the reactor or 5 years before expiration of the reactor operating license, whichever occurs first, submit written notification to the Commission for its review and preliminary approval of the program for funding the management of all irradiated fuel at the affected power plant units. The program shall be designed to manage the irradiated fuel until the title to the irradiated fuel and possession of the fuel is transferred to the Secretary of Energy for its ultimate disposal. Final Commission review will be undertaken as part of any proceeding for continued licensing under this part or part 72 of this chapter. The licensee must demonstrate to NRC that the elected actions will be consistent with NRC requirements for licensed possession of irradiated nuclear fuel and that the actions will be implemented on a timely basis. Where implementation of such actions requires NRC authorizations, the licensee shall verify in the notification that submittals for such actions have been or will be made to NRC and shall identify them. A copy of the notification shall be retained by the licensee as a record until expiration of the reactor operating license. The licensee shall notify the NRC of any significant changes in the proposed waste management program as described in the initial notification.

(l)(1) Each licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy. Each licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against:

(i) The licensee;

(ii) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(iii)An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(2) This notification must indicate:
   (i) The bankruptcy court in which the petition for bankruptcy was filed; and
   (ii) The date of the filing of the petition.

(m) Each license issued under this part authorizing the possession of byproduct and special nuclear material produced in the operation of the licensed reactor includes, whether stated in the license or not, the authorization to receive back that same material, in the same or altered form or combined with byproduct or special nuclear material produced in the operation of another reactor of the same licensee located at that site, from a licensee of the Commission or an agreement State, or from a non-licensed entity authorized to possess the material.

(n) Plants licensed under this part are required to shut down as provided in section 53.30 following certain environmental events. Prior to resuming operations following a shutdown required by this part, the licensee shall demonstrate to the Commission that no functional damage has occurred to those features necessary for continued operation without undue risk to the health and safety of the public and that there is reasonable assurance that the safety-significant functions will be satisfied.

53.85 Combining licenses

The Commission may combine in a single license the activities of an applicant that would otherwise be licensed severally.

53.86 Common standards

(a) In determining that a license will be issued to an applicant, the Commission will be guided by the following considerations:

   (1) The processes to be performed, the operating procedures, the facility or power plant unit and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the foregoing collectively provide reasonable assurance that the applicant will comply with the regulations in this chapter and that the public will not be endangered.
   (2) The applicant is technically and financially qualified to engage in the proposed activities in accordance with the regulations in this chapter. However, no consideration of financial qualification is necessary for an electric utility applicant for an operating license of the type described in §53.65.
   (3) Due account will be taken of the advice provided by the Attorney General, under subsection 105c of the Act, and to any evidence that may be provided during any proceedings in connection with the antitrust aspects.

      (i) For this purpose, the Commission will promptly transmit to the Attorney General a copy of the application for a license under this part. The Commission will request any advice as the Attorney General considers appropriate in regard to the finding to be made by the Commission as to whether the proposed license would create or maintain a situation inconsistent with the antitrust laws, as specified in subsection 105a of the Act. This requirement will not apply with respect to an application, which the Commission, with the approval of the Attorney General, may determine would not significantly affect the applicant's activities under the antitrust laws; and

(ii) The Commission will publish any advice it receives from the Attorney General in the Federal Register. After considering the antitrust aspects of the application, the Commission, if it finds that the license to be issued or continued, would create or maintain a situation inconsistent with the antitrust laws specified subsection 105a of the Act, will consider, in determining whether a license should be issued, other factors the Commission considers necessary to protect the public interest.

(4) The issuance of a license to the applicant will not, in the opinion of the Commission, be inimical to the common defense and security or to the health and safety of the public.

(b) Any applicable requirements of subpart A of part 51 have been satisfied.

(c) In addition the NRC will:

(1) Give notice in writing of each application to the regulatory agency or State as may have jurisdiction over the rates and services incident to the proposed activity;
(2) Publish notice of the application in trade or news publications as it deems appropriate to give reasonable notice to municipalities, private utilities, public bodies, and cooperatives which might have a potential interest in the power plant; and
(3) Not issue a license prior to the giving of this notice and until 4 weeks after the notice is published in the Federal Register.

(d) The licensee who transmits electric energy in interstate commerce, or sells it at wholesale in interstate commerce, shall be subject to the regulatory provisions of the Federal Power Act.

(e) Nothing herein shall preclude any government agency, now or hereafter authorized by law to engage in the production, marketing, or distribution of electric energy, if otherwise qualified, from obtaining a license for the construction and operation of a power reactor for the primary purpose of producing electric energy for disposition for ultimate public consumption.

53.87 Issuance of combined licenses

(a) Pursuant to 10 CFR 52.97, a Combined Operating License (COL) may be issued by the Commission upon finding that:

(1) The facility will operate in conformity with the application, as amended, the provisions of the Act, and the rules and regulations of the Commission; and

(2) There is reasonable assurance (i) that the activities authorized by the COL can be conducted without endangering the health and safety of the public, and (ii) that such activities will be conducted in compliance with the regulations in this chapter; and

(3) The applicant is technically and financially qualified to engage in the activities authorized by the COL in accordance with the regulations in this chapter.

(4) The applicable provisions of Part 140 of this chapter have been satisfied; and

(5) The issuance of the license will not be inimical to the common defense and security or to the health and safety of the public.

53.88 Selective Implementation

(a) The holder of a power reactor license under Part 50 or Part 52 may apply for the use of specific sections of this Part in lieu of the equivalent regulations of Part 50 or Part 52, as amended.

(b) The application under this section shall consist of an analysis of the regulatory equivalency of the regulations in the Part 53 subsection(s) and the replaced regulations of Part 50 and Part 52 for the facility.

(c) Applications under this section must include the entire section or rule of Part 53, e.g., Radiation Protection, shall include the adoption and compliance with §53.33, §53.34, and §53.35, and not just §53.35, or specific paragraphs in §53.34 and §53.33.

(d) Licensees under Parts 50 and 52 applying under this section will follow the same procedures as COL applicants. The use of the term "applicant" in this part applies to license holders utilizing this section as well as license applicants.

(e) Subpart A of this Part will apply to all licensees implementing this section.

(f) Upon completion of the review and approval of an application under this section, the Commission will issue a license amendment to the licensee indicating the regulations in Part 53 that apply to the license and the regulations in Part 50 or Part 52 that no longer apply.

<u>Reporting And Notification</u>

53.90 Documentation update requirements

(a) Each licensee shall maintain all records and make all reports, in connection with the activity, as may be required by the conditions of the license, or by the rules, regulations, and orders of the Commission in effectuating the purposes of the Act, including section

105 of the Act. Reports must be submitted in accordance with §53.4.

(b) Records that are required by the regulations in this part or by license condition must be retained for the period specified by the appropriate regulation, license condition, or technical specification. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the license.

(c)(1) Records, which must be retained pursuant to this part, may be the originals or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(2) If there is a conflict between the Commission's regulations in this part, license condition, or technical specification, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations for this part for such records shall apply unless the Commission, pursuant to §53.62 of this Part, has granted a specific exemption from the record retention requirements specified in the regulations in this part.

(d) (1) Each licensee under this part shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of an application, to assure that the information included in the report contains the latest information developed. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submittal of the original FSAR, or as appropriate, the last update to the FSAR under this section. The submittal shall include the effects of: All changes made in the facility or procedures as described in the FSAR; all safety analyses and evaluations performed by the licensee either in support of approved license amendments, or in support of conclusions that changes did not require a license amendment in accordance with §53.31(b)(2) of this part; and all analyses of new safety issues performed by or on behalf of the licensee at Commission request. The updated information shall be appropriately located within the update to the FSAR.

(2) The licensee shall submit revisions containing updated information to the Commission, as specified in §53.4, on a replacement page basis that is accompanied by a list, which identifies the current pages of the FSAR following page replacement.

(3) The submittal shall include (i) a certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the

previous submittal, necessary to reflect the information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made: and (ii) an identification of changes made under the provisions of §53.31 but not previously submitted to the Commission.

(4) A revision of the original FSAR consisting of updated replacement pages shall be filed within 24 months of the issuance of the license and shall bring the FSAR up to date as of a maximum of 6 months prior to the date of filing the revision.

(5) Subsequent revisions must be filed at least once every 24 months. The revisions must reflect all changes up to a maximum of 6 months prior to the date of the filing.

