



Staff Recommendations Regarding a Risk Management Regulatory Framework

Public Meeting

May 27, 2015

Outline of NRC Staff Presentation on Risk Management Regulatory Framework (RMRF)

- Overview
- Background
- Discussion of Staff White Paper
 - Implementation Options for Power Reactors
 - Re-evaluation of Improvement Activities 1 and 2
 - Example of potential agency-wide policy statement
- Next Steps

Overview

- NRC staff is working to provide the Commission with three related items for their consideration:
 - Evaluation of options for enhancing the risk management approach used to ensure nuclear power reactor safety
 - Reevaluations of two power reactor safety “improvement activities” from Fukushima Near Term Task Force Recommendation 1 that the Commission deferred
 - Possible development of an over-arching, agency-wide policy statement using the risk management approach to ensure safety and security
- White paper (ML15107A402) released on May 6, 2015
- *Federal Register* notice published on May 12, 2015
 - www.regulations.gov Docket ID NRC-2013-0254
 - Comment period ends June 11, 2015

Background

Discussion of Staff White Paper

- White Paper discusses three related items:
 1. Evaluation of options for enhancing the risk management approach used to ensure nuclear power reactor safety (Section I)
 2. Reevaluation of two power reactor safety “improvement activities” from Fukushima Near Term Task Force Recommendation 1 that the Commission deferred (Section II)
 3. Possible development of an over-arching, agency-wide policy statement using the risk management approach to ensure safety and security, including an example of what such a policy statement might include (Section III)

Section I: Options for Enhancing the Risk Management Approach for Nuclear Power Reactor Safety

Staff's evaluation determined that

- Safety Goals for the Operation of Nuclear Power Plants (51 FR 30028),
- Existing Probabilistic Risk Assessment (PRA) Policy Statement (60 FR 42622),
- Extensive experience with risk-informed regulation and risk-informed decision-making

... have already established a de-facto RMRF.

- Section I evaluates 3 power reactor implementation options to increase use of risk information
 - Option 1 – Maintain Current Framework
 - Option 2 – Establish a Risk-Informed Alternative Licensing Basis
 - Option 3 – Establish a Plant Specific Risk Management Regulatory Framework

Power Reactor Option 1 – Maintain Current Framework

- No extensive revision of NRC’s regulatory framework
- The current power reactor regulatory framework meets the RMRF criteria in NUREG-2150
 1. Mission – Public health and safety; common defense and security; protect the environment
 2. Objective – Manage the risks via current regulations, guidance, and oversight (including defense-in-depth, safety margins, single failure criterion, fail-safe design, reactor oversight program, etc.)
 3. Goal – Provide sufficient risk-informed and performance-based protections to ensure risks are acceptably low (utilizing Commission’s Safety Goal Policy Statement and subsidiary risk metrics)
 4. Decisionmaking Process that includes monitoring and feedback (e.g., LIC-504, “Integrated Risk-Informed Decision-Making Process for Emergent Issues;” Regulatory Guide 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis;” Generic Issues Program; Operating Experience Program; Accident Sequence Precursor Program; Industry Trends Program, etc.)
- Not a “do nothing” option -- staff would continue to make safety improvements (based on risk insights or other considerations) whenever necessary using existing regulatory processes
 - Fukushima Near-Term Task Force Recommendation 1 Improvement Activities 1 and 2

Power Reactor Option 2 – Risk-Informed Alternative Licensing Basis

- Maintain existing generic regulatory structure
- Issue rule allowing licensees who upgrade PRAs to apply for approval of a risk-informed alternative licensing basis for certain deterministic regulations of low safety benefit for that plant
 - Licensees allowed to select a plant-specific set of design changes/compliance issues of low risk-significance that would deviate from current deterministic requirements **and** must search for and mitigate all plant-specific risk vulnerabilities meeting NRC-specified criteria
 - New information on mitigation of risk-significant events and/or accident sequences (risk vulnerabilities) must be documented in the plant's updated Final Safety Analysis Report in accordance with 10 CFR 50.71 (e) requirements
 - Mandatory monitoring and feedback (as described in RG 1.174) to ensure changes in risk remain acceptable throughout the lifetime of the facility

