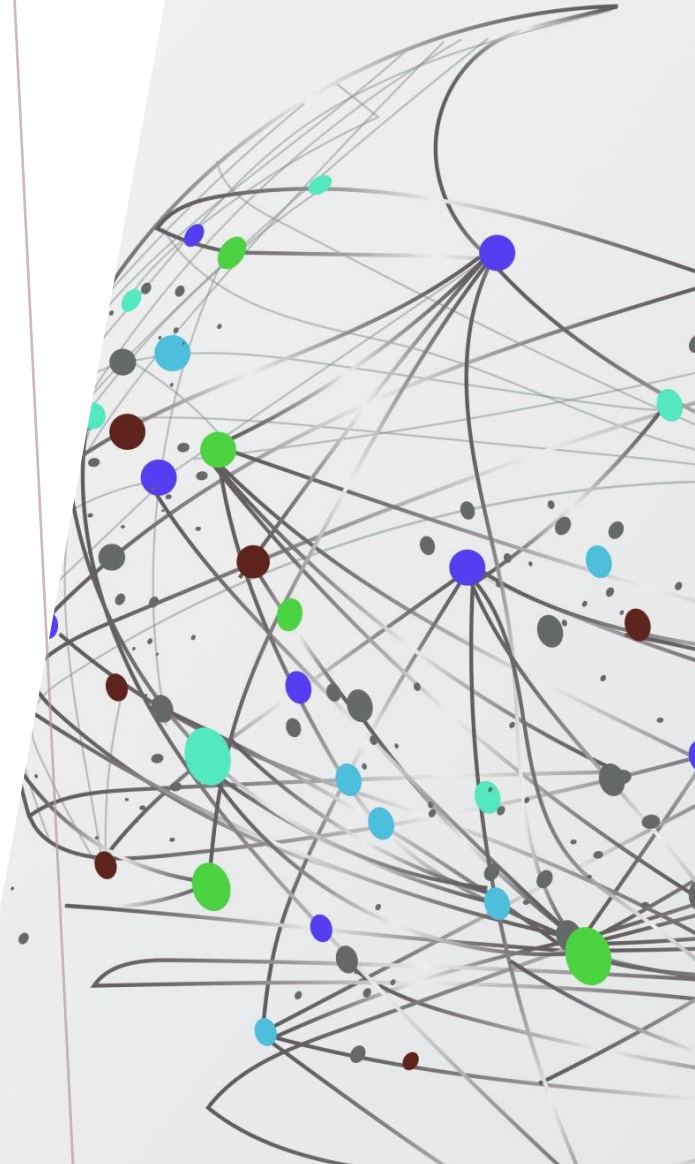


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JULY 2026

*A PERSPECTIVE
ON SYSTEMATIC
RISK EVALUATIONS*



RISK MANAGEMENT

DHS RISK LEXICON, 2010 EDITION

“Risk management is the process for

- identifying, analyzing, and communicating risk
and
- accepting, avoiding, transferring, or controlling it

to an acceptable level considering associated costs and benefits of any actions taken.”