(6) Each replacement page shall include both a change indicator for the area changed, e.g., a bold line vertically drawn in the margin adjacent to the portion actually changed, and a page change identification (date of change or change number or both).

(7) The licensee shall retain the updated FSAR until the Commission terminates the license.

53.91 Notifications

(a) *General Requirements.*

(1) Each licensee under this part shall notify the NRC Operations Center via the Emergency Notification System of:

(i) The declaration of any of the Emergency Classes specified in the licensee's approved Emergency Plan; or
(ii) Those non-emergency events specified in paragraph (b) of this section that occurred within three years of the date of discovery.

(2) If the Emergency Notification System is inoperative, the licensee shall make the required notifications via commercial telephone service, or other dedicated telephone system, or any other method which will ensure that a report is made as soon as practical to the NRC Operations Center.

(3) The licensee shall notify the NRC immediately after notification of the appropriate State or local agencies and not later than one hour after the licensee declares one of the Emergency Classes.

(4) The licensee shall activate the Emergency Response Data System (ERDS) as soon as possible but not later than one hour after declaring an Emergency Class of alert, site area emergency, or general emergency. The ERDS may also be activated by the licensee during emergency drills or exercises if the licensee's computer system has the capability to transmit the exercise data.

(5) When making a report under paragraph (a)(1) of this section, the licensee shall identify:

(i) The Emergency Class declared; or
(ii) Paragraph (b)(1), "One-hour reports," paragraph (b)(2), "Four-hour reports," or paragraph (b)(3), "Eight-hour reports," as the paragraph of this section requiring notification of the non-emergency event.

(b) Non-emergency events.

(1) *One-hour reports.* If not reported as a declaration of an emergency class under paragraph (a) of this section, the licensee shall notify the NRC as soon as practical and in all cases within one hour of the occurrence of any deviation from the plant's Technical Specifications authorized pursuant to §53.83(i) of this part.

(2) *Four-hour reports.* If not reported under paragraphs (a) or (b)(1) of this section, the licensee shall notify the NRC as soon as practical and in all cases, within four hours of the occurrence of any of the following:

(i) The initiation of any plant shutdown required by the plant's Technical Specifications.
(ii) Any event that results in the actuation of a mitigation system as defined in §53.21 due to a valid initiation signal resulting from an actual transient or accident condition.
(iii)Any event or condition that results in actuation of the reactor protection system when the reactor is critical resulting from an actual transient or accident condition
(iv)Any event or situation, related to the health and safety of the public or onsite personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made.

(3) *Eight-hour reports.* If not reported under paragraphs (a), (b)(1) or (b)(2) of this section, the licensee shall notify the NRC as soon as practical and in all cases within eight hours of the occurrence of any of the following:

(i) Any event or condition that results in:

(A) A power plant unit, including its principal safety barriers, being seriously degraded; or
(B) A power plant unit being in an unanalyzed condition that significantly degrades plant safety.

(ii) Any event requiring the transport of a radioactively contaminated person to an off-site medical facility for treatment.
(iii)Any event that results in a major loss of emergency assessment capability, offsite response capability, or offsite communications capability (e.g., significant portion

of control room indication, Emergency Notification System, or offsite notification system).

53.92 Reporting Requirements

(a) License event reports

(1) *Reportable events*

The holder of an operating license for a nuclear facility (licensee) shall submit a Licensee Event Report (LER) within 60 days after the discovery of a safety-significant event that resulted in, or would have resulted in a failure of a safety-significant function. Events include cases of procedural error, equipment failure, and/or discovery of a design, analysis, fabrication, construction, and/or procedural inadequacy that would have resulted in a safety-significant event. The identification of safety-significant events that would have resulted in a failure to satisfy a safety-significant function within three years of the date of discovery regardless of the plant mode or power level shall be reported.

Individual component failures need not be reported if redundant equipment in the same system was operable and available to perform the required safety-significant function. Licensees are not required to report an event if the event results from:

(i) A shared dependency among trains or channels that is a natural or expected consequence of the approved plant design; or

(ii) Normal and expected wear or degradation.

(2) Reportable events include:

(i) (A) The completion of any nuclear plant shutdown required by §53.30,

(B) Any operation or condition that was prohibited by the plant's Technical Specifications except when the Technical Specification is administrative in nature.

(ii) A safety-significant event or condition that resulted in:

(A) A condition of the nuclear facility, including the principal safety barriers, that would have directly resulted in a failure of a safety-significant function; or

(B) The nuclear facility being in an unanalyzed condition that concluded that a safety-significant function would not have been satisfied;

(iii) Any natural phenomenon or other external condition, including a toxic or radioactive release from the plant or other industrial facilities that posed an actual threat to the safety of the nuclear power plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the nuclear facility.

(iv)(A) Any airborne radioactive release that, when averaged over a time period of 1 hour, resulted in airborne radionuclide concentrations in an unrestricted area that exceeded 20 times the applicable concentration limits specified in appendix B to part 20, table 2, column 1.

(B) Any liquid effluent release that, when averaged over a time period of 1 hour, exceeds 20 times the applicable concentrations specified in appendix B to part 20, table 2, column 2, at the point of entry into the receiving waters (i.e., unrestricted area) for all radionuclides except tritium and dissolved noble gases.

53.93 Notification of Change in Operator or Senior Operator Status

Each licensee shall notify the Commission in accordance with §53.4 within 30 days of the following in regard to a licensed operator or senior operator:

(a) Permanent reassignment from the position for which the licensee has certified the need for a licensed operator or senior operator under §55.31(a)(3) of this chapter;

(b) Termination of any operator or senior operator;

(c) Permanent disability or illness as described in §55.25 of this chapter.

Financial Considerations

53.95 Financial assurance for decommissioning

(a) This section establishes requirements for indicating to NRC how a licensee will provide reasonable assurance that funds will be available for decommissioning a licensee's power reactor. The funding for the decommissioning of power reactors may also be subject to the regulation of Federal or State Government agencies (e.g., Federal Energy Regulatory Commission (FERC) and State Public Utility Commissions) that have jurisdiction over rate regulation. The requirements of this section are in addition to, and not substitution for, other requirements, and shall not intended to be used, by themselves, by other agencies to establish rates.

(b) Each power reactor applicant for or holder of an operating license shall submit a decommissioning report, as required by §53.73(k) of this part.

(1) The report must contain a certification that financial assurance for decommissioning will be (for an applicant) or has been provided (for a licensee) in an amount not less than the amount estimated by the licensee and approved by the Commission.

(2) The decommissioning amount and estimate shall be adjusted annually and include an adjustment for estimated labor and energy costs and for high and low level radioactive waste disposal as determined by NRC approved escalation factors.

(3) A biennial report shall be made by the licensee to the NRC on the status of its decommissioning funding for each reactor or part of a reactor that it owns. The information in this report must include: the amount of decommissioning funds

estimated to be required; the amount accumulated to the end of the calendar year preceding the date of the report; a schedule of the annual amounts remaining to be collected; the assumptions used regarding rates of escalation in decommissioning costs, rates of earnings on decommissioning funds, and rates of other factors used in funding projections; any contracts upon which the licensee is relying pursuant to paragraph (c)(1)(v) of this section; and any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and any material changes to trust agreements.

(4) The decommissioning amount and estimates must use one or more of the methods described in paragraph (c) of this section as acceptable to the NRC.

(5) The amount stated in the applicant's or licensee's certification may be based on a cost estimate for decommissioning the facility. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of paragraph (c) of this section must be submitted to NRC.

(c)(1) Financial assurance shall be provided by one of the following methods, or a combination of the methods described in this paragraph. The methods shall take into consideration the designed operating life of the reactor systems that, for these estimates, shall not exceed 60 years, and shall make an assumption on the extent of any safe store period, which shall not exceed 60 years. A licensee may take credit for projected earnings on the prepaid decommissioning trust funds using up to a 2 percent annual real rate of return from the time of future funds' collection through the projected decommissioning period. This includes the periods of safe storage, final dismantlement, and license termination. Actual earnings on existing funds may be used to calculate future fund needs.

(i) *Prepayment*: Prepayment is the deposit made before initial reactor critical operations into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs at the time decommissioning activities are expected to start. Prepayment may be in the form of a trust, escrow account, Government fund, certificate of deposit, deposit of Government securities or other payment acceptable to the NRC.

