



Canadian Nuclear
Safety Commission

Commission canadienne
de sûreté nucléaire

Risk Management at the CNSC

Presentation to Community of Federal
Regulators Regulatory Professional
Development Program

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nuclearsafety.gc.ca

Outline

- Overview of CNSC Enterprise Risk Management
- Application of Risk Management in Regulatory Programs
- Risk Management through Application of Defence in Depth and a Graded Approach

Part 1: Overview of CNSC Enterprise Risk Management

Putting Risk Into Context

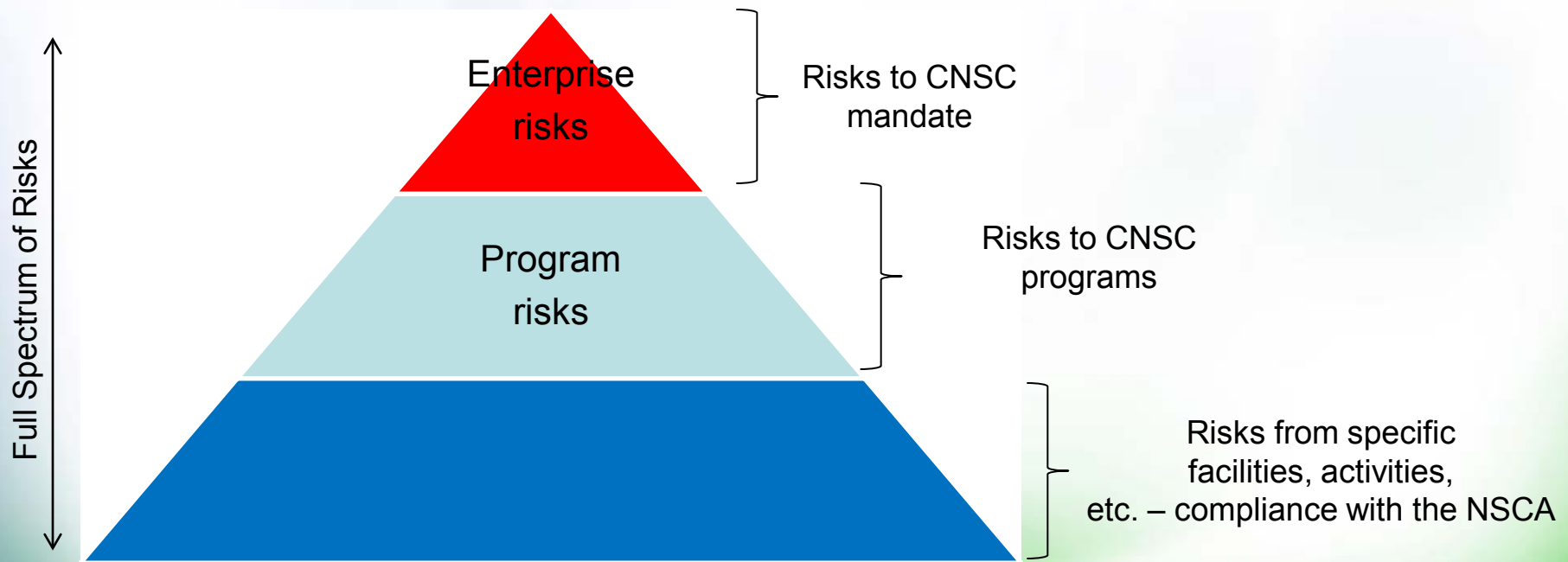
- Risk Management (RM) recognized/expected management practice
 - in both public and private sectors, domestically and internationally
 - *TBS Framework for the Management of Risk (2010)* and *MAF Area of Management*
 - *Federal Framework for the Application of Precaution in Science-Based Decision Making About Risk (2003)*
 - *ISO/CSA 31000 Risk management – Principles and guidelines*
 - Standards Council Canada recently contracted Underwriters Laboratories Inc. (UL) to develop a guideline for managing risks to the public interest in a regulatory context for Canada (target: 2017)
- What does all of this mean?
 - Manage **all** risks in a holistic, integrated manner
 - Success is dependent on building the right framework to establish/strengthen the foundations and arrangements that will embed RM throughout the organization at all levels

Risk Management at the CNSC

- Risk management is fundamental at the CNSC
 - stated in the *Nuclear Safety and Control Act*
 - part of the culture
 - embedded in our management system, reflected in all licensing and compliance activities, and an important consideration in the management of our enabling functions
- CNSC is committed to ongoing strengthening/improvement of its risk management practices

