



Canadian Nuclear
Safety Commission

Commission canadienne
de sûreté nucléaire

Canada

Use of the Graded Approach in Regulation

New Major Facilities Licensing Division
Directorate of Regulatory Improvement and Major Projects
Management



Background Information for

Meeting of the Office for Nuclear Regulation, U.S. Nuclear Regulatory Commission,
Canadian Nuclear Safety Commission and Nuclear Energy Agency
Ottawa, Ontario
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Risk-Informed Regulation in Canada



- The Canadian Nuclear Safety Commission (CNSC) regulates in a risk-informed manner:
 - the CNSC allows proportionality through the articulation of requirements and guidance for activities
 - the regulatory framework allows applicants/licensees to propose alternative methods to meet regulatory requirements
 - the applicant/licensee needs to demonstrate that its proposal meets requirements
- Supporting evidence plays a major role in making a regulatory decision
- A graded approach is established as a framework of decision-making tools and rules, and is supported by an organization's management system
 - documents the analyses supporting decision-making
 - supports robust and transparent regulatory processes

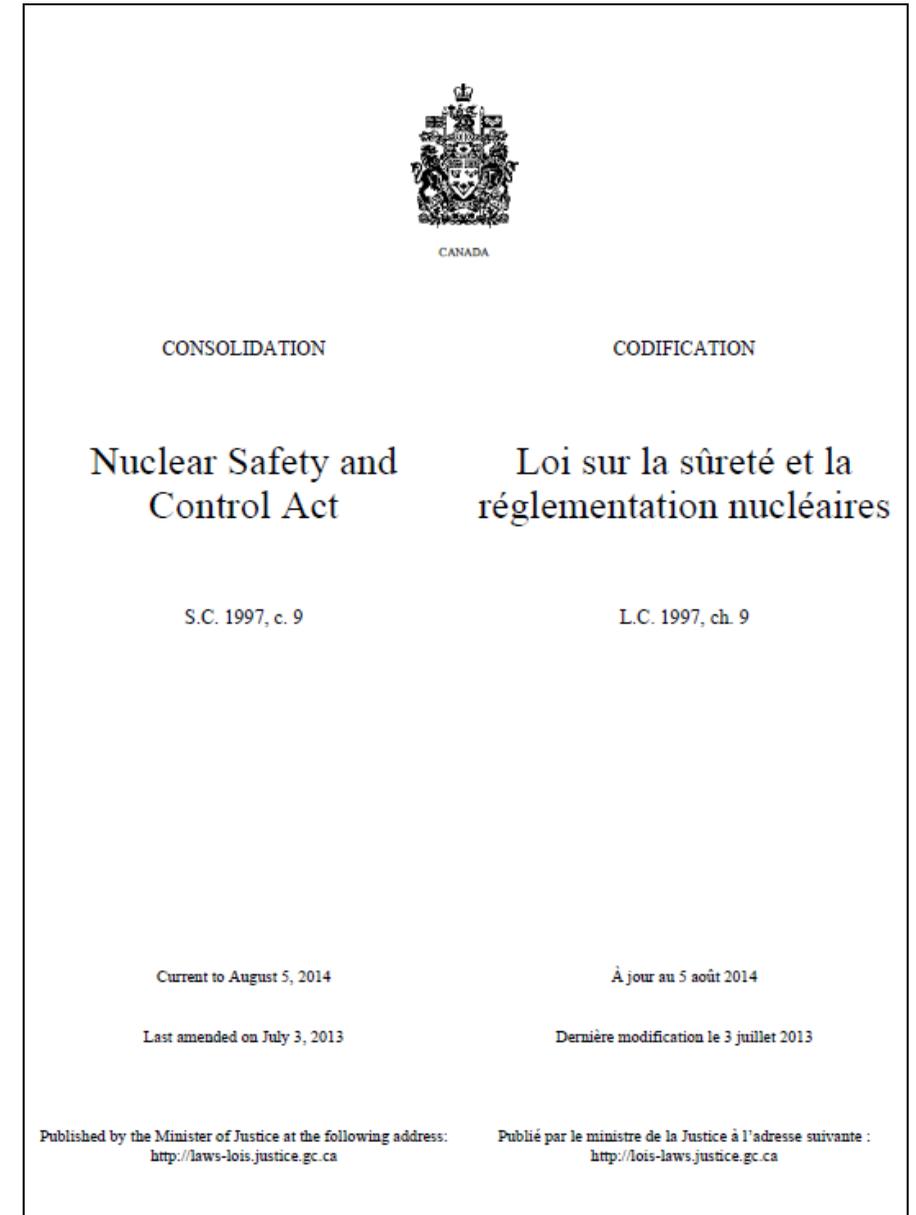
Use of the graded approach in Canada is consistent with International Atomic Energy Agency (IAEA) principles (IAEA Fundamental Safety Principles SF-1 and IAEA GSR Part 1)

