



Canadian Nuclear
Safety Commission

Commission canadienne
de sûreté nucléaire

Canada



INNOVATION IN REGULATION - ENHANCING REGULATORY EFFECTIVENESS

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Working Together to Enhance Cooperation**

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CNSC REGULATES IN A RISK-INFORMED MANNER

- CNSC allows proportionality through the articulation of requirements and guidance for activities
- Regulatory framework allows applicants/licensees to propose alternative methods to meet regulatory requirements
- Applicant/licensee needs to demonstrate their proposal meets requirements

**USE OF THE
GRADED APPROACH
IN CANADA IS
CONSISTENT WITH
INTERNATIONAL ATOMIC
ENERGY AGENCY
(IAEA) PRINCIPLES**

**SUPPORTING EVIDENCE PLAYS A MAJOR ROLE
IN MAKING A REGULATORY DECISION**



NUCLEAR SAFETY AND CONTROL ACT



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).



KEY CONSIDERATIONS IN REGULATORY DECISION-MAKING



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

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:

- (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 THEIR LICENCE**



REGULATORY PRINCIPLES TO ENSURE SAFETY THROUGHOUT ALL LIFECYCLES



Performance-based regulation

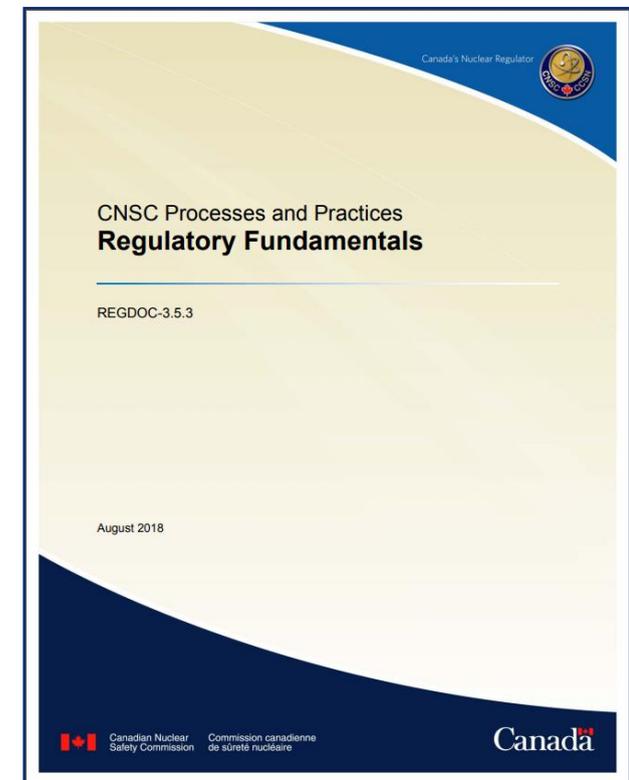
- Many acceptable ways to address CNSC expectations

Fitness for service requirements and guidance

- Regulatory documents on reliability programs, maintenance programs, aging management

Required use of “proven engineering practices”

- Information expected to be credible to the application
- Risks due to knowledge gaps must be understood and addressed



MAINTAIN HIGH CONFIDENCE IN PERFORMANCE OF FUNCTIONS IMPORTANT TO SAFETY



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 research by third parties
- Public input, through the hearing process

Safety case envelopes region of high confidence



UNDERSTANDING RISKS AND MITIGATING THOSE RISKS PLAY A SIGNIFICANT ROLE IN THE DECISION-MAKING PROCESS



GRADED APPROACH : TOOLS FOR REGULATING INNOVATIVE TECHNOLOGIES



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 - **e.g., for reactors:**

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)



GRADED APPROACH: TOOLS FOR REGULATING INNOVATIVE TECHNOLOGIES



**When applying the graded approach,
the following principles are adhered to:**

- Regulatory requirements are met
- Sufficient safety margins are maintained
- Defence in depth is maintained

**RISK IS
DEMONSTRATED
TO BE AT A
REASONABLE
LEVEL**



APPLICATION OF THE GRADED APPROACH: REGULATOR'S PERSPECTIVE



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 a safety case that employs confinement instead of containment).

THE REGULATOR:

- Applies technical requirements in a risk-informed manner to ensure 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: APPLICANT'S PERSPECTIVE



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 use only confinement instead of containment).