Power Reactor Option 2 – Risk-Informed Alternative Licensing Basis (continued)

- Regulatory process for licensees to self-approve certain plant-specific changes would likely be similar to NFPA-805 approval process, i.e., risk-informed changes allowed to license requirements without prior NRC approval if risk increase (Δ CDF) is “no more than minimal” (e.g., $< 1E-7/\text{year}$)
- Facility changes with risk increases “more than minimal” (e.g., $> 1E-7/\text{year}$) require NRC approval
- Plant licensees are expected to have high quality PRAs to support this risk-informed alternative licensing basis approach
- Staff requested public comments on potentially requiring licensees requesting subsequent license renewals (exceeding 60 years) to perform PRAs and look for and address risk vulnerabilities

Power Reactor Option 3 – Plant-Specific RMRF from NUREG-2150

- Issue regulation requiring PRAs and that licensees establish plant-specific licensing basis based on:
 - Plant-specific risk profiles
 - NRC-specified risk management objective
 - Enhanced criteria for determining adequacy of non-risk factors (defense-in-depth, safety margins, etc.)
- Based on the risk profile, licensees would implement the plant-specific licensing basis by:
 - Determining how the risk objective is met
 - Ensuring that the necessary protections are in place to meet the risk management goal
 - Demonstrating the adequacy of non-risk factors (defense-in-depth, safety margins, etc.)
 - Establishing the risk-informed decision-making process
 - Establishing the monitoring/feedback and reporting process

Power Reactor Option 3 – Plant-Specific RMRF from NUREG-2150 (continued)

- Each plant's licensing basis would consist of:
 - "Technical requirements" based upon plant-specific attributes and applicant-selected design specific elements/constraints
 - Rationales (technical bases) why the technical requirements adequately address risk and defense-in-depth in light of the plant-specific attributes and design specific elements/constraints
 - FSAR-level description of the plant-specific attributes and applicant-selected design specific elements/constraints that are the inputs/assumptions for the above rationales (technical bases) which must be maintained
 - Process for maintaining the validity of the rationales (technical bases) throughout the operating lifetime of the facility.
- Structured, risk-informed decision-making process used by both NRC and licensees
- Licensees would be required to use the structured process with monitoring and feedback to ensure that the plant-specific licensing basis remains consistent with the risk profile of the plant, which could change over time.



Questions?

Section II: Reevaluation of Power Reactor Improvement Activities

Background:

- On March 11, 2011, an earthquake near Japan caused series of events that led to core damage at 3 of the 6 nuclear power reactors at Fukushima Dai-ichi site.
- The NRC established a senior level task force -- Near Term Task Force (NTTF) -- to review NRC processes and regulations to determine whether the agency should make improvements to its regulatory system or recommendations for policy direction.
- NTTF report issued on July 12, 2011 (ADAMS Accession No. ML111861807)
- NTTF report contains 12 overarching recommendations for nuclear power reactors.

Section II: Reevaluation of Power Reactor Improvement Activities (continued)

- Recommendation 1 was to establish a “logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations.”
- The NRC staff provided its evaluation of Recommendation 1 on December 6, 2013, in SECY-13-0132
- SECY-13-0132 recommended 3 regulatory framework improvement activities
 1. Establish new design-basis extension category
 2. Establish Commission expectations for defense-in-depth
 3. Clarify the role of voluntary initiatives
- Commission’s May 19, 2014 SRM on SECY-13-0132
 - Directed the staff to evaluate the implementation status of certain safety-significant voluntary initiatives (Improvement Activity 3)
 - Directed staff to reevaluate objectives of Improvement Activity 1 (new design-basis extension category) and Improvement Activity 2 (adequacy of defense-in-depth) within context of Commission direction on the Risk Management Regulatory Framework
- Staff will provide its reevaluations of Improvement Activities 1 & 2 in RMRF SECY paper

Reevaluation of Improvement Activity 1: Establish Design-Basis Extension Category

