# regulatory requirements for MANAGING SUPPLY chain for small modular reactors in canada

DAN PAPAZ

Canadian Nuclear Safety Commission

Ottawa, Canada

 dan.papaz@cnsc-ccsn.gc.ca

**Abstract**

The primary role of the Canadian Nuclear Safety Commission (CNSC) is to regulate the use of nuclear energy and materials to protect health, safety, security, and the environment, including setting regulatory requirements for managing supply chain activities. The CNSC ensures that licensees effectively control the work of suppliers through oversight and inspection activities. Canadian Standard Association (CSA) Group standard N286-12, Management system requirements for nuclear facilities [1] provides requirements for the procurement of services and items for nuclear facilities. CNSC activities related to supply management include conducting technical reviews of the licensees’ and supplier’s documentation, inspection of oversight activities, and, indirectly, inspection of suppliers’ processes.

## INTRODUCTION

The Canadian Nuclear Safety Commission’s (CNSC) Regulatory Framework consists of laws passed by Parliament that govern the regulation of Canada's nuclear industry, regulations, licences, and documents that the CNSC uses to regulate the industry. Prior to any nuclear activity occurring, a licence must be issued by the CNSC. The licensee needs to demonstrate that it has fulfilled the requirements under the Nuclear Safety and Control Act (NSCA) and the associated regulations.

For the major nuclear facilities, such as Small Modular Reactors (SMR), in accordance with Class I Nuclear Facilities Regulations, an application for a licence shall contain a management system. If a licence is issued, the licence will require that “The licensee shall implement and maintain a management system.” The Licence Condition Handbook (LCH) associated to the licence provides the details and specifies the reference standards as the compliance verification criteria. CNSC’s requirement in the LCH for management system refers to CSA N286 Management system requirements for nuclear facilities [1], which was developed and accepted by industry with input from the CNSC. CSA N286-12 has specific requirements related to supply chain activities for nuclear power plants, including SMRs. CNSC does not have a manufacturing licence as other regulatory bodies have. The information related to manufacturing of items is covered under Licence to Construct licence. The factory fabrication activities are covered by industrial standards, standards that are taking in consideration by CNSC when assess the licence to construct application.

Management systems reflect and build on the principles and elements of ‘quality control,’ ‘quality assurance’ and ‘quality management’ as applied more broadly across an organization’s management processes and practices for all activities. An adequately established and implemented management system by a licensee provides CNSC confidence and evidence that the legal bases under which the Commission made its decisions and issued a licence, remain valid.

This article is focused on supply chain activities for Small Modular Reactors (SMR). When contractors working at a nuclear power site procure items and services for licensing activities, the information from this document applies.

The CNSC looks for objective evidence demonstrating that the licensee has established and implemented an adequate management system that is compliant with all regulatory requirements for supply chain activities.

## SUPPLY CHAIN REGULATORY REQUIREMENTS

The CNSC Regulatory Framework applies across all licensed activities. A licensed activity is described in paragraph 26(e) of the Nuclear Safety and Control Act [2] (i.e., prepare a site for, construct, operate, modify, decommission, or abandon a nuclear facility) that a licence authorizes the licensee to carry on in relation to a Class I nuclear facility.

Suppliers are chosen by the licensee based on their ability to provide an adequate service and meet requirements. Different administrative processes are in place to select those suppliers. The technical requirements and management system requirements are part of the bidding and evaluation process. In the end, the licensee will put in place oversight processes of the approved suppliers to ensure the safety of the nuclear facility.

CSA N286-12 is a standard licence condition for CNSC reactor licences and applies to the life cycle of various nuclear facilities, including high energy reactor facilities such as SMRs, from initial conception through completion of decommissioning, including suppliers contracted to perform design, supply chain, construction, commissioning, operation, and decommissioning activities. CSA N286-12 applies to the licensed activity, regardless of the safety classification. Based on CSA N286-12 requirements, the CNSC allows licensees/applicants to establish the suitable quality requirements, with justification, proportionate to the availability requirement of the systems, structures, and components (SSCs) to perform its intended design function when called upon to do so. CNSC does not prescribe the manufacturing Quality assurance/Management System standard for suppliers. However, the fabrication and manufacturing of pressure-boundary items are governed by CSA N285 General requirements for pressure-retaining system and components in (Canada deuterium uranium) (CANDU) nuclear power plants [3] and ASME rules.

