



Canadian Nuclear  
Safety Commission

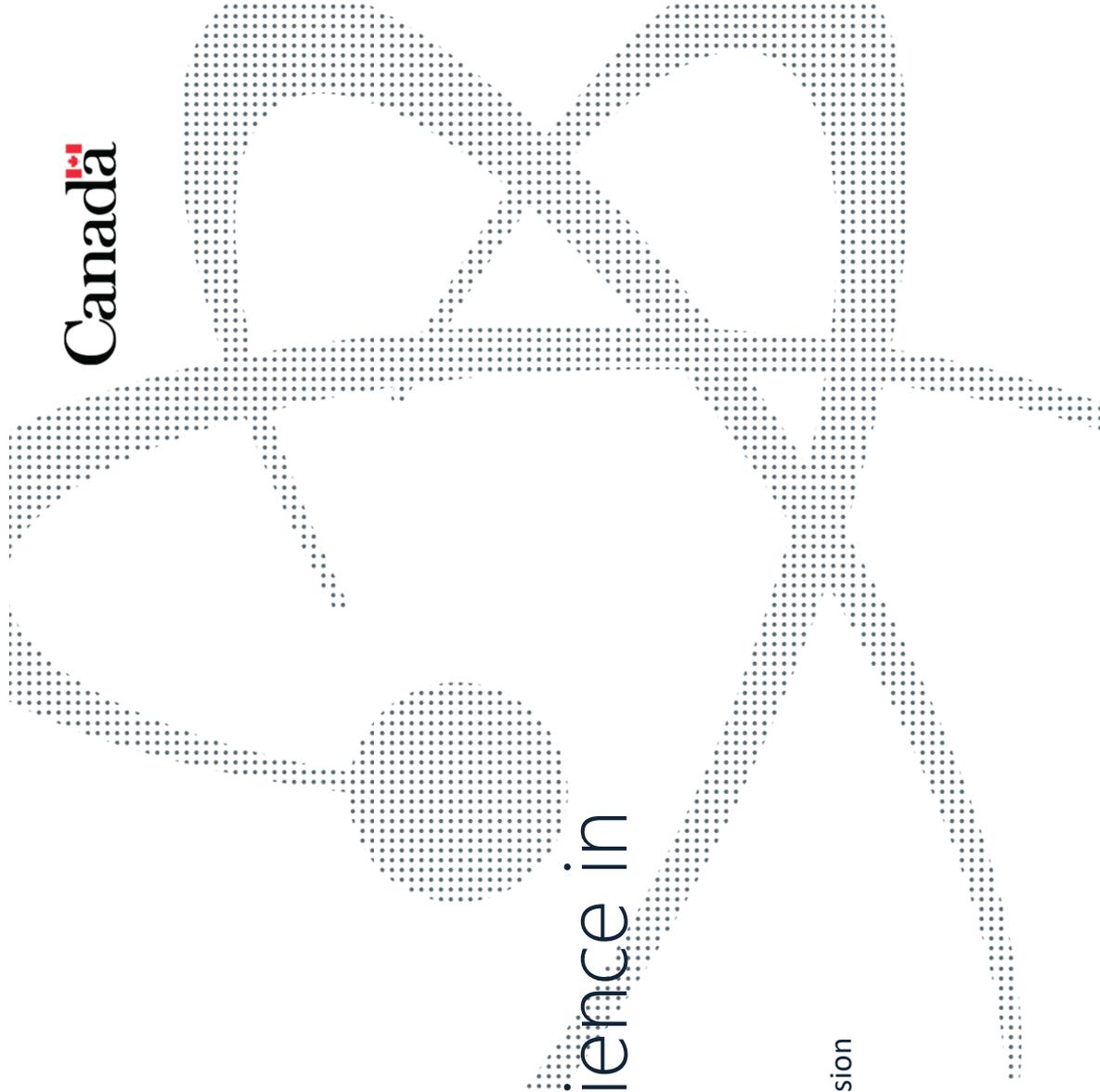
Commission canadienne  
de sûreté nucléaire