RISK MANAGEMENT PRINCIPLES

ISO 31000, RISK MANAGEMENT – GUIDELINES; 2018

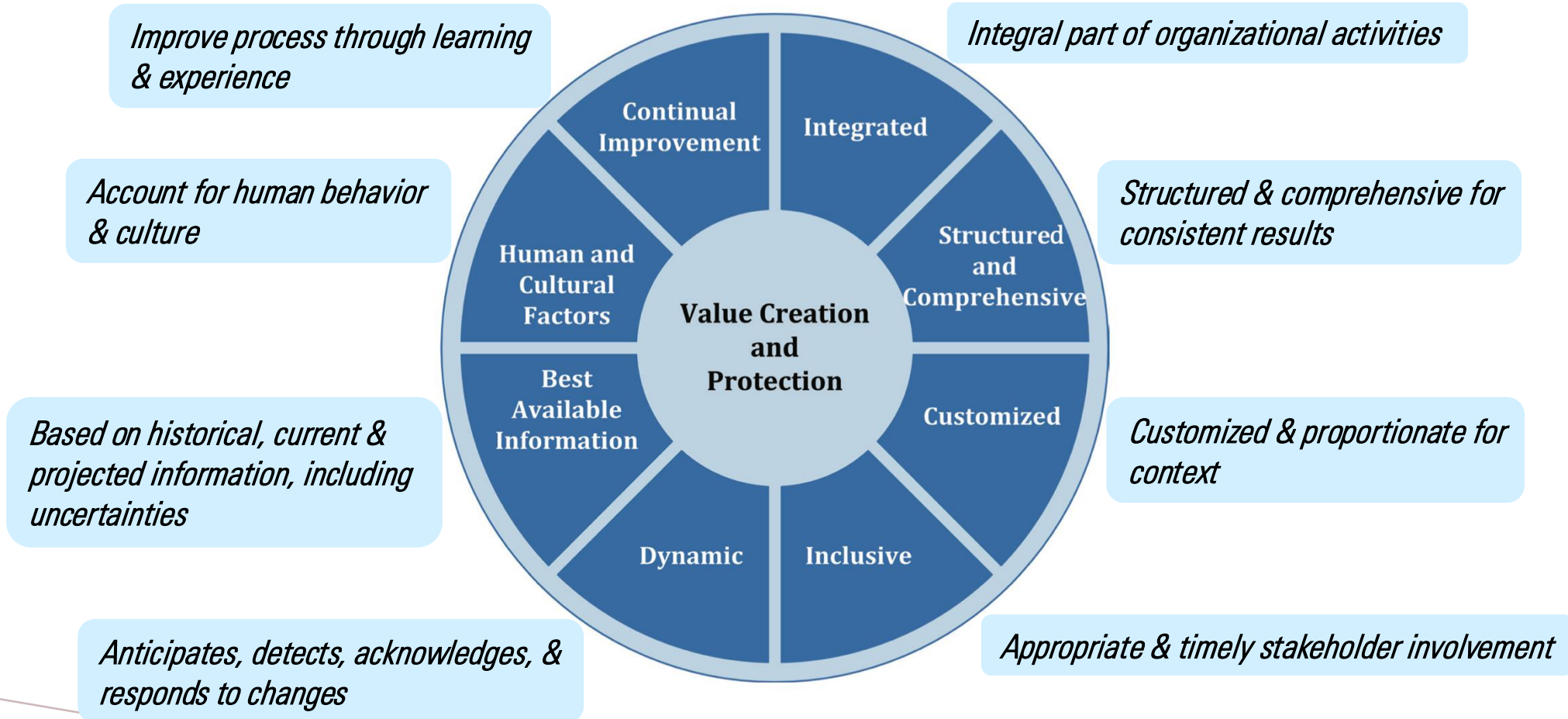


Figure 2 — Principles

RISK MANAGEMENT GOAL

NUREG 2150, "A PROPOSED RISK MANAGEMENT REGULATORY FRAMEWORK," (2012)

Provide risk-informed and performance-based defense-in-depth protections to:

- Ensure appropriate barriers, controls and personnel to prevent, contain, and mitigate exposure to radioactive material according to the hazard present, the relevant scenarios, and the associated uncertainties
- Ensure that the risks resulting from the failure of some or all of the established barriers and controls, including human errors, are maintained acceptably low

RISK MANAGEMENT PROCESS



ISO 31000 Risk Management Process



DHS Risk Management Process



Figure 2-1 The Regulatory Decisionmaking Process
NUREG 2150, "A Proposed Risk Management Regulatory Framework"