- Staff now believes creating new design-basis extension category is not necessary
- For Option 1 (maintain existing framework) and Option 2 (risk-informed alternative licensing basis)
 - Staff would develop clear internal rulemaking guidance to ensure consistent criteria for specifying performance goals, treatment requirements, documentation requirements, change processes, and reporting requirements whenever new regulations (especially beyond design-basis) are developed
 - Develop guidance using existing resources (routine, periodic guidance updates)
 - Developing internal rulemaking guidance on addressing all pertinent regulatory attributes would eliminate the need to establish new design-basis extension category of regulations
- For Option 3 (plant-Specific RMRF)
 - Instead of design-basis extension category, staff would establish design-basis enhancement category of events/requirements (per NUREG-2150)
 - Because implementation of NUREG-2150 approach would take longer than 10 years, staff would still need to develop clear internal rulemaking guidance for interim use until Option 3 fully implemented

Re-evaluation of Improvement Activity 2: Establish Commission Expectations for Defense-in-Depth

- Staff recommends taking action to establish Commission expectations for defense-in-depth
 - Option 1 (Maintain Existing Framework),
 - Option 2 (Risk-informed Alternative Licensing Basis), and
 - Option 3 (Establish Plant Specific Risk Management Regulatory Framework)
- Develop a definition of and decision criteria for determining adequacy of defense-in-depth (DID) for power reactor safety
 - Consistent with the approach recommended in SECY-13-0132
- Reevaluate the need for a DID policy statement for power reactor safety
- Develop or revise existing power reactor safety regulatory guidance, as appropriate



Questions?

Section III: Agency-wide Risk Management Policy Statement

- The consideration of risk and tailoring regulations and oversight to manage these risks is inherent in current NRC programs. The various regulatory approaches
 - have evolved separately (for reactors, materials, and other NRC program areas) based on their own individual attributes and characteristics
 - the various regulatory approaches are sometimes described using inconsistent terminology
- *If the Commission directs that it be developed*, the risk management policy statement could improve and make more consistent the regulatory framework used for all program areas
- The policy statement would establish **by policy** that the NRC uses a risk management approach; as such, the policy statement would establish an aspirational vision for the agency to improve existing agency policies and practices as guided by this vision

Example Policy Statement Concepts

- Applicable to all NRC-regulated program areas (radiological safety and security) and could be composed of:
 - A risk management approach would be used to ensure adequate protection of public health and safety and promote the common defense and security for all NRC regulatory activities
 - In a risk management approach, safety and security are ensured by:
 1. Understanding the risk associated with NRC-regulated activities
 2. Using that risk information to support regulatory decisions, and
 3. Ensuring that defense-in-depth is adequate

Example Policy Statement Concepts (continued)

- The risk management approach would:
 1. Use a structured process to identify issues, identify options, analyze, deliberate, implement decisions, and monitor the effectiveness of regulatory programs to make improvements as necessary
 2. Ensure appropriate regulatory controls and oversight are in place recognizing the variety of risks associated with different uses of radioactive materials, and
 3. Employ risk-informed decision-making, in which risk insights are considered together with other factors commensurate with their importance to public health and safety and common defense and security

Example Policy Statement Concepts (continued)

- The risk management approach would (cont'd):
 4. Recognize the wide range of risk methods and tools in assessing the risk that would be consistent the complexity, hazard and technology of the regulated activity
 - These methods and tools would include, for example, the use of PRAs, integrated safety analyses, failure modes and effects analyses, vulnerability assessments, or more qualitative methods and engineering judgment, as appropriate to the regulated activity
 5. Consider input from stakeholders and other interested parties

Example Policy Statement Concepts (continued)

- The technical analyses supporting the risk-management approach should:
 1. Be based on sound data, information, and methodologies, including consideration of uncertainties
 2. Use techniques or combinations of techniques appropriate for the hazards and complexity of the issue
 3. Be as realistic as practicable, and
 4. Promote and utilize advances in science and technology, as practicable

- The risk management approach, when implemented (e.g., use of a structured decision process, establishment of risk goals, development of risk analyses), would be tailored to each specific regulated activity, as appropriate

Agency-wide Risk Management Policy Statement

- *If the Commission directs the staff to proceed with an agency-wide policy statement,*
 - The NRC staff would follow the normal regulatory process to develop the policy statement for Commission approval
 - This process would involve stakeholder input through public comment periods and public meetings



Questions?