CSA N286-12 applies to suppliers if the supplier is contracted to perform life cycle activities, such as Engineering and Procurement Construction (EPC) activities or the supplier is the Design Authority and procures the items and services for the licensee based on the agreements and project management model. Top management of the nuclear facility remains accountable to ensure the requirements of CSA N286-12 are met.

CSA N286-12 has generic requirements (e.g., organization, human resources, information management, work management, problem identification and resolution, change, assessment, use of experience and continual improvement) that applies to a supply chain program issued by the licensee. For nuclear power plants including SMRs, the licensee shall establish the processes for supply chain activities and control those processes. Through the licensing process CNSC verifies that the submitted supply chain documentation meets the regulatory requirements. If granted a nuclear licence, CNSC conducts compliance activities to verify the licensee implements the following elements, related to supply chain requirements, as per CSA N286-12:

* Establish the purchasing requirements in the procurement specification and administrative documentation/contracts and purchasing orders (e.g., technical specifications, applicable codes and standards and specifications, inspection, tests, acceptance criteria, documentation requirements, reporting and disposition of problems, extending applicable requirements to sub-suppliers, provisions for controlled distribution, retention n, maintenance and disposition of records, apply management system standard to suppliers)
* Supplier acceptability (e.g., audits, assessing the suppliers to meet purchasing requirements, issue approve supplier list)
* Confirmation that suppliers understand the purchasing requirements
* Review of supplier’s proposals including review and acceptance of selected technical documentation
* Monitoring of supplier’s performance (e.g., score carding, reporting delays, obsolescence, surveillance)
* Verification of services
* Receiving and inspection of items (examination of received items, evidence for inspections, testing, documentation specified in purchasing documentation (e.g., “history docket”), evidence of source surveillance.
* Segregation and disposition of problems, and Storage and handling.

Manufacturing control for SSCs is not specified in CSA N286-12. Instead, license holder programs/processes are required by the CNSC Regulatory Framework to ensure that SSCs are fabricated and manufactured with the necessary level of quality to ensure that they are available to perform their intended design functions when called upon to do so. For the supply of items and services, which the licence holder contracts to suppliers, the industry standards are CSA N299 “Quality assurance program requirements for the supply of items and services for nuclear power plants, Category 1, Category 2, Category 3, and Category 4 [4]. CSA N299 does not determine the safety classification, reliability etc., for SSCs. This is a design function prior to selecting a N299 category (1, 2, 3 or 4) appropriate for the design, procurement, and production of the SSCs associated items and services. The previous experience has demonstrated that the implementation of N299 series of standards can satisfy CSA N286-12 requirements and have been used in Canada for many years for CANDU nuclear power plants. Appendix A, “Category Selection,” of each of the CSA N299 standards provides a systematic graded approach to selecting the appropriate category based on safety significance, complexity, and other characteristics of the affected service or component. Section 8 of CSA N299, 2019 describes a dedication process for instances where the license holder was not able to procure an item or service where the supplier’s processes were controlled under the appropriate CSA N299 program category.

CNSC recommends to licensee/applicant that to supply items and services for Canadian nuclear power plants, including SMRs, the users of other industry standards (Quality Assurance Requirement for Nuclear Facility ASME NQA-1 [5], Quality management requirement systems – Requirements, ISO 9001 [6] and Quality management systems, Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of nuclear energy sector supplying products and services important to nuclear safety (ITNS) ISO 19433 [7]) to evaluate their QA program practices and controls to determine their degree of compliance to CSA N299 and N286-12 requirements. If such a procurement quality standard is chosen by the licensee/applicant, a gap analysis clearly detailing a comparison between the chosen standard and CSA N286-12 or CSA N299, is the recommended practice.