(ii) *External sinking fund*: An external sinking fund is a fund established and maintained by setting funds aside periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, Government fund, certificate of deposit, deposit of Government securities, or other payment acceptable to the NRC. Actual earnings on existing funds may be used to calculate future fund needs. This method may be used as the exclusive, or as a partial mechanism to cover the estimated costs for decommissioning. A licensee may make use of this method only for that portion of such costs that are collected in one of the manners described in the following circumstances:

(A) By a licensee that recovers, either directly or indirectly, the estimated total cost of decommissioning through rates established by "cost of service" or similar ratemaking regulation. Public utility districts, municipalities, rural electric cooperatives, and State and Federal agencies, including associations of any of the foregoing, that establish their own rates and are able to recover their cost of service allocable to decommissioning, are assumed to meet this condition.

(B) By a licensee whose source of revenues for its external sinking fund is a "non-bypassable charge," the total amount of which will provide funds estimated to be needed for decommissioning.

(C) By a licensee that qualifies as an Exempt Wholesale Generator as defined in Section 32 of the Public Utility Holding Company Act of 1935, as amended, and that provides information to the Commission:

(1) Sufficient to provide reasonable assurance that funding can be obtained to cover payments into the fund from specific contracts or from estimated revenues;

(2) Indicating that the licensee or the parent company has sufficient financial assets not associated with the facility under review to make payments into the fund sufficient to cover the decommissioning estimate taking into consideration the designed life of the reactor systems and any safe store period, and

(3) Giving estimated operating costs for the next five years of operation of the facility and the sources of funds to cover those costs until payments to the fund are terminated.

(iii) *A surety method, insurance or other guarantee method*:

(A) These methods shall guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(1) The surety method or insurance must be open-ended, or, if written for a specified term, such as 5 years, must be renewed automatically, unless 90 days or more prior to the renewal day the issuer notifies the NRC, the beneficiary, and the licensee of its intention not to renew. If a specified time is used, it shall not exceed the length of time defined by the remaining operational design-life of the reactor system plus a 60-year safe store period. The surety or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the NRC within 90 days after receipt of notification of cancellation.

(2) The surety or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the NRC. An acceptable trustee includes an appropriate State or Federal government agency or an entity that has the authority to act as a trustee

and whose trust operations are regulated and examined by a Federal or State agency.

(iv) For a power reactor licensee that is a Federal licensee, or for a non-power reactor licensee that is a Federal, State, or local government licensee, a statement of intent containing a cost estimate for decommissioning, and indicating that funds for decommissioning will be obtained, when necessary.

(v) Contractual obligation(s) on the part of a licensee's customer(s), the total amount of which over the duration of the contract(s) will provide the licensee's total share of uncollected funds estimated to be needed for decommissioning. To be acceptable to the NRC as a method of decommissioning funding assurance, the terms of the contract(s) shall include provisions that the electricity buyer(s) will pay for the decommissioning obligations specified in the contract(s), notwithstanding the operational status either of the licensed power reactor to which the contract(s) pertains or force majeure provisions. All proceeds from the contract(s) for decommissioning funding will be deposited to the external sinking fund. The NRC reserves the right to evaluate the terms of any contract(s) and the financial qualifications of the contracting entity(ies) offered as assurance for decommissioning funding.

(vi) Any other mechanism, or combination of mechanisms, that provides, as determined by the NRC upon its evaluation of the specific circumstances of each licensee submittal, assurance of decommissioning funding equivalent to that provided by the mechanisms specified in paragraphs (c)(1)(i) through (v) of this section.

(2) The NRC reserves the right to take the following steps in order to ensure a licensee's adequate accumulation of decommissioning funds: review, as needed, the rate of accumulation of decommissioning funds; and, either independently, or in cooperation with the FERC and the licensee's State PUC, take additional actions as appropriate on a case-by-case basis, including modification of a licensee's schedule for the accumulation of decommissioning funds.

(d)(1) Each licensee shall report to the NRC at least once every 2 years the status of its decommissioning funding for each reactor or part of a reactor that it owns. The information in this report shall include: the amount of decommissioning funds estimated to be required to decommission the reactor at the date when decommissioning activities are expected to begin; the amount accumulated to the end of the calendar year preceding the date of the report; a schedule of the annual amounts remaining to be collected; the method or methods being used to collect the funds; the assumptions used regarding rates of escalation in decommissioning costs, rates of earnings on decommissioning funds, and rates of other factors used in funding projections; any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and any material changes to trust agreements.

(2) A licensee for a plant that is within 5 years of the end of its operation, or for plants involved in mergers or acquisitions, decommissioning reports shall be submitted annually.

(e) Each licensee shall at or about 5 years prior to the projected end of operations submit a preliminary decommissioning cost estimate which includes an up-to-date assessment of the major factors that could affect the cost to decommission

(f) Each licensee shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the Commission terminates the license. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of: Records of spills or other unusual occurrences involving the spread of significant contamination in and around the facility, equipment, or site that would present a hazard to public health and safety. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

§53.96 Creditor Regulations

a) Pursuant to section 184 of the Act, the Commission consents, without individual application, to the creation of any mortgage, pledge, or other lien upon any production or utilization facility not owned by the United States which is the subject of a license or upon any leasehold or other interest in such facility: Provided that:
   (1) The rights of any creditor so secured may be exercised only in compliance with and subject to the same requirements and restrictions as would apply to the licensee pursuant to the provisions of the license, the Atomic Energy Act of 1954, as amended, and regulations issued by the Commission pursuant to said Act; and
   (2) No creditor so secured may take possession of the facility pursuant to the provisions of this section prior to either the issuance of a license from the Commission authorizing such possession or the transfer of the license.

(b) Any creditor so secured may apply for transfer of the license covering such facility by filing an application for transfer of the license pursuant to §53.75(b). The Commission will act upon such application pursuant to §53.75(c).

(c) Nothing contained in this regulation shall be deemed to affect the means of acquiring, or the priority of, any tax lien or other lien provided by law.

(d) As used in this section:
   (1) The term license includes any license, final design approval or COL which may be issued by the Commission with regard to the facility;
   (2) Creditor means, without implied limitation:
      (i) The trustee under any mortgage, pledge or lien on a facility made to secure any creditor,

(ii) Any trustee or receiver of the facility appointed by a court of competent jurisdiction in any action brought for the benefit of any creditor secured by such mortgage, pledge or lien,

(iii) Any purchaser of such facility at the sale thereof upon foreclosure of such mortgage, pledge, or lien or upon exercise of any power of sale contained therein, or (iv) Any assignee of any such purchaser.

Backfitting

53.100 Backfitting

(a)(1) Backfitting is defined as the modification of or addition to systems, structures, or components, or a design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position after:

(i) The date of issuance of the COL; or

(ii) The date of issuance of the design approval under Appendix M, N, or O of Part 52.

(2) Except as provided in paragraph (a)(4) of this section, the Commission shall require a systematic and documented analysis pursuant to paragraph (b) of this section for backfits, which it seeks to impose.

(3) Except as provided in paragraph (a)(4) of this section, the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (b) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable and, therefore, backfit analysis is not required and the standards in paragraph (a)(3) of this section do not apply where the Commission or staff, as appropriate, finds and declares, with appropriate documented evaluation for its finding, either:

(i) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or

(ii) That regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or

(iii)That the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

(5) The Commission shall always require the backfitting of a facility if it determines that such regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.

(6) The documented evaluation required by paragraph (a)(4) of this section shall include a statement of the objectives of and reasons for the modification and the basis for invoking the exception. If immediately effective regulatory action is required, then the documented evaluation may follow rather than precede the regulatory action.

(7) If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written license commitments, or there are two or more ways to reach a level of protection that is adequate, then ordinarily the applicant or licensee is free to choose the way that best suits its purposes. However, should it be necessary or appropriate for the Commission to prescribe a specific way to comply with its requirements or to achieve adequate protection, then cost may be a factor in selecting the way, provided that the objective of compliance or adequate protection is met.

(b) In reaching the determination required by paragraph (a)(3) of this section, the Commission will consider how the backfit should be scheduled in light of other ongoing regulatory activities at the facility and, in addition, will consider information available concerning any of the following factors as may be appropriate and any other information relevant and material to the proposed backfit:

(1) Statement of the specific objectives that the proposed backfit is designed to achieve;

(2) General description of the activity that would be required by the licensee or applicant in order to complete the backfit;

(3) Potential change in the risk to the public from the accidental offsite release of radioactive material;

(4) Potential impact on radiological exposure of facility employees;

(5) Installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;

(6) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(8) The potential impact of differences in facility type, design or age on the relevancy and practicality of the proposed backfit;

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(a) No licensing action will be withheld during the pendency of backfit analyses required by the Commission's rules.