Regulatory Decision-Making: *Nuclear Safety and Control Act* (NSCA)



§ 3. The purpose of this Act is to provide for
(a) the limitation, to a reasonable level and in a manner that is consistent with Canada's international obligations, of the risks to national security, the health and safety of persons and the environment that are associated with the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information ...

Legal basis for use of a graded approach in regulation



Key Considerations in Regulatory Decision-Making



Section 24(4) of the *Nuclear Safety and Control Act*

No licence shall be issued, renewed, amended or replaced ... unless, in the opinion of the Commission, the applicant ...:

- (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

The licensee is responsible for safety and is held accountable through its licence

Regulatory Decision-Making



- Decisions made by the Commission take into consideration:
 - regulatory requirements
 - analyses and recommendations from CNSC staff, based on their assessment of both licensee and stakeholder submissions to the Commission
 - best available information, arising from regulatory research or credible third-party research
 - public input, through the hearing process

Understanding risks and mitigating those risks play a significant role in the decision-making process

Graded Approach – Definitions



- The **graded approach** is a method or process by which elements such as the level of analysis, the depth of documentation and the scope of actions necessary to comply with requirements are commensurate with:
 - the relative risks to health, safety, security, the environment and the implementation of international obligations to which Canada has agreed
 - the characteristics of a facility or activity
- From an applicant/licensee perspective, **grading** is the application of the graded approach to a **specific aspect** of their licence application against specific regulatory requirements (e.g., a proposal to only use confinement versus containment)
- From the CNSC's point of view, **grading** is the application of the graded approach to the **overall review** of a submission (e.g., acceptability of the safety case that employs confinement instead of containment)

The use of a graded approach is a proportional application of requirements, not a relaxation of requirements

Role of the Management System



An organization needs processes and procedures to guide its staff on which tools to use when. Examples of risk-informing tools include:

- safety classification
- safety analysis (deterministic and probabilistic)
- process for reviews and approvals for specific decisions
- specific risk-informed decision-making (RIDM) process
- work instructions that specify specific approaches and/or guide the use of expert judgment (e.g., codes and standards)

The reasons for risk-informed decisions need to be clear and documented

Application of the Graded Approach



When a graded approach is applied, factors to be considered include:

- reactor power, reactor safety characteristics, fuel design, source term
- amount and enrichment of fissile and fissionable material
- presence of high-energy sources, and other radioactive and hazardous sources
- uncertainties associated with current level of knowledge
- site characteristics (e.g., external hazards)

The regulator:

- applies technical requirements in a risk-informed manner to ensure that fundamental safety objectives are met
- carries out technical assessment and compliance activities for a project based on risk, complexity and novelty

Application of the Graded Approach by an Applicant/Licensee



An applicant or licensee may:

- demonstrate that specific design measures, analyses or other measures applied to the safety case are commensurate with the level of risks posed
- propose that since an overarching fundamental safety requirement is met, a detailed requirement may not have to be met
- propose alternative methods to meeting requirements

Characteristics of Suitable Information



- Facts and data derived through validated and quality assured (i.e., traceable and repeatable) scientific and engineering processes, such as:
 - experimental or field-derived data
 - operating experience
 - computer modelling
- Uncertainties have been characterized and accounted for
- Information is demonstrated to be relevant to the specific proposal

The more complex the risk characteristics, the greater the burden of evidence needed to support a proposal

Graded Approach Is Not Limited to Design and Safety Analysis



It can also be applied to areas such as:

- scope and depth of environmental characterization (including site evaluation)
- programmatic elements in a licensee's management system (e.g., procurement)
- emergency response and planning programs
- research and development program

Fundamental Principles for Assessment of Applications That Use a Graded Approach



Any assessment of a safety case for a proposed activity is carried out in view of the following:

- defence-in-depth is demonstrated
- fundamental safety functions of “control, cool, contain” have been met
- appropriate safety margins have been established in view of the specific hazards over the lifecycle of the facility
- regulatory requirements have been met

Risk is demonstrated to be at a reasonable level



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Thank you!

Questions?



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