## OVERSIGHT OF SUPPLIERS BY LICENSEES

As required by the licence, the overall responsibility for managing the licensed activities is with the licensee. CNSC performs compliance activities to verify how the requirements stated in the licence regarding supply management are met. To establish the compliance plan for supply chain activities, CNSC should know, understand, and assess the documentation and the licensee’s processes involved in the control of the supply chain, including the oversight plans. Those oversight plans are set by the licensee/applicant for licence application to prepare site, construction, operation, or decommissioning.

Specific documentation is developed by the licensee to describe oversight activities. The documentation for the oversight activities of the licensee, as best practices, includes:

* Review and acceptance of suppliers’ documentation and deliverables with focus on technical documentation.
* Review of findings and observations
* Surveillances
* Field walkdowns
* Residential inspectors on site for key suppliers
* Direct observations of work activities/witnessing of activities
* Interviews with personnel performing the work and supplier’s top management
* Review of records
* Event reviews and trending of events
* Independent verification
* Assessment of activities through review of self-assessment results, management review of commitments, review of corrective actions
* Review of changes
* Management system audits

Assess concessions.

The oversight activities performed by the licensee should be planned and controlled as with any other work activity. The same management system requirements regarding work planning and scheduling, and work control apply to the oversight activities. The organization performing the work shall execute the activities in accordance with contractual requirements and the contracting organization (licensee) shall ensure that these requirements are fulfilled by the performing organization. The contractual requirements shall stipulate provisions for access to suppliers and sub-suppliers by the contracting organization. The licensee establishes an oversight plan, including oversight schedule, preparation (identification of records, documentation, issue the check list), perform work oversight from project and technical point of view, report the observations to stakeholders, progression of the corrective actions, trend the issues, close the oversight plan and identify any lessons learned. CNSC follows the completion of those plans.

## CNSC compliance activities

To meet the licence requirements, CNSC expects that licensee arrangements with any suppliers are effective to meet all applicable regulatory requirements. CNSC is conducting indirect inspections of suppliers and has physical access to the supplier’s site via the regulatory requirements.

CNSC verifies the licence condition pertinent to the management system through a review of information as described in LCH “Compliance Verification Framework” issued for each licensee. In addition to describing the Licence Conditions and their compliance verification criteria, the LCH is organized according to the Safety and Control Area (SCA) framework. A SCA is a technical topic used by the CNSC to assess, review, verify and report on regulatory requirements and performance across all regulated facilities and activities. A SCA contains Specific Areas (SpA). Supply and Contractor Management is one of SpA.

During compliance activities, CNSC verifies that the requirements of the licence are met, and the licensee controls the work performed by a supplier. The following compliance activities are performed by CNSC for the specific area of supply management (suppliers that provide items, suppliers that provide services to licensee’s site) as specified in the 5 years compliance plans:

* Technical assessments of program and process documents, including the “how” those are demonstrated
* Compliance Inspections including baseline, field and reactive inspections
* Compliance assessments
* Reviews of events and trending activities
* Witnessing of inspections/audits organized by the licensee for their suppliers.

For the current operating nuclear power plants CNSC has prepared specific inspection guides for supply management activities based on generic and specific requirements specified in the Regulatory Framework. Those operation guides are not used for SMR activities; however, the operation experience from the currently used operating supply chain guides (baseline and field) are used in developing the SMR inspection guides. CNSC verifies that the licensee’s control of their suppliers is documented to comply with contractual requirements, regulatory and statutory requirements, programs, processes, and technical specifications.

5. SMR READINESS PROJECTS FOR SUPPLY CHAIN

CNSC has initiated the SMR readiness project and issued a specific project governance. The SMR readiness project has a dedicated evergreen plan, with a schedule and dedicated staff to address the needs identified in SMR readiness workplan.

There are four pillars for SMR readiness projects:

* Regulatory Predictability-focuses on optimizing the CNSC’s Regulatory Framework for SMR licensing, providing regulatory clarity to SMR proponents.
* Capacity and Capability-is aimed at improving and expanding the CNSC’s technical ability and competency in SMRs, especially geared towards non-water-cooled reactors.
* Policy and Shared Responsibility- recognizes the opportunities for efficiency improvement and harmonization across Canada’s domestic regulatory space.
* International Collaboration- aims at strengthening existing international collaboration efforts and more strongly pursues international harmonization goals.

