Management System and Quality Assurance Standards for Nuclear Power Plants and Suppliers

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Hosted by the IAEA
Bratislava, Slovakia
January 19–22, 2016

e-Doc: 4917078

nuclearsafety.gc.ca
All stations are CANDU* design

- In service within design life
- In service or returned to service
- Safe storage state

### Canadian Nuclear Power Reactor Fleet

* CANDU (Canada Deuterium-Dranium) is a pressurized heavy water reactor (PHWR) type that uses heavy water for moderator and coolant, and natural uranium for fuel

<table>
<thead>
<tr>
<th>Bruce Nuclear Generating Station, Ontario</th>
<th>Darlington Nuclear Generating Station, Ontario</th>
<th>Pickering Nuclear Generating Station, Ontario</th>
<th>Gentilly-2 Nuclear Facility, Quebec</th>
<th>Point Lepreau Generating Station, NB</th>
</tr>
</thead>
<tbody>
<tr>
<td>A2</td>
<td>In service 1977/2012 Mwe 750</td>
<td>In service 1990 Mwe 881</td>
<td>In service 1971 Safe shutdown state</td>
<td>In service 1983/2012 Mwe 635</td>
</tr>
<tr>
<td>A3</td>
<td>In service 1978/2003 Mwe 750</td>
<td>In service 1972 Safe shutdown state</td>
<td>In service 1971/2003 Mwe 515</td>
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<tr>
<td>A4</td>
<td>In service 1979/2003 Mwe 750</td>
<td>In service 1991 Mwe 881</td>
<td>In service 1971/2003 Mwe 515</td>
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<tr>
<td>B5</td>
<td>In service 1985 Mwe 882</td>
<td>In service 1993 Mwe 881</td>
<td>In service 1983 Mwe 516</td>
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<tr>
<td>B6</td>
<td>In service 1984 Mwe 882</td>
<td>In service 1993 Mwe 881</td>
<td>In service 1984 Mwe 516</td>
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</tr>
<tr>
<td>B7</td>
<td>In service 1986 Mwe 882</td>
<td>In service 1993 Mwe 881</td>
<td>In service 1985 Mwe 516</td>
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<tr>
<td>B8</td>
<td>In service 1987 Mwe 882</td>
<td>In service 1993 Mwe 881</td>
<td>In service 1986 Mwe 516</td>
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</tbody>
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Licensees’ and Suppliers’ QA Programs

Licensees’ quality assurance (QA) programs

• Nuclear power plants (NPPs) shall be in compliance with CSA standard N286, *Management system requirements for nuclear facilities*

Suppliers’ QA programs

• Suppliers shall be in compliance with QA requirements specified by licensees

• For suppliers to Canadian NPPs, licensees cite the CSA Z299 series of standards until the N299 series is published in Q3 2016
CSA N286-12, Management system requirements for nuclear facilities

CSA N286-12

- Aligned with the principles of IAEA safety standards GS-R-3 and SF-1

- Integrates requirements from other management system standards such as quality, health and safety, environment, economics and security

- Primary inputs considered
  - CSA N286-05 - previous version
  - IAEA GS-R-3 - Management system
  - CSA Z299 - Quality
  - ISO 9001 - Quality
  - ISO 14001 - Environment
  - ISO 27001 - Security
  - CSA Z1000 - Occupational Health & Safety
CSA N286-12 suppliers’ requirements:

• requirements of this standard apply to:
  ✓ lifecycle of the nuclear facility
  ✓ suppliers contracted to perform the design, supply chain, construction, commissioning, operation and decommissioning of the nuclear facility

• specific requirements for NPPs’ supply chains apply to potential and current suppliers

Top management of the nuclear facility remains accountable for work performed by its suppliers to ensure the requirements of this standard are met
This section provides requirements for preventing the introduction of counterfeit, fraudulent and suspect items (CFSI) into a licensee’s supply chain

section 7.6.2: Purchasing requirements

- technical performance requirements
- applicable codes, standards and specifications
- management system standard and applicable requirements
- inspection, test and acceptance requirements, including any special instructions
- requirements for reporting and approving the disposition of problems
- the need for right of access to work facilities and records
- provisions for extending applicable requirements to sub-suppliers
These sections provide requirements for ensuring the use of audited, qualified and reputable suppliers

section 7.6.3: Supplier acceptability

✓ potential suppliers shall be assessed on the ability to meet the purchasing requirements, supply history and oversight of supplier’s supply chain

✓ when supplier audits are delegated to another party, the business shall ensure that the results of the supplier’s audit are acceptable

✓ acceptable suppliers shall be included on an approved supplier list

section 7.6.6: Supplier-customer relationship

✓ the performance of the supplier-customer relationship shall be monitored to ensure purchasing requirements will be met

✓ results shall be used as an input in determining the extent and frequency of inspection, verification and audit activities
These sections provide requirements for ensuring that the item or service will be provided as expected

section 7.6.4: Provision of the purchasing requirements to suppliers

✓ potential suppliers shall be provided with the purchasing requirements and it shall be confirmed that the potential supplier understands these requirements

section 7.6.5: Supplier selection and award

✓ the supplier’s proposal shall be reviewed against the purchasing requirements and any exceptions resolved
CSA N299 standards series