Canada

# Quality Assurance

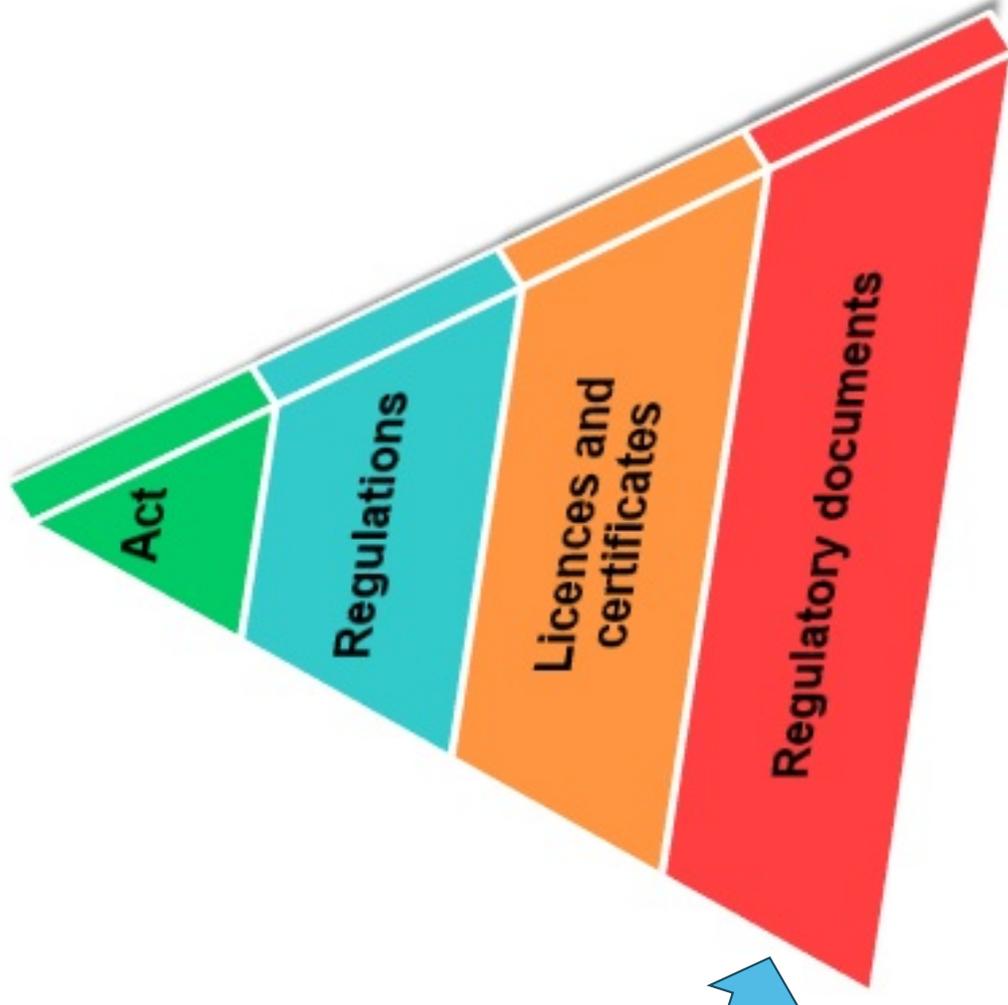
Supply chain experience in  
Canada

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# CNSC Regulatory Framework

- REGDOCS – explain how to meet requirements set out in the NSCA (the ACT) and Regulations.
- CNSC maintains streamlined framework by also using industry standards
  - CSA
  - ASME
  - ICRP
  - IEEE



# Canadian Licensing Basis for Management System and Supply Chain

## Nuclear Safety and Control Act (NSCA)

- Law that establishes the regulator and licensing for nuclear activity

## Class 1 Facilities Regulations

- Paragraph 3(d) states that an application for a licence to operate a Class 1 nuclear facility shall contain “the proposed management system for the activity to be licensed...”