Regulatory compliance activities including the compliance inspection methods are critical in consideration of the supply of items for novel SMR technology and “first-of-a-kind” (FOAK) designs. First time suppliers to the nuclear industry will emerge and existing suppliers will be manufacturing novel items. There will also likely be a greater dependence on service providers throughout the lifecycle of these novel installations.

The following initiatives are raised for the SMR readiness project for supply chain activities:

* + 1. Initiating a large international benchmarking activity through the NEA Working Group on Supply Chain (WGSUP) aimed at defining and confirming, for the CNSC, the best practices in regulatory supply chain oversight. The analysis of the survey was not surprising yet demonstrated and confirmed CNSC view that direct regulatory oversight of the supply chain (inspecting suppliers independently) and / or indirect oversight (direct inspection of suppliers with licensee presence) were necessary for regulators to better understand and confirm that the licensee activities were indeed in compliance with requirements.
		2. For Regulatory Predictability project REP 1 “Process to manage Long Lead Items” CNSC issued a work instruction [6]. The work instruction supports the assessment of Long Lead Items (LLI) by providing step-by-step guidance to assess the submission(s) as applicable for LLIs. This work instruction begins with description of what typical LLI are, the identification of requirements in the CNSC Regulatory Framework related to Long Lead Items, expectations of licensee’s oversight, expectations for procurement, manufacturing and fabrication, codes and standards, pressure boundary quality assurance program and ends with Conclusions and Recommendations. As LLIs will have a long fabrication period and high cost associated with them, a more rigorous Quality Control (QC)/Quality Assurance (QA) program will be needed. As procurement of component(s) or item(s) with long lead times is entirely at the risk of the licensee, procurement of LLI can occur at any stage of the licensing process, including at the Licence to Prepare Site stage. CNSC can conduct compliance activities focusing on LLI items at any stage in the licensing process, provided the licensing basis for the facility has been established.
		3. The Capacity and Capability project CAC 22 “Utility, Factory, Transporter Relationship and Interconnections- Intelligent Custom” report will present the CNSC position regarding the modularity aspects in the CNSC Regulatory Framework regarding the fabrication, manufacturing, and transportation of modules. The report is not applicable for any kind of radioactive/fuel loaded module or contains any activation or contamination; this activity will be covered by two SMR projects. The report will be only focused on transport strategies for unloaded modules and challenges associated width safely transportation. The report will provide the expectations for oversight processes for module as a whole or sub assembled, expectations for procurement, manufacturing and fabrication, codes and standards, pressure boundary quality assurance program, quality control, inspections, informed customer approach (i.e., “intelligent customer”), conclusions and recommendations for applicant/industry and CNSC. The most significant issue with SMR technology/modularity is that there is little regulatory operating experience as to how they shall be manufactured and deployed. CNSC does not have this working experience, operational experience and lesson learned will be built. The report has analyzed the current international documentation related to SMR, mainly from IAEA sources. For example, the report analyzed the US NRC information regarding inspection of modules and manufacturing licence, IAEA TEC-DOC-2003 Lesson Learned in Regulating Small Modular Reactors, Challenges, Resolutions and Insights [8], IAEA SMR Regulators’ Forum: Working Group on Manufacturing, construction, commissioning, and Operation Phase 2 Report [9], and Small Modular Reactors Regulator’s Forum Design and Safety Analysis Working Group Report on Multi-unit/multi-module aspects specific to SMRs Interim Report 15 December 2019[10].
		4. Regulatory Predictability project REP 17 “Inspection requirements for Supply Chain Oversight for SMRs” objective is to develop and document an internal CNSC solution/mechanism for determination of inspection requirements for Supply chain oversight for SMRs. The project plan has been approved and the due date for completion of the project in in Q1 2025. The Objective Initiation Form specifies the following topics: regulatory bases, competence of staff, application of risk informed, enforcement, international collaboration, third party audits of suppliers, Counterfeit, Fraudulent or Suspect Items. This project is a holistic assessment of supply chain at CNSC.
		5. Under Regulatory Predictability project REP 5, “Licence to Construct Compliance Plan”, CNSC issued plans for supply chain activities for single GE Hitachi (GEH) Boiling Water Reactor (BWR) X-300. The inspection guide for supply chain was issued and includes inspection of LLI and other FOAK items. The inspection will take place at the respective facilities of the suppliers. The licensing basis reference in the inspection guides includes CSA N299[4], CSA N286-12 [1], other regulatory requirements and documentation from Ontario Power Generation and contract partners.

