Organizational Infrastructure – Regulatory Authority

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Introduction

❑ Risk management implementation in a regulatory authority

- Has important parallels to that in a licensee/operator organization (as discussed earlier)

- Requires consideration of both strategic and tactical issues

  - Establishing policies

  - Defining intended staff functions

  - Issuing implementation guidance

  - Developing (or otherwise obtaining) expertise

Establishing policies

☐ Characterization of the role of risk management
- Regulatory standing
  - Policy
  - Rule
- Applicability to
  - Staff
  - Licensees
- Relative to traditional engineering and regulatory practices
  - Deterministic analysis
  - Defense in depth
- Acceptance standards
  - Overall level of safety (safety goals)
  - Incremental safety changes
    - Risk benefit of additional requirements
    - Potential relaxations

☐ USNRC model
- PRA Policy Statement provides fundamental principles
  - Applies to both licensees and staff
  - Broadly defines complementary role of risk analysis
- Safety Goal Policy Statement defines acceptable level of safety/risk

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Defining intended staff functions

❑Clear definition of staff functions
- Reviewing licensee-generated risk analyses
- Generating risk information, in support of:
  - Judging significance of new information
    - Operating experience
    - Inspection findings
    - Research
  - Taking regulatory actions
    - Determining need for additional requirements
    - Allocating (reallocating) staff resources
    - Relaxing requirements

❑USNRC model
- Reviews licensee risk analysis submittals
- Performs risk analyses in particular areas
  - Backfit analyses
  - Significance determination process

Issuing implementation guidance

❏Translate strategic policies into practical tools
- For licensees
  - Acceptable topics
  - Submittal guidance
  - Standards for underlying risk models and data
- For regulatory staff
  - Reviews of licensee submittals
    - Guidance
    - Acceptance criteria
  - Staff-generated risk analyses
    - Guidance
    - Standards for underlying risk models and data
    - Acceptance criteria

❏USNRC model
- For licensees
  - Regulatory guides
- For regulatory staff
  - Standard review plans
  - Regulatory analysis guidelines (for backfit analyses)
  - Inspection manual (including for significance determination process)

Example of traditional licensee submittal (e.g., license amendment)

❑Licensee

- Identify issue
- Develop technical and regulatory basis document
- Develop submittal

- Respond to questions

- Take implementation actions

❑Regulatory Staff

- Review submittal
  - Is it risk-informed?
  - Should it be risk-informed?
- Issue questions

- Issue safety evaluation

Example of regulatory staff action (e.g., backfit analysis, significance determination)

❑Licensee

- Review and provide comments

- Implement decision in facility

❑Regulatory staff

- Identify issue
  - New rule or change to rule
  - Inspection finding
- Develop technical and regulatory basis document
- Issue for comment

- Review comments and finalize decision
- Implement decision (generically)

Developing expertise

❑ **Staff with necessary expertise**

- Types of expertise
  - Within agency
  - Available under contract
- Location of expertise (organizationally)
- Training programs
  - Internal
  - External

❑ **USNRC model**

- Centralized and extensive expertise in PRA methods
  - Extensive contractor support in particular areas
- De-centralized expertise in PRA implementation
  - License amendment reviews
  - Senior reactor analysts (regions)
- Agency-maintained training program