Risk Management

- o Enterprise risk management (ERM) is a strategic business discipline that supports the achievement of an organization's objectives by assessing and managing the full spectrum of risks in a holistic, systematic, disciplined and consistent manner across all areas of work and at all levels



CNSC Risk Management Policy

- The risk management policy is a critical component through which organizations set their framework
 - reflects prevalent and best practices (private and public sectors), complies with TB requirements and aligns with ISO/CSA 31000
 - articulates key principles, identifies the main elements of the risk management process, and identifies roles and responsibilities
 - applies to all CNSC business lines and all employees

Embedding Risk Management Into Key Decision Processes

- Usefulness of risk information is limited unless utilized for decision making
- It is critical to embed risk into the organization's key decision processes - only then can the best trade-offs be made in terms of rational priority setting and responsible spending materialize
- Embedding risk management into the management system is crucial
- Important to remember that embedding goes two ways:
 - leveraging existing risk information into future enterprise risk profile's to maximize alignment and increase rigour
 - leveraging enterprise risk profile's to strengthen decision making:
 - priority setting
 - resource allocation
 - in-year reporting
 - audit/eval. planning
 - entity-level controls
 - etc.

Part 2: Application of Risk Management in the Regulatory Program

Nuclear Safety and Control Act (1)

The objects of the Commission are

(a) to regulate the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information in order to

- (i) **prevent unreasonable risk**, to the environment and to the health and safety of persons, associated with that development, production, possession or use,
- (ii) **prevent unreasonable risk** to national security associated with that development, production, possession or use, and
- (iii) achieve conformity with measures of control and international obligations to which Canada has agreed; and

(b) to disseminate objective scientific, technical and regulatory information to the public concerning the activities of the Commission and the effects, on the environment and on the health and safety of persons, of the development, production, possession and use referred to in paragraph (a).

Nuclear Safety and Control Act (2)

24(4) No licence shall be issued, renewed, amended or replaced — and no authorization to transfer one given — unless, in the opinion of the Commission, the applicant or, in the case of an application for an authorization to transfer the licence, the transferee

- (a) is qualified to carry on the activity that the licence will authorize the licensee to carry on; and
- (b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

P-299, Regulatory Fundamentals

- Policy document that directs CNSC activities
- Section 4.2, “Basing regulatory action on levels of risk” states that the CNSC
 - regulates persons, organizations, and activities that are subject to the Act and Regulations in a manner that is consistent with the risk posed by the regulated activity
 - recognizes that risk must be considered in the context of the CNSC’s mandate under the Act
 - makes regulatory decisions and allocates resources in a risk-informed manner

Risk-Informed Regulatory Approach

- For licensing and compliance, assess risk associated with facilities and activities according to probability and consequences of potential events
- Factors that affect risk ranking include
 - risk associated with the type/complexity of the facility or activity
 - licensee performance and compliance history
- For all facilities and activities, CNSC expects continuous enhancement of safety and control measures to address changing risk profiles and new information
- For facilities or activities where accidents or malfunctions could have severe consequences, CNSC requires designs and operating procedures that include multiple layers of defence to manage risk

CNSC Programs: Basic Attributes

Nuclear reactors

- Small # licensees
- Similar designs, operations
- Potential consequences to large populations, environment
- Historically, very low frequency of events

Fuel cycle facilities

- Larger # licensees (~80)
- Wide range of designs, operations
- Potential consequences to individuals, larger populations, environment (e.g., mines)
- Historically, low frequency of events

Substances & prescribed equipment

- Large # licensees (~1700)
- Wide range of facilities, activities
- Potential low consequences/ consequences to individuals
- Historically, higher frequency of events (e.g., radiological exposures)

CNSC - Safety and Control Areas

- Safety and control areas (SCA) are the technical topics CNSC staff use across all regulated facilities and activities to assess, evaluate, review, verify and report on regulatory requirements and performance. This framework is used throughout our core processes.
 - the SCAs are linked to the objects of the *Nuclear Safety and Control Act* and its regulations and are way of organizing the information presented in a safety case

CNSC - Safety and Control Areas

- Management system
- Human performance management
- Operating performance
- Safety analysis
- Physical design
- Fitness for service
- Radiation protection
- Conventional health and safety
- Environmental protection
- Emergency management and fire protection
- Waste management
- Security
- Safeguards and non-proliferation
- Packaging and transport

CNSC - Other Matters of Regulatory Interest

- Environmental assessment
- CNSC consultation – Aboriginal
- CNSC consultation – other
- Cost recovery
- Financial guarantees
- Improvement plans and significant future activities
- Licensee public information program
- Nuclear liability insurance

Nuclear Reactors Program

Risk-Informed Aspects of Nuclear Power Plant (NPP) Regulation (1)

o Licence renewal:

- based on risk-informed assessment of safety performance
- focuses on safety significant issues & challenges, and licensee's safety improvement plans
- Canada is adopting Periodic Safety Review (PSR) within the licensing process
 - systematic consideration of the adequacy of the facility design and operation

Risk-Informed Aspects of Nuclear Power Plant (NPP) Regulation (2)

o Verification:

- risk-informed compliance baseline program
 - reflects relative importance of safety areas and programs in controlling risk
 - similar programs for existing operating NPPs
 - adjust program to address developments
 - Fukushima upgrades are now addressed in day-to-day operations and regulatory oversight
- focused activities, based on safety performance

Risk-Informed Aspects of Nuclear Power Plant (NPP) Regulation (3)

- Resolution of specific issues
 - CANDU safety issues (e.g., items that need further work to confirm adequacy of safety margins)
 - specific operational developments
- Enforcement
 - graded enforcement based on safety significance
- Safety significance determined using a risk-informed decision-making process

Nuclear Fuel Cycle Program

Nuclear Fuel Cycle Program

- ~ 80 facilities to regulate
 - uranium mining and milling facilities
 - nuclear processing facilities
 - waste management facilities
 - historical waste sites
 - research facilities

Risk Ranking/Performance Rating

- Applied expert judgment approach; based on CSA risk management standards
- Developed risk factors/performance indicators for each technical area
- A risk level of Low, Moderate or High is assigned for each facility (or group of similar facilities) for each risk area:
 - three sub-levels within each level using relative risks (L1 to H3)
 - revisited periodically
- Performance component: performance rating for each facility is evaluated on a regular basis for each risk area using performance indicators

Uranium Mines and Mills: Ranking Example

Safety and control areas	Rabbit Lake	Cigar Lake
Operating performance	H1	H2
Physical design and fitness for service	H1	H2
Emergency preparedness	H1	H1
Security	H1	H1
Environmental protection	H2	H1

Nuclear Substances and Prescribed Equipment Program

Development of the Risk-Informed Regulatory Program

- Grouping use types (a specific licensed activity)
 - 80 use types put into 12 use-type groups
- Risk ranking of groups
- Determine applicable requirements
 - Act, Regulations, licence conditions for each group
- Risk ranking of requirements and grading
- Selection of compliance verification methods
- Common format and integrated reporting

Risk Ranking of Non-Compliance With Requirements

- Ranked the impact of non-compliance of each applicable regulatory requirement for each use-type group:
 - high risk: immediate or serious health, safety, or security issue
 - medium risk: health, safety or security issue
 - low risk: no health, safety or security issues (generally administrative issues)

CNSC Ranking of Licence Use-Types (1)

- Radiological risk, based on annual potential dose for workers:

Level	Dose
Low	< 1 mSv/y
Medium	1 mSv/y < 5 mSv/y
High	> 5 mSv/y

- Complexity of radiation protection program

CNSC Ranking of Licence Use-Types (2)

Use-Type Group	Risk Rank	No. of Licences
Class II	High	228
Consolidated	High	67
Radiography	High	110
Manual brachytherapy	High	18
Well logging	High	42
Servicing	High	66
Open sources/labs	Medium	111
Distribution	Medium	50
Gauges	Medium	914
Large sealed sources	Medium	92
Nuclear med.	Medium	358
Small sealed sources	Low	446

Part 3: Risk Management Through Application of Defence in Depth and a Graded Approach

Implementation of Defence in Depth

Implementation of defence in depth framework ensures safety objectives and safety goals are met

- **General nuclear safety objective**

- NPPs are designed and operated in a manner to protect individuals, society and the environment from harm

- **Technical safety objective**

- provide all reasonably practicable measures to prevent accidents and mitigate their consequences if they occur
- take into account all possible accidents considered in the design, including those of very low probability
- any radiological consequences will be below prescribed limits, and the likelihood of accidents with serious radiological consequences will be extremely low

- **Qualitative safety objectives exist to limit the risks to reasonable levels**

Defence-in-Depth: Concept

- Applied throughout the design process and operation of the plant to provide a series of levels of defence aimed at preventing accidents, and ensuring appropriate protection in the event that prevention fails
 - allows the failure to be detected and compensated for or corrected
 - considers organizational and human performance
- The levels of defence in depth shall be independent to the extent practicable and subject to overlapping provisions

Defence-in-Depth Framework for Nuclear Power Plants

(from: Implementation of Defence in Depth at Nuclear Power Plants, NEA 2016)