(b) The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director of Operations or his designee.

Enforcement

53.105 Violations

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of:

(1) The Atomic Energy Act of 1954, as amended;
(2) Title II of the Energy Reorganization Act of 1974, as amended; or
(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of:
(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954 as amended;
(ii) Section 206 of the Energy Reorganization Act;
(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;
(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(c) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

53.106 Criminal penalties

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o, of the Act. For purposes of section 223, all the regulations in Part 53 are issued under one or more of sections 161b, 161i, or 161o.

US/IAEA Safeguards Agreement

53.110 Installation information and verification

Each holder of a Combined Operating License shall, if requested by the Commission, submit installation information on form N-71, permit verification thereof by the International Atomic Energy Agency, and take such other action as may be necessary to implement the US/IAEA Safeguards Agreement, in the manner set forth in §75.6 and §75.11 through §75.14 of this chapter.

APPENDIX B
BASIS FOR NEW PART 53 REGULATIONS

This Appendix presents a comparison of sections of Part 53 to counterpart sections of Part 50. It is organized by regulation section with a general description followed by a more detailed description of each subsection.

C.2.53.4, "Written Communications

This section provides the requirements for written communications from applicants/licensees to the Commission. It is very similar to 10 CFR 50.4. The primary differences between §53.4 and §50.4 are the elimination of reference to non-power reactor facilities, the recognition of the Electronic Information Exchange (EIE) system, and the recognition of capability for submitting information via CD-ROM. The specific comparison is listed below.

B53.4(a). This section is nearly identical to §50.4. The new section recognizes the option of filing information using the EIE system or by CD-ROM.

B53.4(b). This section is also nearly identical to its counterpart section, §50.4. The new section does not contain references to non-power reactor submittals, which are not included in Part 53. This section also would allow submittals under the EIE process or by CD-ROM in lieu of written submittals. If a licensee/applicant chooses to make written submittals, the requirements are identical to those of §50.4.

B53.4(c) and (d). These two subsections are the same as §50.4(c) and (d) except or the recognition of electronic submittals.

C.2.53.15, "Quality Assurance"

This section includes the requirements for design, construction, and operational QA programs. It also includes the requirements for providing descriptions of those programs to the NRC. The elements of this section are very similar to 10 CFR 50, Appendix B.

The elements addressed in this section are the same as those addressed in Part 50, Appendix B. The subsection titles have been modified slightly, but cover the same areas. The major difference between the new regulation and Appendix B is the emphasis on safety-significant SSCs. A principle of the new framework is that it is risk-informed. Requirements for SSCs would be based on risk assessments and identification of SSCs that are relied upon to prevent and mitigate plant transients and accidents. The new set of QA requirements, therefore, differentiates between safety-significant and other systems instead of the current differentiation between safety-related and non safety-related SSCs. The Assessments and Audits element provides additional flexibility of using performance-based assessments as opposed to the narrow and specific "audit" term.

The new regulation allows licensees the use of suppliers that have a quality program that has been certified by an independent, nationally accredited registrar as satisfying the requirements of a nationally recognized quality standard such as ISO 9000 or ASME.

C.2.53.20 "Initiating Events and Prevention"

Section 53.20 contains the regulatory requirement for determining the events that must be analyzed as part of the licensing basis for a plant. The required events are determined using a risk-informed methodology documented in the application for a Design Certification, Operating License or a Combined Operating License (COL). The requirements of this section and the results of the analysis determine the requirements for facility design and for operation and maintenance for the duration of the license. These requirements provide a design and operation basis consistent with the Commission safety goals and with the Initiating Events cornerstone of the Reactor Oversight Policy.

This section establishes a probabilistic basis for those events that must be analyzed and mitigated. This concept assures that the public health and safety is adequately protected. It also provides a systematic approach to the regulation of a facility's design basis, i.e., an applicant for an operating license or COL has a consistent set of criteria for determining the analyses that must be performed and the design specifications for systems, structures and components. The approach also provides this consistency for operational and maintenance requirements.

The following basis sections are referenced to the specific subsections of the proposed §53.20.

B53.20(a)(1): This subsection establishes the limits of frequency for Anticipated Operational Occurrences (AOO) or events, which may be expected to occur once, or more during the life of a plant. Numerically, an event with an expected frequency of occurrence of 10^{-2}/year is equivalent to one occurrence in 100 years of operation that bounds the expected number of years of operation of a plant. The selection of 10^{-2}/year as the limit is consistent with the ROP cornerstone as documented in SECY 99-007, *Recommendations for Reactor Oversight Process Improvements* and its follow-up SECY, 99-007A. Since AOOs are the events with the highest frequency of occurrence, they should result in the lowest consequences (radiation exposure) to members of the public.

B53.20(a)(2): This subsection delineates the criteria for plant design basis events (PDBE) in terms of frequency of occurrence. It is required that the facility to be licensed be evaluated to determine which events will occur with a frequency between 10^{-5}/year and 10^{-2}/year. This new regulation provides a systematic basis for determining which events must be considered for the analysis. The frequency range for DBEs is consistent with the ROP policy discussed in SECY 99-007 and its follow-up SECY, 99-007A.

B53.20 (a)(3). Plant Protected Design Events (PPE) are treated separately from internal events due to the dependence on reactor design and site characteristics. This section of the regulation requires an analysis but recognizes that these events will be plant-specific.

B53.20 (a)(4): Consistent with risk-informed methodology, regulatory provisions are provided for emergency planning basis events (EPBE). Since EPBEs are not expected to occur, the design requirements to respond to them are limited to those features necessary to ensure that the consequences and probabilities of EPBEs are within the specified limits and to support offsite and onsite emergency response, such as monitoring and notification equipment. Procedures and coordination of all involved agencies may also be required to respond to EPBEs.

The basis for selecting EPBEs includes an offsite dose criterion and a large release criterion. The numerical values for selecting EPBEs for consideration are consistent with the ROP policy and supporting documentation.

B53.20 (b): This paragraph imposes a requirement to maintain the frequency analysis and process changes as changes to the plant similar to design changes. This provision is consistent with the provisions of 10 CFR 50.59 for analysis changes.

B53.20(c): This section gives the requirements for SSCs that are relied upon in the facility safety analysis to prevent transients and accidents. The requirements are necessarily generic for most plant SSCs. The specific requirements are given for reactor design and reactivity control that are expected to apply to all future designs. The requirements of this section replaces several GDCs of 10 CFR 50, Appendix A, including GDCs 4, 10, 11, 12, and 28.

C.2.53.21, "Mitigation"

This section contains the requirements for systems, structures and components (SSC) determined to be required to mitigate DBEs and AOOs. The proposed regulation would support the Commission safety goals and directly relates to the mitigation cornerstone of the Reactor Oversight Process. This section corresponds to several counterpart sections in 10 CFR 50 which are much more detailed. The reduced level of detail in the new section is driven by the fact that it must apply to multiple reactor designs and, in accordance with the framework principles; it contains the fundamental regulatory criteria. It is anticipated that detailed criteria will be recommended in associated Regulatory Guides. An example of this difference is the level of detail in Part 50 related to Emergency Core Cooling Systems (ECCS). Since Part 50 has evolved based on light-water reactor (LWR) technology, the detailed requirements of §50.46 and Appendix K are included in the regulations. In contrast, §53.21 presents the general requirements for all SSCs determined by a design specific analysis to be safety-significant. Specific systems required to mitigate DBEs will vary by reactor type and, therefore, will have specific requirements determined during the licensing process, but must satisfy the probabilistic criteria in the regulation.

Other subsections of §53.21 address requirements for systems and issues that are expected to be common to all designs such as control rooms and fire protection systems.

The following sections present the detailed bases for the new regulation.

B53.21 (a). This section requires an evaluation as part of the license application to determine which SSCs are relied upon to mitigate AOOs and DBEs. The analysis is probabilistic and combines the effects of prevention and mitigation to determine the offsite consequences of plant events. This approach allows the reactor designer to choose the combination of preventive and mitigative measures to meet a requirement of mean core damage frequency less than 10^{-4}/year for light-water reactors (LWRs). The metric for gas reactors and other non-light water reactors will be based on pilot licensing activities for these reactors. As a result, the rule metric would be more practical and stable having been based on an actual example as opposed to theoretical concepts. 10 CFR 50 includes several sections that present requirements for LWR systems that have been determined to be safety related. Examples of these sections are §50.46, §50.44, §50.63 and 10 CFR 50, Appendix A, Criteria 30, 34, 35, 17, 19, 16 and 41. These deterministic requirements constrain the design authority and owners from designing the facility or power plant in an effective and efficient manner.