## 6. COMPARISON OF SUPPLY CHAIN COMPLINCE ACTIVITIES (CURRENT CANADIAN REACTORS VS., SMR PROJECTS)

For licence to construct application requirements in CSA N286-12 [1] are supplemented by the specific requirements in REG DOC 1.1.2 Licence Application Guide: Licence to Construct A Reactor Facility [11], and REG DOC 2.3.1. Conduct of Licensed Activities: Construction and Commissioning Programs [12]. The two regulatory documents have specific information applicable for managing supply chain activities, such as Long Lead Items, informed customer, receiving, organizational arrangements, on site manufacturing, and testing and commissioning of module-based construction. Those additional regulatory documents’ requirements are taken in account in the compliance activities for SMRs.

Section 4 of this report describes the generic CNSC compliance inspections. For the current CANDU units and refurbishment projects the design is well known and understood by the licensee, procurement specifications are not changing, the suppliers are well known and controlled, and management system is mature and effective. The frequency of the inspections is lower compared with a new SMR applications. The inspection compliance plan for SMRs, and supply inspection guides are taking in account the operating experience including lessons learned from those inspections.

The following paragraphs describe what is new for SMR compliance activities including challenges and provide some information from licence application for Darlington New Nuclear Power (DNNP) project for construction of General Electric Hitachi (GEH) BWXR-300 SMR.

The SMR application has specific and new challenges regarding the assessment of the application’s information for supply chain activities. For the supply chain, more commercial items may be used than CANDU units, commercial quality standard [6] are proposed in the licence application, different quality standards are proposed by the applicant, design is not completed, or new suppliers are assessed. Therefore, for the SMR application for licence to construct, CNSC asks for detailed information from the designer regarding the procurement specification process, how the management standard/Quality Assurance standard is linked to the safety classification, how the graded approach is demonstrated, how the dedication will be performed, how the pressure boundary items are managed, and, of course, how the regulatory requirements are met. The Designer could be different than licensee, novel design features are specified, or technology should be proven. During licence application CNSC raises Information Request (IR) for the issues identified in the applicant’s complex documentation and the IR is tracked for completion. During the hearings CNSC presents in the front of Commission public hearings for licence to construct detailed information about supply chain documentation.

The organizational arrangements can be different for a SMR application. For example, the DNPP large project will use an Integrated Project Delivery (IPD) model that is based on multi-party agreement between the licensee and contact partners for design and construction. This is the first time this contract arrangement model has been used in nuclear business in Canada. CNSC assesses the project governance and the project model and their implications on the compliance activities.

The SMR supply chain inspection guide has additional tasks compared with the inspection guides for the current CANDU units. Inspection tasks such as first article inspection, informed customer, novel material, and module fabrication are considered. Planning of compliance inspections as risk informed approach can be challenging when design is evolving and many design changes are in progress. The following are the main differences in the inspection guides for SMR:

* The inspection will take place at the respective facilities of the vendors of selected items.
* Technical specialists will be always part of the inspection team.
* Long lead items will be selected for the inspection; the long lead items information is provided to CNSC as per requirements in the Regulatory documentation; procurement of the long lead items is on the risk of the applicant.
* The number of the regulatory management system inspection activities deemed as mandatory, have been reduced to self-assessment, problem identification and resolution, document control and records management (completeness, traceability, storage, and maintenance of records), personnel training and procedure adequacy.
* The inspection activity includes information from CSA N299 series [4] in Licensing basis reference inspection guide. Using CSA N299 series in the inspection guide is a novel approach.
* Management of work is focused on detailed information from CSA N299 series. For example, one of the inspection activities is related to “production and service activities” or “verification of special processes.”
* Performance of work verification inspection activity is more complex. For example, the inspection team will assess if verification is planned to verify critical characteristics, or, tools, gauges and other measuring and testing devices are controlled.