- Licensees, suppliers, and CNSC staff are working with the Canadian Standard Association to issue the CSA N299 standards series:
  - Describes the QA program requirements for the supply of items and services for NPPs
  - Contains specific requirements addressing CFSI
  - Applies to suppliers and sub-suppliers when specified by the customer
  - There is no requirement for commercial grade dedication

- The CSA N299 series of standards is triggered by an NPP adhering to a management system based on CSA N286 standard and applies to suppliers and sub-suppliers.
CSA N299 series QA program requirements for the supply of items and services for NPPs

- revision of the former CSA Z299 series of standards started in April 2015
- public review completed in January 2016
  - CNSC
  - Organization of Canadian Nuclear Industries (OCI)
  - CSA online community of interest
- target issue date Q3 2016
- documents considered
  - Z299 series
  - N286
  - ISO 9001
  - NPPs’ quality specification
  - other regional and international QA and management system (MS) standards, including ASME NQA-1 and NSQ-100
History of QA standards used by Canadian NPP suppliers

• former Z299 series (in use from the late 1970s to 1994)
  ✓ developed in the late 1970s as QA standard for the procurement of items and services for nuclear facilities
  ✓ commercial standard, not a nuclear standard
  ✓ precursor to the development of the ISO 9000 series of standards
  ✓ ISO 9001:1994 became the commercial quality standard that was generally adopted by industry
  ✓ Z299 became an orphan standard used by the nuclear industry only; it has not been updated since 1986

• since 1994, Canadian NPPs use ISO 9001 and Z299
Description of the CSA N299 series of standards

- The series is composed of four standards

- N299.4: Category 4 = Sorting
- N299.3: Category 3 = Sorting + Verifying
- N299.2: Category 2 = Sorting + Verifying + Reacting
- N299.1: Category 1 = Sorting + Verifying + Reacting + Preventing
Requirements contained in each category

• suppliers’ QA programs
• interfaces with customers
  ✓ record keeping
  ✓ document submittal
  ✓ approvals
  ✓ right of access

When suppliers subcontract part of the work to sub-suppliers, suppliers become customers in the N299 series of standards
QA program consists of

N299.4: Category 4 = Sorting

- training requirements
- contract review
- document control
- calibration
- procurement
- inspection and tests
- identification
- handling and storage control
- production
- packaging and shipping
- CFSI
- quality records
- non-conformance and corrective action
- customer-supplied items and services
- statistical techniques

No design activities for N299.4
QA program consists of

- all Category 4 requirements
- additional requirements in the verifying category
  - personnel qualification program
  - QA manual
  - tender review
  - program description
  - design
  - inspection, test and production planning
  - identification and traceability
  - use of experience
  - special processes
  - external audits

N299.3: Category 3 = Sorting + Verifying
QA program consists of:

N299.2: Category 2 = Sorting + Verifying + Reacting

- all Category 3 and 4 requirements
- additional requirements in the reacting category
  - program procedures
  - additional design requirements
  - non-conformance cause analysis
  - internal audits
QA program consists of:

N299.1: Category 1 = Sorting + Verifying + Reacting + Preventing

• all Category 2, 3 and 4 requirements
• additional requirements in the preventing category
  ✓ process review
  ✓ additional requirements for design
  ✓ non-conformance preventive measures
  ✓ corrective action for potential non-conformances
Description of categories

• Category 1
  ✓ suitable for custom-designed items
  ✓ first of a kind
  ✓ high-technology items and services that tend to require many complex processes and extensive design effort

• Category 2
  ✓ suitable for relatively high-technology items or services that tend to require design activities, design verification, production planning, and that have a significant number of complex processes
Description of categories

• Category 3
  ✓ suitable for items or services requiring some complex processes; these might be high-volume services or mass-produced items and might include design changes and associated verification and production activities.

• Category 4
  ✓ suitable for mass-produced items or high-volume services that are designed to commercial technical standards, or for simple processes such as custom machining and assembly.
  ✓ designs are usually mature and established, and the production and interfaces are not complex (design activities not required).
CFSI requirements in N299.1 and N299.2

5.2: Management Responsibilities

5.2.6.3: Qualification

• define and document activities/job functions that require specialized qualifications and competencies (e.g., engineers, cause analysis personnel, CFSI detection personnel, nondestructive examination technicians, welders, software programmers, inspection and test personnel and auditors), and their minimum qualification and requalification requirements
CFSI requirements in the N299 series

4.6: Supplier’s Responsibilities

- develop and implement a process for the detection and prevention of CFSIs to ensure that genuine parts and services duly tested and verified to meet specified requirements are provided
- ensure that personnel involved in CFSI detection are provided with the necessary training to perform these functions
- identify CFSI, report those items to the customer, and process those items in accordance with section 5.5.15 (non-conformances)
CFSI requirements in the N299 series

5.5.5: Procurement

5.5.5.2: Subcontract Requirements

• requirements for prevention and detection of CFSIs taking into consideration the complexity of the supply chain

5.5.11: Production

5.5.11.2: Process Procedures

• prevention, detection and removal of foreign material including CFSI
CNSC oversight of licensee management systems provides assurance that management and support processes are properly implemented across all safety and control areas and all licensees’ supply chains.