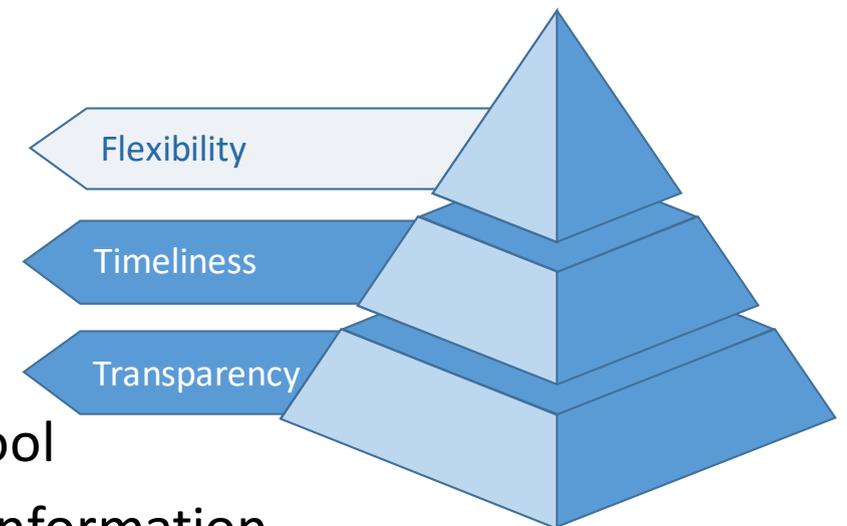
AN APPLICANT OR LICENSEE MAY:

- Demonstrate that specific design measures, analyses or other measures applied to their 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

**THE USE OF A GRADED APPROACH IS A PROPORTIONAL APPLICATION
OF REQUIREMENTS, NOT A RELAXATION OF REQUIREMENTS**

AGILE REGULATORY APPROACH

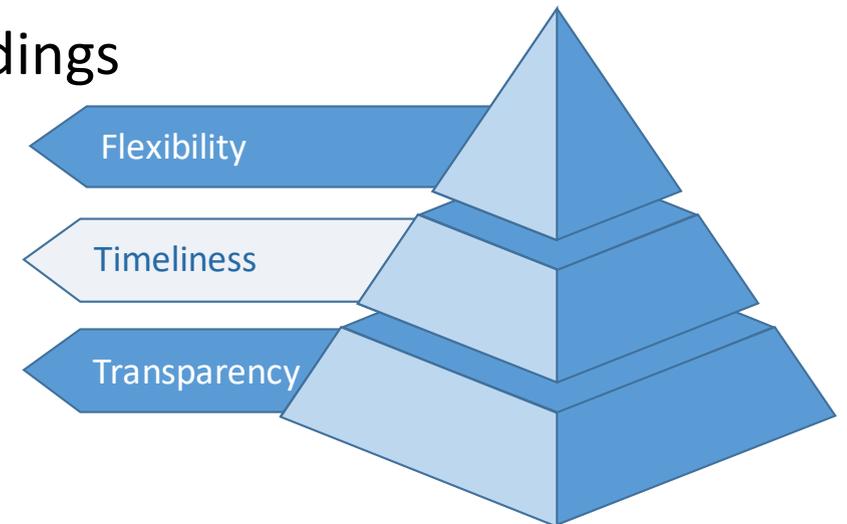
- Technology-neutral framework to regulate innovative technologies
- Authorizations set at a level commensurate with the risk of the regulated activity
- Applicants and licensee can propose how to meet regulatory requirements & safety objectives
- Carrying out the right inspections
- not “one size fits all”
- Selecting the appropriate enforcement tool
- Communicating the appropriate level of information



**OPEN TO INNOVATION –
WHILE NOT COMPROMISING SAFETY**

TIMELINESS IN

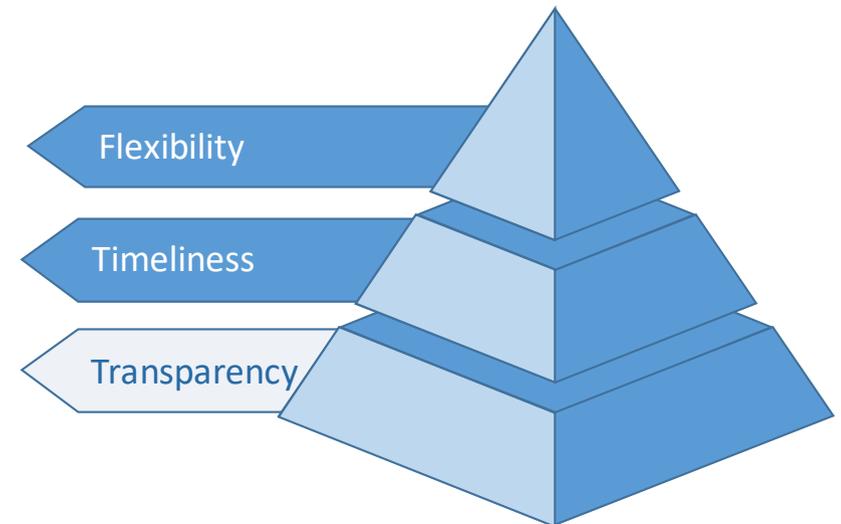
- Development and updates of the regulatory framework
- Decision-making
- Response to review & assessment findings
- Response to inspection findings
- Enforcement actions
- Stakeholder communication