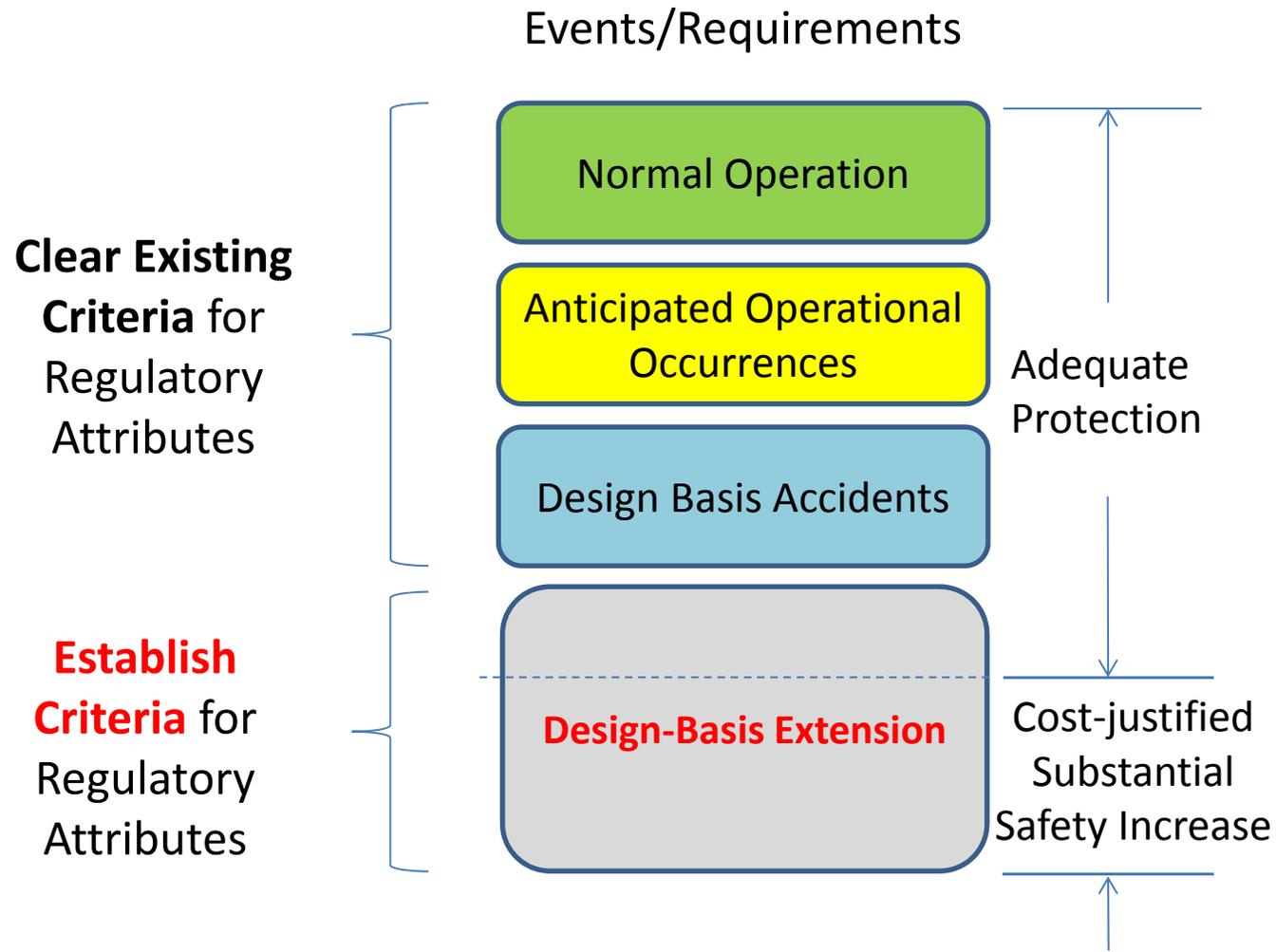
Path Forward on RMRF

- ACRS subcommittee meeting on June 8, 2015
- Public comments due on June 11, 2015
- Review public comments
- Meet with ACRS subcommittee and full committee (Nov.)
- Provide RMRF SECY paper to Commission by December 18, 2015