## REGDOC-2.1.1

- “The CNSC expects licensees to adhere to all CSA N286-12 principles as the basis of their management system.”

## CSA N286-12 – Management system requirements for nuclear facilities

- Includes requirements for controlling supply chain

**CSA N299-19** – Quality assurance program requirements for the supply of items and services for nuclear power plants

- Licensee chooses to set this standard for suppliers.

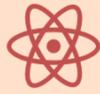
# Regulatory Requirements – Quality standard for manufacturing



There is no manufacturing licence issued by CNSC-Part of licence to construct or operation



Licence holder programs must ensure SSCs are fabricated with the appropriate quality level, so they perform their intended function when called upon, as required by the Regulatory Framework

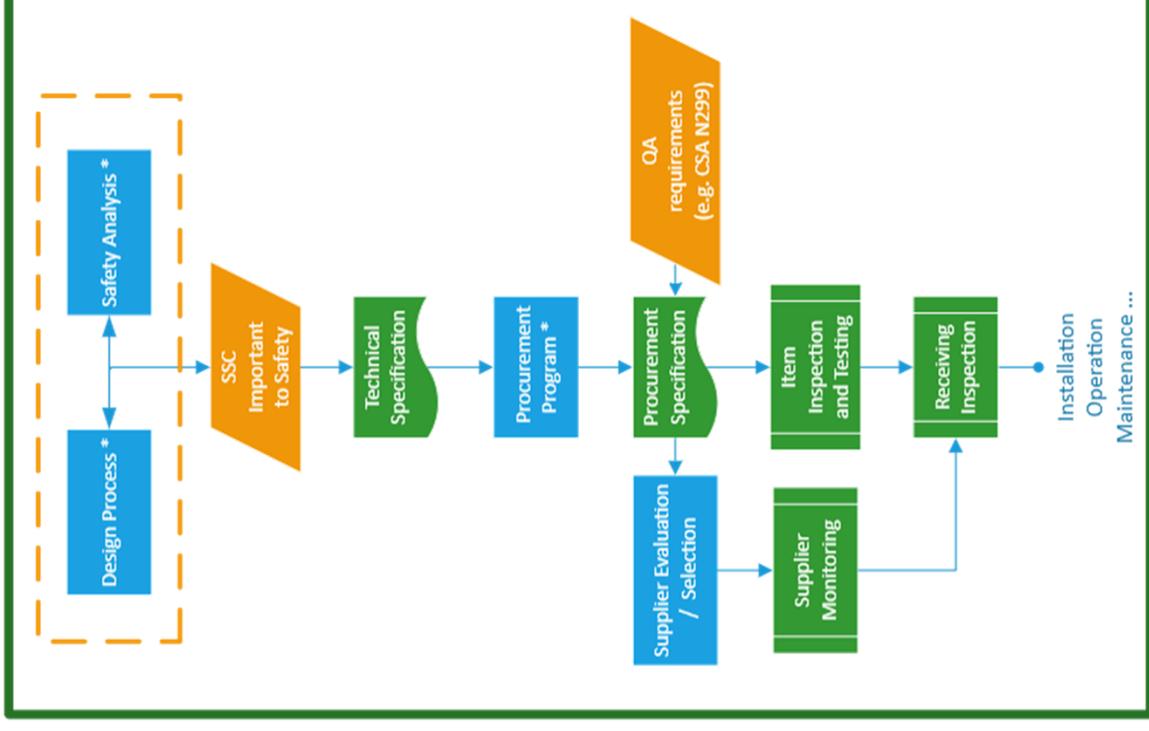


CSA N299 series of standards shown to satisfy CSA N286-12 requirements based on many years of experience for CANDU nuclear power plants

# Establishment of Quality requirements in Design

REGDOC-2.5.2 (Design)  
REGDOC-2.4.1 & REGDOC-2.4.2  
(Safety Analysis)

- In some cases, processes have been outsourced
  - Design
  - Safety Analysis
  - Procurement
- Informed customer principles are important
- Licence holder remains accountable for results (bound to CSA N286)



# New Joint Report

- <https://www.nrc.gov/docs/ML2502/ML25024A256.pdf>
- “The report concludes that **CNSC and NRC largely agree on design requirements and, with application of risk-informed methods, minor differences can be addressed** and common application inputs may be developed for both regulatory bodies.”



