The Role of Research and Development Information in Supporting a Safety Case

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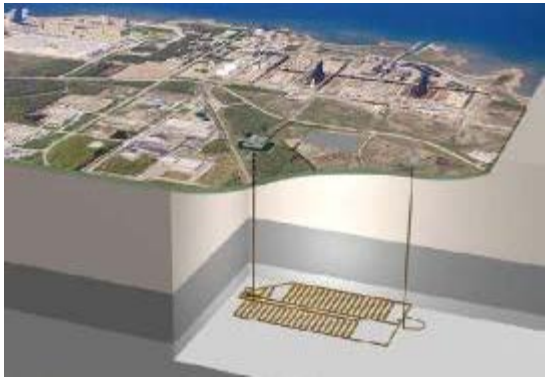
The Canadian Nuclear Safety Commission

- Regulates the use of nuclear energy and materials to protect **health**, **safety**, **security** and the **environment**
- Implements Canada's **international commitments** on the peaceful use of nuclear energy
- **Disseminates objective** scientific, technical and regulatory **information** to the public

We will never compromise safety

The CNSC Regulates All Nuclear-Related Facilities and Activities in Canada…

- Uranium mines and mills
- Uranium fuel fabrication and processing
- Nuclear power plants
- Nuclear substance processing
- Industrial and medical applications
- Nuclear research and educational activities
- Import and export controls
- Waste management facilities



Over the Entire Lifecycle

The Commission

- Quasi-judicial administrative tribunal
- Reports to Parliament **through** the Minister of Natural Resources
- Commission members are independent and part-time
- Commission hearings are public and webcast
- Staff presentations in public

Transparent, science-based decision making

Safety Focus

Essential conditions to issue a licence (NSCA 24(4))

- No licence issued unless the CNSC is satisfied that the applicant is qualified
- Provisions are in place to ensure safety

"Safety" is not a defined term

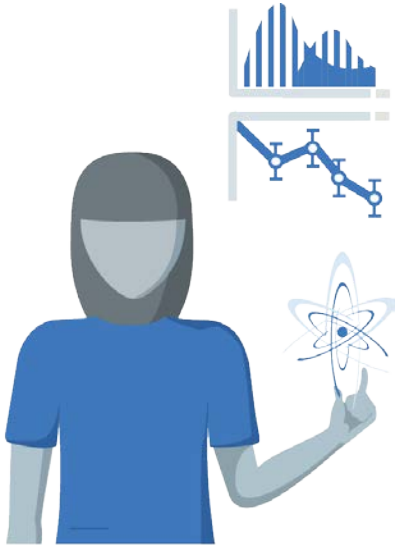
- Commission has statutory authority to judge safety and consider unreasonable risk

Benchmark to international safety standards

- International Atomic Energy Agency, International Commission on Radiological Protection, World Health Organization, Canadian Standards Association

Precautionary and ALARA (as low as reasonably achievable) principles

Science-Based Decision Making



Decisions are risk informed, based on sound technical and scientific grounds

- How safe is safe?
- Ongoing compliance for the life of the project
  - licence conditions handbook and compliance verification criteria

Decisions have a clear focus on safety

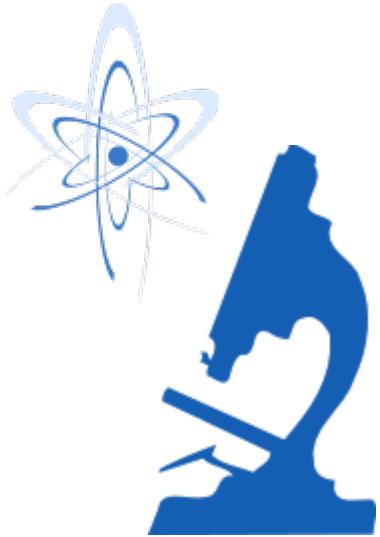
- Social acceptability and economic concerns are not a consideration for licensing