Backup Slides

Improvement Activity 1- Establish Design-Basis Extension Category



NUREG-2150 Design Enhancement Category

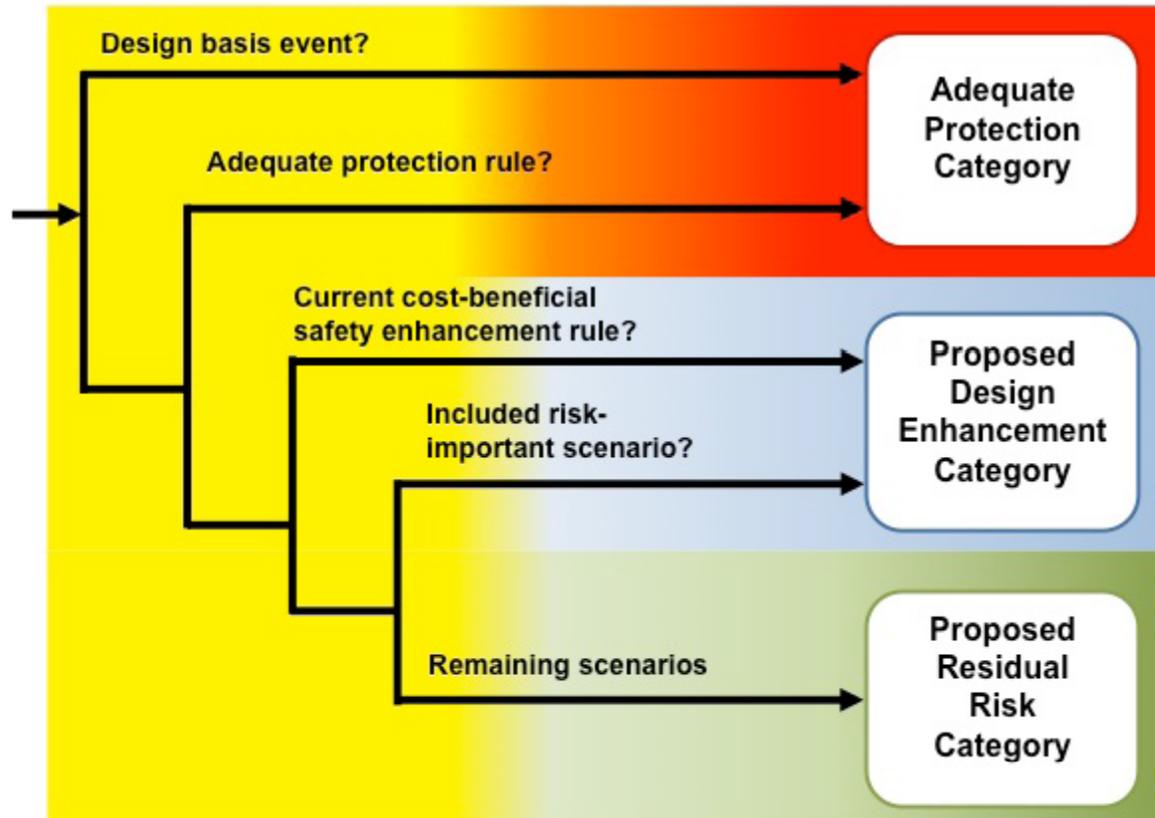
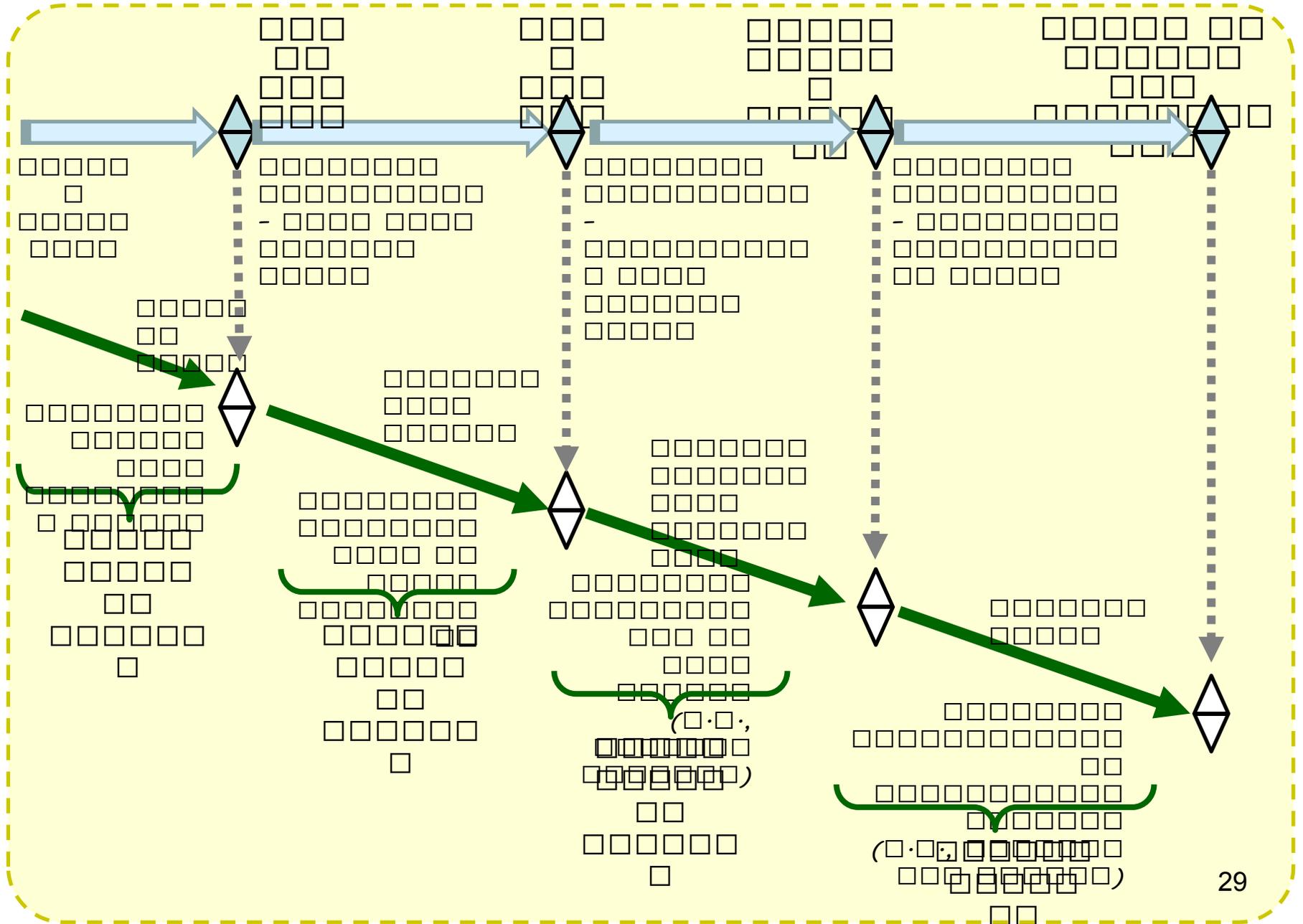