RISK ANALYSIS AND EVALUATION

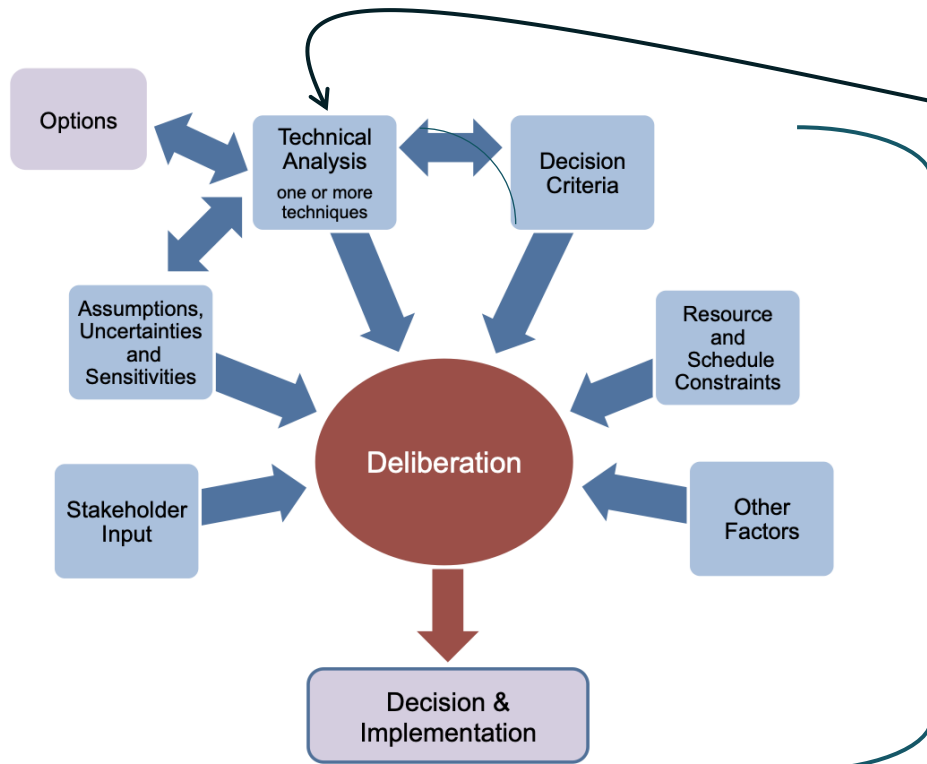


Figure 3-2 Deliberations

NUREG 2150, "A Proposed Risk Management Regulatory Framework"

ISO 31000

Risk Analysis:

... to comprehend the nature of risk and its characteristics including, where appropriate, the level of risk. Risk analysis involves a detailed consideration of uncertainties, risk sources, consequences, likelihood, events, scenarios, controls and their effectiveness..

Risk Evaluation

... to support decisions. Risk evaluation involves comparing the results of the risk analysis with the established risk criteria to determine where additional action is required...

REGULATORY EXAMPLE

10 CFR PART 53, RISK ANALYSIS

10 CFR 53.450, "Analysis Requirements"

(a) Requirement to have a probabilistic risk assessment (PRA), or other systematic risk evaluations (SREs), or a combination thereof. A PRA, other SREs, or a combination thereof for each commercial nuclear plant must be performed and used together with other generally accepted approaches for systematically evaluating engineered systems to identify potential failures, susceptibility to internal and external hazards, and other contributing factors to event sequences that might challenge the safety functions identified in § 53.230 and to support demonstrating that each commercial nuclear plant meets the safety criteria of § 53.220.

REGULATORY EXAMPLE

10 CFR PART 53, DECISION CRITERIA

§ 53.220 Safety criteria for licensing-basis events other than design-basis accidents.

Design features and programmatic controls must be provided for each commercial nuclear plant such that identification and analysis of licensing-basis events (LBEs) other than DBAs in accordance with § 53.240 demonstrate the following:

- (a) Plant structures, systems, and components (SSCs), personnel, and programs provide the necessary capabilities and maintain the necessary reliability to address LBEs other than DBAs in accordance with §§ 53.240 and 53.450(e), and provide measures for defense in depth in accordance with § 53.250; and
- (b) The analysis of risks to public health and safety resulting from LBEs other than DBAs under § 53.450(e) includes comprehensive risk metrics that satisfy associated risk performance objectives that are acceptable to the U.S Nuclear Regulatory Commission (NRC) and provide an appropriate level of safety.

REGULATORY EXAMPLE

DECISION CRITERIA – CONTINUED (10 CFR PART 53 PREAMBLE)

- Comprehensive risk metrics should ... approximate the total, overall risk from the facility ...
- Screening tools and bounding or simplified methods may be used for any mode or hazard, provided that the applicant provides an acceptable technical basis.
- As with all risk-informed methodologies, treatment of uncertainties must be addressed.
- The use of comprehensive risk metrics, such as the individual early fatality risk (IEFR) and the individual latent cancer fatality risk (ILCFR), and associated risk performance objectives, such as the QHOs, from the Safety Goals Policy Statement, could form the basis for one approach to meet § 53.220(b).
- Applicants under part 53 may choose to develop and seek NRC approval of comprehensive risk metrics or sets of risk metrics and associated risk performance objectives beyond those previously discussed, including the use of surrogate measures for use in specific analyses to satisfy the requirements in § 53.220(b).