Regulatory Involvement in Deployment of New Reactor Technologies

- New reactor research and development activity will be addressed accordingly
- Facilities developed to support various stages of development may be subject to licensing:
  - e.g., prototypic experiments (loops), sub-critical/critical prototypes, demonstration reactor
- CNSC VDR process offers pre-licensing opportunity for vendors:
  - provides an opportunity early feedback on how regulatory requirements are addressed
  - examines adequacy of R&D activities
  - Not a commitment for licensing – the Commission makes the final licensing decision
- Eventual licensing of commercial design would take into consideration the results of VDR reviews and conclusions

VDR process may lead to streamlining at licensing stage

CNSC Technical Support Branch – CNSC's Technical Support Organization



Contributing and supporting the licensing and compliance processes established for the CNSC's regulatory program

- Providing specialized expertise across all of the CNSC's safety and control areas
- A culture of learning and critical thinking centered around key safety principles to be addressed in technology development that may lead to licensed activities

Risk-Informed Processes

- Processes and tools exist to use professional judgement while recognizing that flexibility may be required on a case-by-case basis

Technology neutral

The Licensee as a Technology User

- Responsible for safe performance of activities and providing safety and operational evidence to support safety claims
  - reflects the demonstrations in their safety and control measures in their safety case
- Normally derived from **combination of** industry standards, supporting research and development programs and relevant operating experience (OPEX)
- If standards and/or relevant OPEX not sufficient, then **R&D program and/or use of conservatism needs to address gaps that represent uncertainties**

CNSC requirements and guidance do not prescribe how to do this – but provide a framework for doing so in a pragmatic way

Composition of R&D Program

- **Research:** Investigating and understanding the scientific bases that will support the safety case and engineering decision-making in development activities
  - are phenomena credited in passive features well understood?
  - will materials behave in predictable and controllable ways over time?
  - determination of residual uncertainties and their implications on the safety case?
- **Development:** Engineering activities to establish product features that will perform as specified
  - focused on meeting engineering specifications used to support safety claims

R&D program for new technologies integral in the project management system; soundness supported by a rigorous quality program

Complementary Ways to Generate Supporting Information

- **Numerical analysis and modelling:** to establish/inform design assumptions
- **Engineering (e.g., bench-top) tests:** to demonstrate engineering characteristics of a technology and support numerical analysis and modelling
- **Prototype or prototypical systems:** to demonstrate some novel elements of a new technology
  - basic technological components are integrated to establish that the pieces will work together
- **Demonstration facility:** to show integrated operation of all novel elements and generate OPEX
  - can be a first-of-kind reactor to be used for commercial operation

No prescribed regulatory strategy

Pre-Licensing Vendor Design Review Process – Vendor's R&D Program

- Opportunity for a technology vendor to obtain early feedback from the CNSC on how vendor is addressing CNSC requirements

- CNSC will review:
  - how the R&D program is being managed under quality-assured processes
  - the overall strategy to identify and address gaps in information needed to support design and safety analysis
  - how outcomes of R&D are integrated into processes for design and safety analysis

The Commission makes final licensing decisions

Licensing Process for a Project

- Focus changes to the user of the technology (licensee)
- Safety and control measures must be commensurate with risks presented by activities:
  - consistent with a defence-in-depth approach
  - informed by certainties in safety analyses
  - applying conservative regulatory decisions to address uncertainties requiring further research
- Licence conditions may be included to ensure regulatory oversight during the implementation of a new project:
    - regulatory hold points during commissioning
    - confirmation of system compliance with design requirements
    - confirmation of safety analysis assumptions
- Licence conditions handbook would provide compliance verification criteria applicable to commissioning and early operation

CNSC Conduct of Technical Assessment

- Documented in CNSC Management System
- Informs decision making in ongoing licensing and compliance
- Scope and depth of CNSC work is risk-informed:
  - Processes established with associated service standards
  - Establish regulatory position on safety case:
    - review of the complete safety case
    - risk informed: provide for more focus in areas of greater hazards and uncertainties
    - takes into account professional judgment
  - Provides a documented regulatory position

Conclusion

- **Decisions by the CNSC are risk informed, based on sound technical and scientific grounds**
- **This means that the applicant for a licence needs to demonstrate their safety case**
- **SMR deployment will need to be supported by sound R&D programs**
  - approach not prescribed by the CNSC
  - may call for prototypic or demonstration facilities also subject to licensing
- **Suggest early discussion on the establishment of the R&D program and associated strategy**

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