**U.S. NRC – CNSC Memorandum of Cooperation**  
**JOINT REPORT**  
concerning

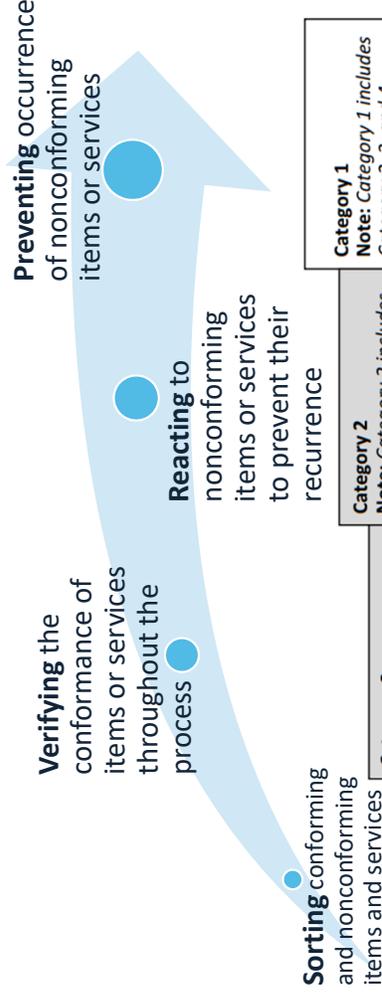
**Classification and Assignment of Engineering Design  
Rules to Structures, Systems, and Components**

January 2025

# Regulatory approaches to safety significance

Safety Significance	High		Low	
	CNSC	Important to Safety (ITS) Safety Systems	Not Important to Safety (NITS)	ITS - High
NRC LMP	LMP Risk Significant (and Safety Significant)	LMP Safety Significant	Not Safety Significant	
	Safety-Related Non-Safety-Related with Special Treatment		Non-Safety-Related No Special Treatment	
NRC Traditional	Important to Safety		NITS	
	Safety-Related (RISC-1) ITS (Not Safety-Related) (RISC-2)	Safety-Related (RISC-3) ITS (RISC-4)		

# CSA N299 – QA for the supply of items and services



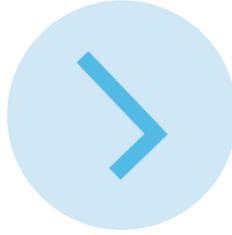
- Set of 4 comprehensive industry consensus standards documenting Canadian best practices
- Harmonized with national and international standards where possible.
- Selection process uses two methods:
  - Analytical method
  - Factor rating method
  - The higher quality level result is used.