d. There are other inspections that are not directly focused on supply chain activities performed by the suppliers, which provide items for construction and are more focused on the licensee’s suppliers/contract partners licensing activities for construction and design activities. The complexity of those inspections is wider than the operating units and refurbishment projects:

* Contractor management inspection will be focused on licensee’s process oversight of the contract partners as per project management organizational arrangements requirements, including the oversight of procurement activities. Oversight of procurement activities for CANDU units is less complex as the risk is lower.
* Construction, installation, and special processes inspection will assess the contract partners work activities at site as described in the project documentation. During this activity, CNSC will review the storage and preservation of items at site. The verification of assembly at the construction site will also be an inspection activity that will be also tracked in the field guides including module base construction, which starts at the supplier’s site.
* The objective of design inspection is to verify the design controls implemented by the designer to ensure that the design requirements are accurate and complete, and the design outputs meet the design input requirements. The verification of procurement specification is part of the inspection.

For the DNNP project for construction of BWRX 300, the criteria for inspection include regulatory requirements (CSA N286-12) and Licensing Basis Reference (e.g., CSA N299 [4], and selected submitted licence documents. Innovative design items such as diaphragm plate steel composite and isolation container will be inspected.

## 7. CONCLUSIONs

The licence issued for SMRs requires that the licensee implements and maintains a management system. Supply chain management is a regulatory requirement, and the licensee remains accountable for safety even when work activities are contracted to suppliers. The current licence condition for supply chain management is CSA N286 standard. CNSC uses a variety of compliance activities to verify how the licensee controls the work performed by a supplier. During those compliance activities CNSC indirectly assesses supplier’s processes and practices. The inspection guides for SMRs including BWRX-300 project will have specific information related to the inspections of suppliers at their site involving many technical specialists. The oversight performed by the licensee on their suppliers is observed by CNSC staff during compliance activities. As the CNSC gains more experience, lessons learned will be applied to improve compliance activities for SMR facilities.

CNSC has raised many initiatives addressing supply chain for SMR. Regulatory compliance activities including the compliance inspection methods are critical in consideration of the supply of items for novel SMR technology and FOAK design. The completion of the SMR readiness projects for supply chain would improve CNSC activities for assessment at the suppliers. As in any other high reliability industry, the nuclear supply chain has its challenges and opportunities. CNSC has stayed current with these, providing information, guidance, and support to the CNSC to drive regulatory improvement for SMRs.

References

1. CSA N286-12, Management system requirements for nuclear facilities
2. Nuclear Safety and Control Act, S.C 1997, c.9, last amended on January 1, 2017
3. CSA N285 General requirements for pressure-retaining system and components in CANDU nuclear power plants
4. CSA N299 Quality assurance program requirements for the supply of items and services for nuclear power plants, Category 1, Category 2, Category 3, and Category 4
5. Quality Assurance Requirement for Nuclear Facility ASME NQA-1
6. Quality management requirement systems – Requirements, ISO 9001
7. Quality management systems, Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of nuclear energy sector supplying products and services important to nuclear safety (ITNS) ISO 19433
8. IAEA TEC-DOC-2003 Lesson Learned in Regulating Small Modular Reactors, Challenges, Resolutions, and Insights [8]
9. IAEA SMR Regulators’ Forum: Working Group on Manufacturing, construction, commissioning, and Operation Phase 2 Report
10. Small Modular Reactors Regulator’s Forum Design and Safety Analysis Working Group Report on Multi-unit/multi-module aspects specific to SMRs Interim Report 15 December 2019.
11. REG DOC 1.1.2 Licence Application Guide: Licence to Construct A Reactor Facility

 REG DOC 2.3.1 Conduct of Licensed Activities: Construction and Commissioning Programs.