This section does impose general requirements for systems that are determined to be required for mitigation. The specific requirements for those systems will be included in each facility application. The imposition of these requirements assures that the assumptions used in the plant risk assessment remain valid.

B53.21 (b). This section anticipates that a fire hazards analysis will be a part of each application and that a fire protection program will apply to each facility licensed under this part. This subsection requires licensees to develop a program for fire protection, to complete a fire hazards analysis and to identify requirements for facility and fire protection design. Regulatory Guides would be developed to address specific requirements for each reactor design. Fire hazards methodology would be developed in a generic regulatory guide. This regulatory content is significantly different from that of 10 CFR 50.48 and 10 CFR 50, Appendix R. The basis for the difference is the application of the principle that the regulation would include generic requirements and that detailed requirements would be recommended in Regulatory Guides and imposed as a result of the license application review and approval.

B53.21(c). Protection against the environmental and dynamic effects of natural phenomena and design basis events would be required for safety significant SSCs of all reactor designs. Specific natural phenomena effects will be determined on a site basis with recommendations for evaluation given in Regulatory Guides. Environmental effects on safety-significant SSCs would be determined by analysis and the capability of those SSCs to perform under those conditions would be determined by a combination of analysis and testing. These new requirements are similar to those in Part 50, specifically §50.49, Appendix A to Part 50, GDCs 2 and 4.

B53.21 (d). A regulatory requirement to monitor safety significant, mitigation SSCs is consistent with current requirements such as 10 CFR 50.65. Such a requirement assures that the risk assessments relied upon for issuance of the license remain valid for the life of the power plant unit.

B53.21 (e). This section discusses the requirements for reactivity control and is generic to all reactor types. The counterpart sections in 10 CFR 50 are in Appendix A, Criteria 10, 11, and 12. The requirements in the new regulation are essentially the same as those in Part 50. Regulatory

Guides would be developed to provide acceptable means to meet these requirements for specific reactor designs.

B53.21 (f). This section contains the general requirements for reactor protection systems. It is similar to 10 CFR 50, Appendix A, Criteria 20, 21, 22, 23, 24, 25 and 26. The provisions in the new regulation are those that would apply to all reactor designs. The new section refers to the FSAR for the identification of appropriate design criteria. Regulatory Guides would provide design specific, acceptable means of meeting the regulation with specific criteria.

C.2.53.22, "Barriers to Radionuclide Release"

Section 53.22 contains the general requirements for barriers to the release of radionuclides. Specific requirements will depend upon the reactor and fuel design proposed in an application. Regulatory Guides will be developed for each reactor/fuel type to present an acceptable means of implementing this regulation. This section supports the Reactor Oversight Process cornerstone, "Barriers", and the Commission Safety Goals. These requirements would replace some of the current Part 50 requirements of §50.60, §50.61, 10 CFR 50, Appendix A to Part 50, Criteria 10,14, 15, 16, 50, 51, and 10 CFR 50, Appendix J.

This section also ties the facility design to specific offsite consequences. AOOs, which have a higher probability of occurrence than accidents, may not result in significant offsite consequences. PDBEs and PPEs occur less frequently and may result in greater offsite consequences. There is also an overall requirement that the total mean frequency of a large release be less than 10^{-5}/year. Monitoring of safety significant barriers is required to assure that the risk assessments used in the license application remain valid.

C.2.53.30, "Operational Requirements"

Subpart C of the proposed regulation includes the regulatory requirements for plant operation. It is anticipated that licensees of facilities licensed under Part 50 could utilize the provisions of this subpart. This section follows the framework guidelines and, therefore, is less detailed than counterpart sections in Part 50. Sections or parts of sections of Part 50 replaced by this section are §s 50.65, §50.36, §50.34 and §50.54. 10 CFR 53.30 imposes requirements for operations equivalent to those of Part 50. Specific comparisons are described in the following list.

B53.30 (a). This section imposes a requirement for licensees to establish and implement operational programs. The programs would be described in the SAR. This is equivalent to current requirements in various sections of Part 50.

B53.30 (b). This section identifies the timing for effectiveness of operational programs relative to the Part 52 licensing process. It also specifies that the rule is applicable to safety-significant SSCs in accordance with the new framework.

C53.30(c). This section requires licensees under Part 53 to establish, implement and maintain a training program as required by 10 CFR 55.4. This requirement is equivalent to current requirements under Part 50.

C53.30 (d). This section imposes a requirement for licensees to perform an analysis to determine the qualifications and number of operating personnel for a facility. 10 CFR 50.54 currently provides specific, minimum requirements for all Part 50 power plant licensees. The new regulation provides the flexibility necessary to accommodate a number of reactor designs anticipated to be licensed under Part 53. The imposition of minimum staffing and qualification requirements determined in the SAR through the licensing process will be equivalent to the current requirements.

C.2.53.30 (e). This section contains the requirement for a licensee to monitor safety-significant SSCs against pre-determined performance criteria. The monitoring program and its required actions would assure that the facility would respond to AOOs and PDBEs as discussed in the SAR. This section provides requirements equivalent to those in 10 CFR 50.65 and part of 10 CFR 50.36.

C.2.53.30 (f). Technical Specifications would change significantly under the new Part 53. New technical specifications would be risk-informed and would be streamlined from the current Standard Tech Specs. They would still include Safety Limits and Limiting Safety System Settings similar to those required by 10 CFR 50.36. The fundamental difference between the new specifications and current specifications is the inclusion of "Risk Configuration Limits" and the exclusion of "Limiting Conditions of Operation" (LCO). The Risk Configuration Limits would specify licensee actions in response to changes in the plant risk profile in contrast to current LCOs, which list many specific action items for individual SSCs. The new approach integrates the configuration management program requirements of §53.30(e) and the technical specifications rather than imposing two independent sets of SSC availability requirements.

The proposed, risk-informed approach would be more efficient and provide a clear, concise set of requirements for licensee actions in response to decreased SSC availability. The proposed rule also requires that specific actions be proposed by the licensee and approved by the NRC in response to degraded conditions. This approach is equivalent to the current one in 10 CFR 50.

C.2.53.30 (g). This section provides the requirements for licensee response to an Operating Basis Earthquake (OBE) or other severe environmental event. A reactor shutdown required in response to such an event would be followed by reports to the NRC and damage assessment prior to restart. This proposed requirement is similar to those in 10 CFR 50.

C.2.53.30 (h). This requirement is imposed to assure that an on-going monitoring program will be in place at operating plants. The program will assure that safety-significant SSCs will be available to respond to AOOs, PDBEs and PPEs. Age-limited SSCs service lives must be updated throughout the life of the facility through analysis, refurbishment or replacement. This requirement is similar to those of 10 CFR 50.65, 60, 61, 49 and Appendices G and H.

C.2.53.31, "Changes, Tests and Experiments"

Section 53.31 contains the requirements for licensee changes to the facility and procedures or to conduct tests or experiments not described in the FSAR. It has the same scope as its counterpart, 10 CFR 50.59, but has been modified to take advantage of a risk-informed approach. The format of the new regulation is essentially the same as the counterpart regulation format.

The principle for the new regulation is the same as for 10 CFR 50.59. A licensee would be allowed to make changes to the facility or his procedures, or conduct tests or experiments not described in the FSAR without prior NRC approval if certain criteria were met. Those criteria are that the change cannot involve a Tech Spec change or not meet one of 5 specified criteria. The bases for the detailed requirements that are changed from the current rule are listed below.

B53.31 (a)(1). The definition of "change" refers to "safety-significant function" instead of "design function". This change is to make the regulation consistent with the risk-informed basis for Part 53.

B53.31 (a)(2). The methods of evaluation to be addressed are limited to those described in the PRA and safety analyses sections of the FSAR. The reason for this change is that the evaluation methods that would have a significant impact on the basis for the issuance of the license and potentially impact safety and will affect the PRA section or the safety analyses sections. This is consistent with the risk-informed basis for the new rule.

B53.31 (a)(3). The definition of tests or experiments not described in the FSAR is limited to those activities that involve a safety-significant SSC being utilized or controlled outside the bounds described in the risk assessment sections of the FSAR. This change is consistent with a risk-informed regulatory approach.