<p><b>Category 4</b></p> <p><b>QA program</b></p> <ul style="list-style-type: none"> <li>• Training requirements</li> <li>• Contract review</li> <li>• Document control</li> <li>• Calibration</li> <li>• Procurement</li> <li>• Verification activities</li> <li>• Identification</li> <li>• Handling and storage control</li> <li>• Production</li> <li>• Packaging and shipping</li> <li>• CFSIs</li> <li>• Records</li> <li>• Nonconformance and corrective action</li> <li>• Customer-supplied items and services</li> <li>• Statistical techniques</li> </ul>	<p><b>Category 3</b></p> <p><b>Note: Category 3 includes Category 4 requirements.</b></p> <p><b>QA program</b></p> <ul style="list-style-type: none"> <li>• Training and qualification program</li> <li>• QA manual</li> <li>• Tender and contract review</li> <li>• Program descriptions</li> <li>• Design                             <ul style="list-style-type: none"> <li>– Interfaces</li> <li>– Design inputs</li> <li>– Software</li> <li>– Design outputs</li> </ul> </li> <li>– Design verification</li> <li>– Design changes</li> <li>• Verification planning and traceability</li> <li>• Production planning</li> <li>• Use of experience</li> <li>• Special processes</li> <li>• External audits</li> <li>• Dedication</li> </ul>	<p><b>Category 2</b></p> <p><b>Note: Category 2 includes Category 3 and 4 requirements.</b></p> <p><b>QA program</b></p> <ul style="list-style-type: none"> <li>• Program procedures</li> <li>• Design                             <ul style="list-style-type: none"> <li>– Planning</li> <li>– Preliminary design</li> <li>– Design analysis</li> <li>– Detailed design</li> </ul> </li> <li>• Nonconformance cause analysis</li> <li>• Internal audits</li> </ul>	<p><b>Category 1</b></p> <p><b>Note: Category 1 includes Category 2, 3, and 4 requirements.</b></p> <p><b>QA program</b></p> <ul style="list-style-type: none"> <li>• Process review</li> <li>• Design                             <ul style="list-style-type: none"> <li>– Alternatives (preventive measures)</li> </ul> </li> <li>• Corrective action for potential nonconformances</li> </ul>
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Least comprehensive

Most comprehensive

# CNSC Work With Positive Impact on Harmonization



Vendor Design Review



Benchmarking



SMR Readiness Projects



Sharing Lessons Learned

# Benchmarking

- CNSC staff conducted benchmarking of different international regulators and their method of supply management
- Staff comparison of international supply chain standards
  - CSA N299.1:19 and ASME NQA-1-2015
  - CSA N299.1:19 and ISO 19443:2018
  - CSA N299.3:19 and ISO 9001:2015\*
  - CSA N299.4:19 and ISO 9001:2015\*
- Comparison was direct requirement mapping, not fully implemented programs (no interpretation)

# Benchmark Project: International Regulatory bodies and their method of supply management

Country (Regulatory Body)	Inspection Type	Additional Comments
Canada (CNSC)	Indirectly	
Korea (KINS)	Directly/Indirectly	
Japan (NRA)	Indirectly/Directly	Directly on construction primarily
Finland (STUK)	Indirectly/Directly	Directly for some specific items
UK (ONR)	Directly/Indirectly	Directly at vendor sites with or without licensees
Hungary (HAEA)	Indirectly	
France (ASN)	Directly/Indirectly	Always directly at vendor site for Nuclear Pressure Equipment vendors
Poland (PAA)	Directly	
Czech Republic (SÚJB)	Directly/Indirectly	
US (USNRC)	Directly/Indirectly	Directly at vendor site without licensees
Spain (CSN)	Indirectly	Direct inspection only for state companies

# Comparison of supply chain compliance activities (current Canadian reactors vs. new SMR projects)



The CNSC has made specific provisions for supply chain oversight for SMRs in Regulatory Documents



REGDOC-1.1.2 Licence Application  
Guide: License to Construct a Reactor  
Facility

Examples: CNSC right access to premises of any supplier to the construction program (including off-site testing), informed customer, Long lead items



REGDOC- 2.3.1 Conduct of Licence  
activities: Construction and  
Commissioning Program

Examples: Oversight of contractors, management and organization, on site manufacturing, informed customer

# Considerations for future improvement efforts

## Risk

- Definition and categorization differences
- Different cultural tolerances reflected in laws and regulations

## Language

- Industry terms vs. standard definition
- Safety Significant vs. Important to Safety

## Oversight

- Licensee and Supplier from different countries/regulations
- How much oversight, and by whom

## Responsibility

- Complex partnership models (Integrated Project Delivery model)
- Design Authority different than the licensee

# Thank you

Stay connected!

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[nuclearsafety.gc.ca](http://nuclearsafety.gc.ca)