Figure 4.2-1 Regulatory Framework for Nuclear Power Reactors

Nuclear Power Reactor Safety DID May Consist of Four Levels



Definitions

To ensure a common understanding of this example policy statement, it is important to know the differences between the terms “risk management,” “risk assessment”, and “risk-informed approach.”

- *Risk management* is the recognition of the threat or danger involved with the use of nuclear materials and establishing controls and oversight to manage the potential threat or danger. That is, it is coordinated activities to direct and control an organization with regard to risk. [From ISO 31000, “Risk Management – Principles and Guidelines”]
- *Risk assessment* is the evaluation of what can go wrong, how likely is it, and what would be the consequences? This consideration may be addressed either qualitatively or quantitatively. [From SRM-SECY-98-144, “White Paper on Risk-Informed and Performance-Based Regulation,” March 1999]

Definitions (continued)

- *Risk-informed approach* to regulatory decision-making represents a philosophy whereby [quantitative and qualitative] risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety. A risk-informed approach enhances the deterministic approach which is used to define many of the design and operational requirements for NRC licensees. Risk-informed approaches lie between the risk-based and purely deterministic approaches. *[From SRM-SECY-98-144, "White Paper on Risk-Informed and Performance-Based Regulation," March 1999]*

NUREG-2150 Hierarchy and Structured Decision-making Process

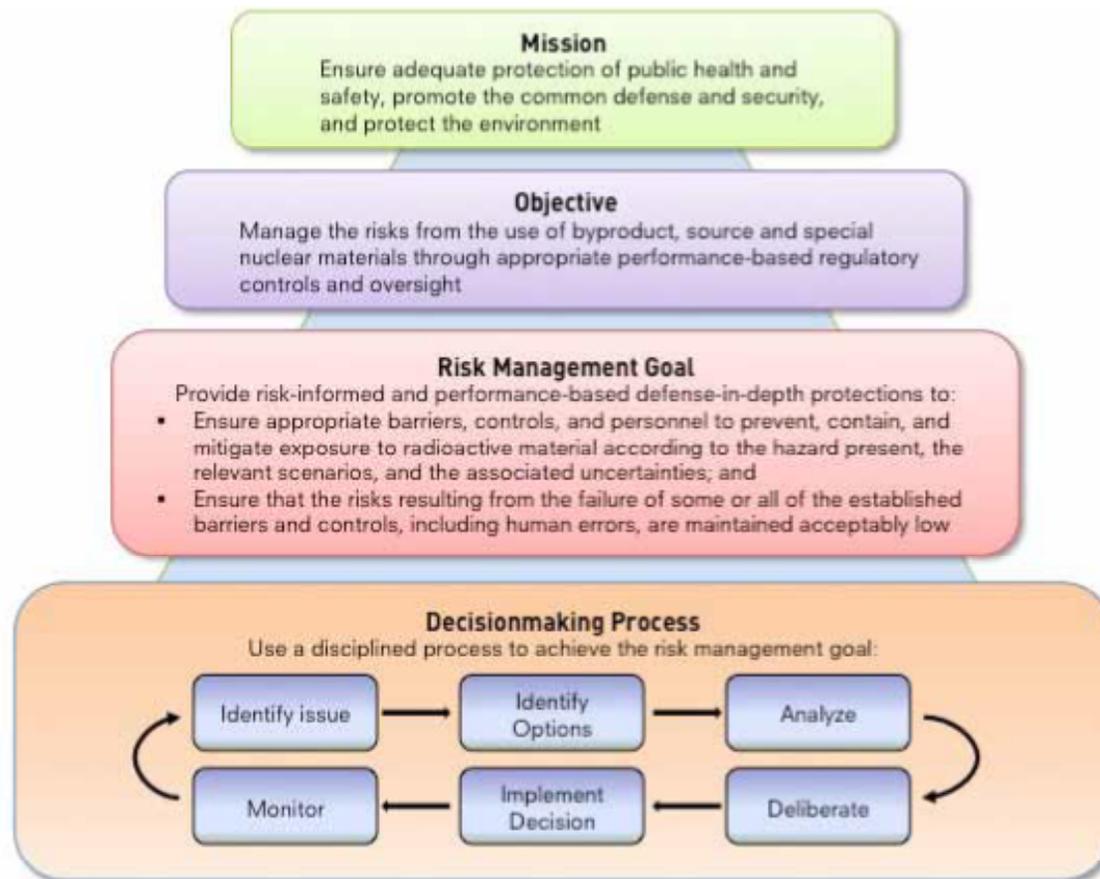


Figure ES-1 A Proposed Risk Management Regulatory Framework