REGULATORY EXAMPLE

10 CFR PART 53, MONITORING

10 CFR 53.450(b), – Specific uses of analyses

* * *

6) Inform the establishment and updating of appropriate measures for plant operations, including availability controls, to ensure that the configurations and special treatments for SR SSCs and NSRSS SSCs provide the capabilities, availability, and reliability consistent with satisfying the safety criteria under §§ 53.220 and the analyses of licensing-basis events other than design-basis accidents (DBAs) under § 53.450(e)

10 CFR 53.710, Maintaining capabilities and availability of SSCs

Measures must be provided for each commercial nuclear plant licensed under this part such that the capabilities, availability, and reliability of plant SSCs, when combined with corresponding programmatic controls and human actions, provide that the safety criteria defined in §§ 53.210 and 53.220 will be met.

(a) Technical Specifications, SR SSCs, § 53.210

(b) Control Measures, SR and NSRSS SSCs, §§ 53.220 & 53.450(e)

SYSTEMATIC RISK EVALUATIONS

ISO 31010, “RISK MANAGEMENT – RISK ASSESSMENT TECHNIQUES

6 Implementing risk assessment

6.1 Plan the assessment

- 6.1.1 Define purpose and scope of the assessment
- 6.1.2 Understand the context
- 6.1.3 Engage with stakeholders
- 6.1.4 Define objectives
- 6.1.5 Consider human, organizational and social factors
- 6.1.6 Review criteria for decisions

6 Implementing risk assessment

6.3 Apply risk assessment techniques

- 6.3.1 Overview
- 6.3.2 Identifying risk
- 6.3.3 Determining sources, causes and drivers of risk
- 6.3.4 Investigating the effectiveness of existing controls
- 6.3.5 Understanding consequences, and likelihood
- 6.3.6 Analysing interactions and dependencies
- 6.3.7 Understanding measures of risk

SYSTEMATIC RISK EVALUATIONS

ISO 31010, “RISK MANAGEMENT – RISK ASSESSMENT TECHNIQUES (EXAMPLES)”

Risk Identification

- Failure Modes and Effects (FMEA)
- Hazard and Operability (HAZOP)
- Structured what-ifs (SWIFT)

Risk Evaluation

- As low as reasonably practicable (ALARP)
- Frequency-number diagrams (F-N)
- Risk indices

Risk Analysis

Analyzing Controls

- Bow tie analysis
- Hazard analysis and critical control points (HACCP)
- Layers of protection analysis (LOPA)

Consequences and Likelihood

- Bayesian analysis
- Event tree
- Fault tree
- Monte Carlo

SYSTEMATIC RISK EVALUATION

EXAMPLE ALTERNATIVE TO PRA

- Alternative Evaluation of Risk Insights (AERI)
 - Element of Framework B in Draft Proposed Part 53 (Subsequently removed from final rule)
 - Provided rationale for not including PRA in a manner like 10 CFR Part 52
 - Recognized that large LWR studies and actions strongly influenced by low frequency but high consequence event sequences (i.e., severe accidents)
 - Assessed potential for some designs to potentially have lower consequences based on reduced radionuclide inventories, low operating pressures, inherent features, etc.
 - Evaluated what potential consequence could meet NRC safety goals with less focus on estimating event frequencies
 - Proposed criteria of offsite consequences of 2.5 rem over first year of an accident for bounding event
- DG-1413, "Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants" (RG 1.254)
- DG-1414, "Alternative Evaluation for Risk Insights Methodology" (not completed)

ONGOING ACTIVITIES

EXAMPLES

- Part 53 Related guidance
 - Siting (cost/benefit assessment)
 - Comprehensive Risk Metrics and Associated Risk Performance Objectives ... (RG 1.263/DG-1443)
 - Evaluations of Risk Assessments for Risk-Informed Decision-Making ... (DANU-ISG-2026-xx)
- NRC/Industry Efforts on Using PRA in combination with other SRE
 - PRA Scope
 - Low Frequency/High Magnitude/High Uncertainty External Hazards
- Bounding event approaches
 - Part 57 (MHA/MCA)
 - Unmitigated events (DOE, NRC graded site characterization (DG-4036))
 - ANS 2.26, DOE-STD-1020
- Modernizing Reactor Licensing, Safety Oversight and Siting Practices Rulemaking
 - Proposed 10 CFR 50.220 & 52.220

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