EFFECTIVE AND EFFICIENT DECISION-MAKING

CLARITY OF REGULATORY DECISIONS, INCLUDING RATIONALE, FOR

- Structure and content of the regulatory framework
- Authorizations
- Review & assessment outcomes
- Inspection program and outcomes
- Enforcement actions
- Communication strategies



CLEAR, TRACEABLE REGULATORY DECISIONS



KEY ASPECTS

Demonstrating Proven-ness, Alternative Approaches, and Regulatory Collaboration



REGDOC-3.5.3

“An applicant or licensee may put forward a case to demonstrate that the intent of a requirement is addressed by other means and demonstrated with supportable evidence.” (This is also stated in the *Preface* of many Regulatory Documents)

Section 6.4:

“Information submitted in support of an application must demonstrate that proposed safety and control measures will meet or exceed CNSC expectations.

All submissions are expected to be supported by appropriate analytical, experimental or other suitable evidence.”

**THERE ARE MANY ACCEPTABLE WAYS
TO ADDRESS CNSC EXPECTATIONS**



CNSC REQUIREMENTS FOR NEW DESIGNS, FEATURES OR ENGINEERING PRACTICES



REGDOC-2.5.2: Design of Reactor Facilities: Nuclear Power Plants

Section 5.4: Proven Engineering Practices

*When a **new** SSC design, feature or engineering practice is introduced, adequate safety shall be **demonstrated** by a combination of supporting research and development programs and by examination of relevant experience from similar applications.*

An adequate qualification program shall be established to verify that the new design meets all applicable safety requirements.

New designs shall be tested before being brought into service and shall be monitored while in service so as to verify that the expected behaviour is achieved.

**VENDORS
MAY PROPOSE
DESIGN SOLUTIONS,
BUT APPLICANTS &
LICENSEES MUST
ULTIMATELY DECIDE
HOW TO USE
THEM**



MAKING A CASE FOR USE OF ALTERNATIVE APPROACHES



Section 11 REGDOC-2.5.2

When proposing a new practice, existing Canadian practice and the proposed practice need to be systematically compared:

- How are fundamental safety objectives in Canadian requirements being met?
- How are they broadly equivalent?
- What does “equivalent” mean in the specific application?
- How do the practices differ? (gaps)
- What is the safety significance of the gaps?
- How will safety significant gaps be addressed in the application of the proposed approach? (for example, R&D activities)
- What qualification will be needed to use the proposed approach?

**USERS
PROPOSING AN
ALTERNATIVE APPROACH
NEED SYSTEMATIC
METHODOLOGIES
FOR ANALYZING,
ACCEPTING AND
IMPLEMENTING**



DEMONSTRATING PROVEN-NESS



Scientific and engineering information can be leveraged from a wide variety of sources:

Quality assured
research and
development
activities

Other countries'
nuclear power
programs

Other industrial
applications

Information is expected to be shown to be credible and relevant to the specific application.

Risks presented by knowledge gaps must be understood and addressed.



INDUSTRY ROLE IN INFORMATION SHARING



INDUSTRY HAS A ROLE IN FACILITATING SHARING OF THEIR RELEVANT INFORMATION BETWEEN THE REGULATORS

To leverage information from other regulators' activities, including where they have accepted the use of technologies and approaches, **industry must present:**

- The basis for the adequacy and completeness of information, and how it has been used in a safety case
- Information to support proven-ness
- The basis for acceptance by the other regulator, including information supporting safety claims

CNSC HAS
AGREEMENTS WITH
OTHER REGULATORS TO
SHARE INFORMATION
BUT MAY REQUIRE
PERMISSION OF
TECHNOLOGY
DEVELOPERS

**THIS SUPPORTS THE REGULATOR IN ITS
“INTELLIGENT CUSTOMER” ROLE**



INTERNATIONAL COLLABORATION



THE CNSC IS COOPERATING AND SHARING INFORMATION WITH A NUMBER OF COUNTRIES ON ADVANCED TECHNOLOGIES



Working closely with IAEA and the NEA on sharing best practices in the regulation of SMRs.

Working bilaterally with a number of countries (e.g., United States, United Kingdom).

- On August 15, 2019, CNSC signed a MoC with US NRC to increase regulatory effectiveness through collaborative work on advanced reactors and SMRs

Leveraging the experience of others – CNSC technical reviews can be informed by other regulators' assessments and international scientific work.



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