B53.31 (b)(4). This section contains the criteria for determination if a change, test or experiment would require NRC approval prior to implementation. The eight criteria of 10 CFR 50.59 would be replaced by five new criteria reflecting the risk-informed basis of Part 53. The purpose of §53.31 is to assure the NRC that the licensing basis is maintained. Since the licensing basis under this part is risk-informed, the basis for change approval should also be risk-informed. Instead of criteria for minimal increase in the likelihood of an accident or malfunction of equipment, the new criteria relate to change in the frequency of an initiating event. The new criterion combined with the criteria for increase in consequences assures that the same level of changes would be submitted for approval as is currently done. The criteria for increase in consequences, creation of a new event, and departure from a method of evaluation are essentially the same. The new criterion for exceeding a design basis limit would be simplified from the current one.

C.2.53.32, "Radiation Safety"

This section utilizes, by cross-reference, definitions, public and occupational dose limits, and units of radiation and radioactivity from 10 CFR Part 20. It is intended that, as Part 20 is changed in the future to reflect updates in scientific concepts and recommendations, such changes shall also be reflected in the requirements for nuclear power reactors licensed under Part 53.

C.2.53.33, "Public Radiation Safety"

This section consolidates applicable sections from 10 CFR Parts 20 and 50. Radiation protection limits (defining adequate level of protection of health and safety) have not been changed. The technical basis for numerical guidance for design criteria and limiting conditions for operation has been updated to reflect current NRC radiation protection standards and concepts, i.e., a total effective dose equivalent constraint. The section is performance based with reduced prescriptive detail and improved flexibility in implementation. Programmatic requirements have been included in the rule, eliminating the need for such requirements in technical specifications. Staff positions for acceptable required programs will be provided in regulatory guides.

C.2.53.34, "Occupational Radiation Safety"

This section incorporates current radiation protection standards contained in 10 CFR Part 20 that are applicable to nuclear power reactors. Radiation protection limits (defining adequate level of protection of health and safety) have not been changed. With the exception of cross-referenced provisions in 10 CFR Part20, nuclear power plants will not be regulated under Part 20. The section is performance based with reduced prescriptive detail and improved flexibility in implementation. Programmatic requirements have been included in the rule, eliminating the need for such requirements in technical specifications. Staff positions for acceptable required programs will be provided in regulatory guides.

C.2.53.35, "Source Term"

This section incorporates the applicable criteria from §50.34 that reflect current NRC radiation protection standards and concepts.

C.2.53.40, "Emergency Preparedness"

Section 53.40 includes the overall requirements for Emergency Preparedness. The new section maintains the requirement for a licensee to have an onsite Emergency Plan, to establish communication and support relationships with State and local jurisdictions, and to analyze the need for offsite plans. It also recognizes the authority of the Federal Emergency Management Agency (FEMA) for offsite plan review and approval.

The fundamental difference between §53.40 and 10 CFR 50.47 and 10 CFR 50, Appendix E is the amount of detail specified in the rule. The new section provides overall requirements and a general discussion of the issues to be addressed in applicant's plans. In accordance with the principles for the new framework, much of the detail currently contained in 10 CFR 50 would be contained in Regulatory Guides or in a Standard Review Plan (SRP). For example, 10 CFR 50, Appendix E, Section IIIC refers to "pressure in containment and the response of the Emergency Core Cooling System". This language applies to current LWR designs but may not apply to all future reactor designs. Acceptable specific requirements for notification of emergency personnel, under the new framework, would be in a Regulatory Guide for each reactor design.

The bases for adequacy for individual sections of the proposed rule are listed below.

B53.40 (Introduction): The introduction to §§53.40 sets the requirement to use the facility risk assessment to determine the set of events that must be evaluated for emergency planning purposes. The current Part 50 regulation uses a deterministic basis for this analysis. NRC still has the responsibility to review FEMA's findings relative to State and Local plans and assure that the plans will ensure adequate protection of the public health and safety.

A new concept in the rule is that the need for offsite plans would be based on an analysis of potential offsite exposure due to EPBEs. Licensees would always be required to develop onsite plans and to establish communications with offsite agencies relied upon for site response. This approach would recognize the potential that some reactor designs at some sites might not exceed the minimum offsite dose levels requiring offsite plans.

B53.40 (a): This section contains on-site emergency planning requirements. The primary difference between this section and 10 CFR 50.47 is the level of detail in the regulation versus the plan. All the subject areas required by §50.47 for on-site planning are listed in §53.40(a) and would be required to be addressed in the licensee's emergency plan. The nature of radiological emergencies is expected to vary according to reactor design and, therefore, the specific requirements will differ. It is anticipated that regulatory guidance will be provided in Regulatory Guides specific to reactor types.

B53.40 (b)(1). This section contains the requirements for those facilities with an analysis result of greater than 10^{-6}/year probability of an EPBE resulting in an exceedance of the limits of §53.35 or a greater than 10^{-7}/year probability of a large release. Those facilities would be required to develop plans for interfacing with State and local agencies. The specific requirements for (A) Notification Criteria and (B) Communication and Interface with State and Local Agencies are the same as those in 10 CFR 50.47.

B53.40 (b)(2). This section contains offsite planning requirements for those facilities with analysis results of less than 10^{-6}/year probability of an EPBE resulting in offsite exposure greater than the limits of §53.35 and less than 10^{-7}/year probability of a large release. Facilities with these analysis results would not be required to develop the same extensive plans as those meeting the criteria of §53.40(b)(i). It would, however, be necessary for them establish procedures, define responsibilities, develop training, etc. for offsite responders to onsite emergencies. Those requirements are contained in this section and are similar to those for non-power reactor facilities with similar offsite release potential.

B53.40(c). This section provides the requirements for a licensee to maintain and update emergency plans. It also gives the requirements for NRC review of plan changes prior to implementation. This section does not use the "decrease in effectiveness" standard currently in §50.54q. Instead, it requires that the applicant determine measures of effectiveness, e.g., notification time, evacuation times, etc., in the application to be used to determine when prior NRC review is required. These measures would be approved by NRC as part of the licensing process.

B53.40 (d). This section contains the same provisions as §50.47(c)(1). These provisions would apply in those cases where the analysis determined that offsite plans were necessary but the responsible State or local entities refused to participate.

C.2.53.45, "Security"

The introduction of Part 53 would not introduce any additional to NRC's security requirements. If changes are necessary, a different regulatory action will assess and develop such changes.

C.2.53.53, "Hearings and Report of the ACRS"

This section is similar to 10 CFR 50.58 in defining the procedures for hearings and reviews and reports by ACRS. The language in the proposed rule is written differently to recognize that most applications under Part 53 will take advantage of the processes of 10 CFR 52.

B53.53 (a). This section compares to 10 CFR 50.58(a). The process has been modified to recognize the procedures of Part 52. The proposed regulation would only require the ACRS to review the standard part of applications once. Review of specific applications would only cover those portions not already reviewed as part of a standard application.

C.2.53.60, "License Required"

This section is essentially the same as 10 CFR 50.10. The only differences are those necessary to recognize the new Part 53 license process.

C.2.53.74, "Contents of Applications; Technical Information"

This section compiles all the information requirements for license applications from 10 CFR 52 and 10 CFR 50 that are applicable to the anticipated licensing approaches to be used under Part 53. The interfaces between Part 52 and Part 53 relative to information required for different types of applications are very complex. A feature of the new rule is Table 53.74-1which displays the information requirements for different applications.

A fundamental difference between 10 CFR 50.34 and 10 CFR 53.74 is the level of detail included in the rule. §50.34 gives very specific requirements for some SAR information and general requirements for other information. §53.74 references the Standard Format and Content Guide instead of listing specific requirements. This approach will reduce the need to update information requirements through rulemaking. Some specific features of the new rule are given in the following list.

B53.74 (b) through (m). The topics addressed in these subsections are the same as those listed in 10 CFR 50.34. The new rule does not prescribe the same level of detail as the current regulation. It relies upon the published Standard Format and Content Guide in existence 24 months prior to a license application for that detail. The topics covered in the rule are the same as those currently required by 10 CFR 50.34.

B53.74 (n). This section includes a new requirement to include the plant PRA results and insights in applications. This requirement is necessary to support a risk-informed framework.

B53.74 (o). Since the proposed Part 53 would not include the requirements for specific industry codes and standards currently included in 10 CFR 50.55a, this section specifies that such information be included in license applications.