Level	Implementation
1. To prevent deviations from normal operation, and to prevent failures of structures, systems and components (SSCs) important to safety	<ul style="list-style-type: none">• Conservative design• High quality construction (e.g., appropriate design codes and materials, design procedures, equipment qualification, control of component fabrication and plant construction, operational experience)• A suitable site was chosen for the plant with consideration of all external hazards (e.g. earthquakes, aircraft crashes, blast waves, fire, flooding) in the design• Qualification of personnel and training to increase competence.• Strong safety culture• Operation and maintenance of SSC in accordance with the safety case
2. To detect and intercept deviations from normal operation, to prevent AOOs from escalating to accident conditions and to return the plant to a state of normal operation	<ul style="list-style-type: none">• Inherent and engineered design features to minimize or exclude uncontrolled transients to the extent possible• Monitoring systems to identify deviations from normal operation.• Operator training to respond to reactor transients
3. To minimize the consequences of accidents, and prevent escalation to beyond design basis accidents	<ul style="list-style-type: none">• Inherent safety features• Fail-safe design• Engineered design features, and procedures that minimize consequences of DBAs• Redundancy, diversity, segregation, physical separation, safety system train/channel independence, single-point failure protection• Instrumentation suitable for accident conditions• Operator training for postulated accident response

Defence-in-Depth Framework for Nuclear Power Plants (2)

(from: Implementation of Defence in Depth at Nuclear Power Plants, NEA 2016)

Level	Implementation
4. To ensure that radioactive releases caused by severe accidents OR Design Extension Conditions are kept as low as practicable	<ul style="list-style-type: none">• Equipment and procedures to manage accidents and mitigate their consequences as far as practicable• Robust containment design• Complementary design features to prevent accident progression and to mitigate the consequences of Design Extension Conditions• Severe accident management procedures
5. To mitigate the radiological consequences of potential releases of radioactive materials that may result from accident conditions	<ul style="list-style-type: none">• Emergency support facilities• Onsite and offsite emergency response plans• Plant staff training on emergency preparedness and response

Post-Fukushima Enhancements to Defence in Depth: NPP Example (1)

- **Level 3: Protecting facilities including spent fuel pools**
 - Flood protection
 - Makeup water capability and instrumentation

- **Level 4: Preventing and mitigating severe accidents**
 - Enhanced backup power for equipment, telecommunications, and emergency facilities
 - Upgraded instrumentation
 - Protecting fuel
 - makeup water capability to steam generator and primary heat transport emergency core cooling and dousing spray systems
 - Preventing severe core damage
 - makeup water capability to moderator system and calandria vessel/vault
 - enhanced pressure relief for calandria vessel/vault

Post-Fukushima Enhancements to Defence in Depth: NPP Example (2)

- **Level 4: Preventing and mitigating severe accidents (cont'd)**
 - Protecting containment
 - passive hydrogen recombiners
 - containment cooling and filtered venting
 - Severe Accident Management Guidelines validation/exercise

- **Level 5: Protecting the public**
 - automated real-time boundary radiation monitoring
 - source term estimation capability
 - integrated emergency plans and full-scale emergency exercises
 - study of consequences of hypothetical severe nuclear accident
 - pre-distribution of potassium-iodine pills

Graded Approach - Definition

- The graded approach is a method in which the stringency of the design measures and analyses applied are commensurate with the level of risk posed by the reactor facility
- Factors to be considered include:
 - reactor power, reactor safety characteristics, fuel design, source term
 - amount and enrichment of fissile and fissionable material
 - utilization of the reactor
 - presence of high-energy sources and other radioactive and hazardous sources
 - safety design features
 - siting, proximity to populated areas

How the Graded Approach is Applied

- Use of the graded approach in Canada is consistent with International Atomic Energy Agency (IAEA) principles
- Both applicants/licensees and the CNSC use it, and it is codified in CNSC regulatory documents for design and safety analysis
 - most safety requirements in Canada can be implemented in a way that is commensurate with the potential hazards posed by the facility/activities
 - this means requirements can be used for a wide range of reactor designs, power levels and uses, without compromising safety (**requirements are not relaxed**)
- An applicant can propose to address requirements in a risk-informed alternative manner – proposals must demonstrate an equivalent or superior level of safety

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Reminder of Nuclear Industry in Canada

Bringing It All Together

- How does the CNSC regulate across different sectors?
 - **Assess the risk** associated with activities and facilities in view of complexity and consequences of incidents, events, accidents
 - **Defence in depth** provides a framework to meet safety goals and objectives for the facility or activity
 - elements of defence in depth are embodied in the regulatory framework (NSCA, regulations, regulatory documents, national and international standards)
 - A **graded approach** is used to implement defence in depth
 - details of implementation are based on the **risks** of the facility or activity



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