C.2.53.77, "Amendment to a License"

C.2.53.77 (a), "Issuance of an Amendment"

Section 53.77(a) includes the requirements equivalent to 10 CFR 50.92, "Issuance of Amendment". The new section keeps in place the public notice and, therefore, public participation aspects of §50.92. The current regulatory procedures for COLs are recognized in this version. The criteria for No Significant Hazards Consideration determinations are modified to be consistent with the risk-informed objectives of Part 53. The new section also eliminates the requirement for issuing a Construction Permit for a "material alteration" of a licensed facility. The following sections discuss the basis for each change.

B53.77 (a)(1): This section provides the same function as §50.92(a). The provision for issuance of a construction permit for the material alteration was eliminated since the regulatory process for issuing a license amendment allows for the appropriate regulatory scrutiny and an opportunity for public participation.

The new section also recognizes the COL process of 10 CFR 52, Subpart C.

B53.77 (a)(2): This section is a word for word replacement for §50.92(b).

B53.77 (a)(3): This section recognizes that Part 53 only applies to power reactors. It also changes the criteria for a no significant hazards consideration determination to be risk-informed. Consistent with the definitions in §53.71, "significant increase in the probability or consequences of an accident previously evaluated" is replaced by two criteria. First, the risk-significant equivalent of an "increase in the probability of an accident" is a significant increase in a Design Basis Event (DBE) frequency. Second, a "significant increase in the consequences of an accident" is replaced by "a significant increase in the offsite doses from a DBE" consistent with the regulatory background for 10 CFR 50.59 (definition of consequences) and the definitions of §53.20.

A new or different kind of accident is replaced by a new or different kind of DBE to be consistent with §53.20. A "reduction in a margin of safety" is replaced by a "significant increase to the design basis limit for any fission product barrier". This is considered to be more definitive and is consistent with the most recent changes to 10 CFR 50.59. Specifically, §50.59(c)(2)(vii) uses the change to a fission product barrier design basis limit as the test for prior Commission approval for a change to a facility or procedure. The proposed change in §53.77(a)(iii) would make the no significant hazards test consistent with the new §50.59 and with the risk-informed approach of 10CFR 53.

C.2.53.83, "License Conditions"

This section contains requirements similar to those of 10 CFR 50.54. The primary differences between the two are related to the fact that Part 53 only applies to power reactors, the QA program requirements were moved to §53.30, the level of detail about licensed operator staffing, the requirements for preparing and maintaining security plans were moved to §53.45, the requirement to submit and maintain an emergency plan and to submit State and local plans were moved to §53.40, and the elimination of requirements related to 10 CFR 50, Appendix S. The following are the specific changes from §50.54.

B53.83 (e). The language of this section is modified from that of §50.54(f). The new rule would always require the NRC to prepare the reasons for licensee information requests and would not exclude such requests for information sought to verify compliance with the licensing basis. Currently, almost all requests under §50.54(f) are to verify compliance with the licensing basis. The intent of the new wording is to assure that NRC has a valid basis for any requests for information.

B53.83 (h). The current §50.54(i) includes detailed requirements for operator qualification and shift staffing. The proposed rule would apply to several types of reactors and, therefore, does not contain the same level of detail. The detailed issues to be addressed in each application and maintained should be defined in design-specific Regulatory Guides.

C.2.53.90, "Documentation Update Requirements"

This section is very similar to 10 CFR 50.71, "Maintenance of records, making of reports". The major differences between the two are related to the recognition of Part 52 processes, the deletion of the initial timing requirements in the current regulation, and the inclusion of a single, fixed submittal period for FSAR updates. The following are specific proposed changes.

B53.90 (e)(3) and (4). This subsection eliminated the initial reporting dates provided in 10 CFR 50.71(e) since they are no longer pertinent. It also fixes the period for FSAR updates as once every 24 months, the maximum allowed by the current rule.

C.2.53.91, "Notifications"

The requirements of this section are very similar to those in 10 CFR 50.72. The primary difference is the elimination of requirements to report specific system actuations such as PWR Auxiliary Feedwater or BWR Standby Liquid Control System. The proposed rule would require immediate notification of mitigation system actuations with the specific systems identified in the SAR.

C.2.53.92, "Reporting Requirements"

The changes made to this section are similar in nature to those made

C.2.53.95, "Financial Requirements"

B53.95(c)(1) The change to this paragraph beyond that provided in Part 50 is to take into account the change in the term of the license. Under Part 53, the term of the license is linked to the designed life of the reactor vessel and associated systems, as approved by the Commission in approving the design. However, for the purposes of evaluating the funds that are necessary for decommissioning a reactor a limit is impose for this specific regulation of 60 years. The 60-year period is based on the expected life of current reactors, 40 plus a renewed license interval of 20 years. In addition, like today, the licensee is also allowed to take credit for a safety store period of 60 years, which is unchanged from current requirements.

B53.95(c)(2) This paragraph relating to the licensee requirements required to qualify for using an external sinking fund is changed in one aspect. The change appropriately broadens the scope of licensees that qualify to use a sinking fund to those licensees that satisfy the definition of an Exempt Wholesale Generator in Section 32 of the Public Utility Holding Company Act of 1935, as amended. In addition, a licensee has to provide information to the NRC that is described in an accompanying regulatory guide. Such information would be sufficient to provide reasonable assurance that funding can be obtained to cover payments into the fund from specific contracts or estimated revenues, and that the licensee or parent company has sufficient financial assets not associated with the facility under review. In addition, the licensee would be expected to provide estimated operating costs and the sources of funding to cover such costs for the next five years until such payments into the decommissioning fund are terminated.

These changes reflect the advances made in technology, design and operations as well as the dramatic changes in the way electricity is marketed and sold generation and sale of electricity over the last 10 years.

APPENDIX C
ISSUES IDENTIFIED IN DEVELOPING NEI 02-02

1) Is there a need for an improved, risk-informed, performance-based set of regulations for power reactors?

2) Should existing licensees have the option of adopting the new Part, in whole or selectively? Should applicants and power reactor licensees have the option of adopting Part 50 or the new Part?

3) Should the framework focus only on those regulations related to technical (design), operational and programmatic requirements and exclude those requirements that are identical to Part 50 requirements?

4) Should the new Part 53 include in the definitions section, §53.2, definitions that duplicate definitions in other Parts or Title 10, or just reference the regulations where the terms are defined?

5) What is the correct degree of selective implementation that should be allowed? Should future, or existing licensees be allowed to implement only selected sections; for example; only implement Part 53 operational sections, with all other requirements being taken from Part 50?

6) Should defense-in-depth be defined in the regulations? What should be the criteria for including deterministic requirements?

7) Should the new regulatory framework specifically define the required balance between mitigation and prevention?

8) What is the level of PRA quality needed to support an application under the proposed new part? Should semi-quantitative risk assessment methods such as seismic margins assessments be permitted as opposed to full scope PRAs?

9) Should the terms core damage frequency and large early release frequency be used in the regulations? Should the term Large Release Frequency replace Large Early Release Frequency (LERF) in Part 53?

10) In a risk-informed regulatory regime should probability numbers be included in the regulations?

11) Should the 40-year duration limit on power reactor licenses be changed for Part 53 licenses to a duration that is linked to the design life of the reactor systems, as defined by the design authority and approved by the NRC?

12) Should a new equipment safety classification, safety-significant, be introduced that would be based on risk-informed metrics and that would replace the current *safety-*

related classification term?

13) Should programmatic requirements be changed to a risk-informed, performance-based structure?

14) Should QA, as it is currently defined in Appendix B to Part 50, be a regulation in the new risk-informed, performance-based regulatory framework? Should NRC regulations defer to nationally recognized, independent certification schemes for assessing quality processes at commercial nuclear facilities and at suppliers of equipment and services?

15) Should technical requirements such as, general design criteria, seismic, and environmental qualifications be part of the regulations, as opposed to being prescribed technical regulatory guidance that become license conditions?

16) Should there be fixed emergency preparedness zones, or should the need for an emergency preparedness plan be linked to the risk profile of the plant, with zones being based on risk-informed exposure and ingestion pathways?

17) Should terms in the new Part 53 have identical definitions to terms in Part 50?

18) What is the extent to which standardization be imposed through regulations, Part 53?

19) In a performance-based regulatory framework, should requirements on notification and deficiency reporting be linked only to a failure to satisfy a safety-significant function as determined through testing, inspection, or analyses?

20) Should the term *safety-significant functional bases* replace the term, *design bases* in a risk-informed, performance-based regulatory framework?

21) Is there a need to change the definition of basic component in a risk-informed regulatory regime?

22) Should the new Part 53 specify specific codes and standards in the regulations, or have a general reference to the use of codes and standards with the specific codes and standards being listed in regulatory guides or in specific license applications?

23) Should the structure and format of the Safety Analyses Report be the same as the one used for Part 50?

24) Should Part 53 encompass Siting requirements that are defined in 10 CFR 100?

25) Should reporting requirements be solely linked to safety and listed in the regulations?

APPENDIX D - CONFORMING CHANGES TO 10 CFR

Nearly all the conforming changes require only the addition of a reference to the proposed Part 53.

10 CFR 1.43(a)(2), Office of Nuclear Reactor Regulation
10 CFR 2.4, Definitions
10 CFR 2.101(a)(3)(i), Filing of application
10 CFR 2.101(a)(5), Filing of application
10 CFR 2.101(a-1)(1), (2), (3), (5), Filing of application
10 CFR 2.104(a), (b), (c), Notice of hearing
10 CFR 2.105(a), Notice for proposed action
10 CFR 2.106(a), Notice of issuance
10 CFR 2.202(e), Orders
10 CFR 2.401(a), Notice of hearing
10 CFR 2.402(a), Separate hearing on separate issues
10 CFR 2.501(a), Notice of hearing on application
10 CFR 2.600, Scope of subpart
10 CFR 2.602, Filing fees
10 CFR 2.603(b), Acceptance and docketing
10 CFR 2.605(b), Additional considerations
10 CFR 2.606(a), (b), Partial decisions on site suitability issues
10 CFR 2.752(a), Prehearing conference
10 CFR 2.761a, Expedited decisional procedure
10 CFR 2.1103, Scope
10 CFR 2.1201(a), Scope of subpart
10 CFR 2.1205(c), (d), Request for hearing
10 CFR 2.1207(b), Designation of presiding officer
10 CFR 2.1301(b), Public notice of receipt
10 CFR 2, App. A, VIII (b)(4), Statement of General Policy and Procedure
10 CFR 8.4(b), Interpretations
10 CFR 11.7, Control of SNM
10 CFR 19.2, Notice to workers
10 CFR 19.3, Definitions
10 CFR 19.13, Notice to workers
10 CFR 19.20, Employee protection
10 CFR Part 20, *(Additional Work to Identify Specific Sections)*

Regulations Requiring a Conforming Change, Cont'd

10 CFR 21.2, Reporting defects
10 CFR 21.3, Definitions
10 CFR 21.21, Notification of failure to comply or existence of a defect and its evaluation
10 CFR 25.5, Access authorization, definitions
10 CFR 25.17, Approval for processing applicants for access authorization
10 CFR 50.10(a), License required
10 CFR 50.44 (*Under review, being amended*)
10 CFR 50.68(a), Criticality accident requirements
10 CFR 51.20(b)(1), (2), Criteria for and identification of licensing and regulatory actions for EIS
10 CFR 51.22(c)(3), (9), (10), (12), (17), Criteria for identification and exclusion of licensing and regulatory issues from environmental review
10 CFR 51.54, Environmental report
10 CFR 51.101(a)(2), Limitations of actions
10 CFR 51.106(b), Public hearings in proceedings for issuance of operating licenses.
10 CFR 52.3, Definitions
10 CFR 52.17(a)(1), Contents of applications
10 CFR 52.17(b)(2)(ii), (c), Contents of application
10 CFR 52.18, Standards for review of applications
10 CFR 52.25(a), Extent of activities permitted
10 CFR 52.37, Reporting of defects and noncompliance
10 CFR 52.39(a)(1), Finality of early site permit determination
10 CFR 52.47(a)(1)(i), (ii), Contents of applications
10 CFR 52.48, Standards for review of applications
10 CFR 52.51(c), Administrative review of applications
10 CFR 52.63(a)(1), (3), (b)(1), (2), Finality of standard design certifications
10 CFR 52.75, Filing of applications
10 CFR 52.77, Contents of application; general information
10 CFR 52.78(b), Contents of application; training and qualification of nuclear power plant personnel
10 CFR 52.79(a)(2), (3), (b), Contents of application; technical information
10 CFR 52.81, Standards for review of application
10 CFR 52.83, Applicability of part 50 provisions

10 CFR 52.91, Authorization to conduct site activities
10 CFR 52.93, Exemptions and variances
10 CFR 52.97(a), (b)(2)(ii), Issuance of combined licenses
10 CFR 52.99, Inspection during construction
10 CFR 52, Early Site Permit
10 CFR 55.1, Purpose
10 CFR 55.2, Scope
10 CFR 55.4, Definitions
10 CFR 55.5(b)(2), Communications
10 CFR 55.25, Incapacitation because of disability or illness
10 CFR 70.22(k), Contents of applications
10 CFR 70.32(d), Conditions of licenses
10 CFR 70.50(d), Reporting requirements
10 CFR 73.50, Requirements for physical protection of licensed activities
10 CFR 73.55(a), (c)(8)(ii), Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage
10 CFR 73.56(a)(1), (2), (3), Personnel access authorization requirements for nuclear power plants
10 CFR 73.56(d)(2), Requirements during cold shutdown
10 CFR 73.57(a)(1), (2), (3), Requirements for criminal history checks
10 CFR 95.5, Definitions
10 CFR 100.1(a), Purpose
10 CFR 100.2, Scope
10 CFR 100.3, Definitions
10 CFR 100, Reactor Site Criteria
10 CFR 140.2, Scope
10 CFR 140.10, Scope
10 CFR 170.2(g), Scope
10 CFR 170.3, Definitions
10 CFR 170.12, Payment of fees
10 CFR 170.21, Schedule of fees
10 CFR 171.5, Definitions
10 CFR 171.15, Annual Fees

APPENDIX E – LIST OF ACRONYMS

1) ACRS	Advisory Committee on Reactor Safeguards
2) AEA	Atomic Energy Agency
3) ALARA	As Low As Reasonably Achievable
4) AOO	Anticipated Operational Occurrence
5) ASME	American Society of Mechanical Engineers
6) ATWS	Anticipated Transients Without Scram
7) BWR	Boiling Water Reactor
8) CDF	Core Damage Frequency
9) CD ROM	Compact Disk Read Only Memory
10) CFR	Code of Federal Regulations
11) COL	Combined Construction Permit and Operating License
12) CP	Construction Permit
13) EAB	Exclusion Area Boundary
14) ECCS	Emergency Core Cooling System
15) EIE	Electronic Information Exchange
16) EP	Emergency Planning
17) EPA	Emergency Preparedness Agency
18) EPBE	Emergency Planning Basis Event
19) ERDS	Emergency Response Data System
20) ESP	Early Site Permit
21) FEMA	Federal Emergency Response Agency
22) FERC	Federal Electricity Regulatory Agency
23) FSAR	Final Safety Analysis Report
24) GDC	General Design Criteria
25) IAEA	International Atomic Energy Agency
26) IEEE	Institute of Electrical and Electronic Engineers
27) IPE	Individual Plant Examination
28) ISA	Instrument Society of America
29) LER	Licensee Event Report
30) LERF	Large Early Release Frequency
31) LRF	Large Release Frequency
32) LWR	Light Water Reactor
33) MW	Megawatt
34) NEI	Nuclear Energy Institute
35) NOPR	Notice of Proposed Rulemaking
36) NRC	Nuclear Regulatory Commission
37) NUMARC	Nuclear Utility Management and Research Council
38) OBE	Operating Basis Earthquake
39) OL	Operating License
40) OMB	Office of Management and Budget
41) PDBE	Plant Design Basis Event
42) PIE	Plant Internal Initiating Events
43) PPE	Plant Protected Design Events
44) PRA	Probabilistic Risk Assessment

45) PSA/IDP	Probabilistic Safety Assessment/Integrated Decisionmaking Process
46) PUC	Public Utility Commission
47) PWR	Pressurized Water Reactor
48) QA	Quality Assurance
49) Rem	Roentgen Equivalent Man
50) RG	Regulatory Guide
51) ROP	Reactor Oversight Process
52) SAR	Safety Analysis Report
53) SRP	Standard Review Plan
54) SSC	Structure, System, Component
55) Sv	Sievert
56) TEDE	Total Effective Dose Equivalent
57) UFSAR	Updated Final Safety Analysis Report