

STANDARDS RESEARCH

# Applicability of CSA N299 Quality Assurance Standards for Small Modular Reactor Supply Chain

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# Executive Summary

This report provides an evaluation of the CSA N299 series of quality assurance (QA) standards, with a focus on their applicability for small modular reactor supply chains. Through information obtained via interviews, comparative analyses of international standards, and lessons learned from other industries, such as aerospace and oil and gas, the study identifies potential gaps and opportunities to enhance the CSA N299 standards and their application.

The analysis indicates challenges with the understanding of the CSA N299 categorization framework, inconsistent auditing practices, and lack of training for QA program certifications. These can pose challenges for existing and new suppliers, particularly non-nuclear and international participants.

The report finds that many of the issues raised are not deficiencies in the standard, but rather stem from inconsistent interpretation of the requirements by auditors, suppliers, and utilities, as well as missing guidance for the application of the standards. As a result, suppliers can face increased costs and limited clarity on how to meet compliance expectations.

The recommendations for consideration focus on updates that could contribute to improved audit consistency, simplified QA program categorization, and enhanced common understanding and application of the requirements. The report proposes leveraging proven practices from the aerospace and oil and gas industries, including modular construction guidance and risk-informed supplier oversight models. These recommendations are intended to support Canada's nuclear industry in SMR deployment, increased supplier diversity, and continued excellence in nuclear safety and QA.



**"Interest in and support for nuclear energy have grown due to the increase in net-zero policies and commitments and the need for reliable baseload electricity within a diversified energy mix."**

## 1. Introduction

Driven by multiple factors, there has been a resurgence of interest in nuclear energy in recent years. Global energy demand continues to grow. Increasing concerns over climate change and the push by investors for improved environmental, social, and corporate governance performance have intensified pressure on corporations to reduce the carbon intensity of their energy sources. These policies and market forces are driving electrification and the adoption of low-carbon generation technologies.

Interest in and support for nuclear energy have grown due to the increase in net-zero policies and commitments and the need for reliable baseload electricity within a diversified energy mix. This renewed focus was evident at the COP 28 conference held in November 2023, where over 30 nations committed to tripling nuclear power generation by 2050 [1]. In the fall of 2024, major data-centre operators—Microsoft, Google, and Amazon—announced separate agreements to support the development of nuclear power to meet the low-carbon energy demands of their US-based data centres [2].

In parallel with these market and policy trends, the nuclear industry has been advancing the development of small modular reactor (SMR) technologies. SMRs differ from conventional CANDU reactors in design, manufacturing, and deployment. Unlike some large, site-built reactors, SMRs are being designed for factory-based modular construction, enabling off-site fabrication and on-site assembly. SMRs offer versatility for a broader range of applications due to their smaller size, modular construction techniques—which aim to reduce deployment timelines and costs—and innovative safety enhancements enabled by next-generation nuclear technologies. Although SMRs have been under development for decades, the emerging market readiness of many designs now aligns with the growing demand for flexible, baseload, low-carbon energy solutions.

The anticipated increase in nuclear power plant construction, including SMR technologies, will involve an increase in demand for items and services from the nuclear supply chain. This demand shift will require new entrants into the supply chain, as well as the supply of new components and technologies. These factors are among the key drivers for the need to assess nuclear quality programs to confirm they effectively address SMR applications.

In supply chains, achieving consistent alignment between expectations and outcomes depends on a clear understanding and application of the principles of quality, quality product, quality assurance (QA), design specification, and procurement. These interconnected elements are used to verify that what is requested aligns with what is delivered. Together, they reduce the likelihood of costly discrepancies, delays, and regulatory issues. Definitions for these key terms are summarized as follows [3]:

- **Quality** is defined as meeting defined expectations for a product's functional and performance criteria. Note that the term "product" encompasses both items and services and will be referred to in this way throughout this paper [3].
- **Design specification** is an engineering document, or set of documents, that provides a precise, authoritative statement of requirements necessary to ensure that the purchase of a component satisfies its intended purpose [4].
- **Quality Assurance** is a planned and systematic pattern of means and actions that is designed to provide confidence that items or services will meet specified requirements and perform satisfactorily in service [3].
- **Quality product,** as used in this report, is the actual outcome produced with an acceptable QA program that fully meets the predefined expectations that were defined in the design specification and/or procurement documents.
- **Procurement** is the process by which an organization buys the products or services it needs from other organizations [5]. It formalizes the requirements and standards within supplier contracts, aligning suppliers with expectations to deliver products that meet requirements. This process ensures effective sourcing and repeatability while creating records that establish traceability and accountability [6].

Supplier organizations in the nuclear sector in Canada are required to develop and maintain QA programs, which they use to confirm that the supply of the items and services they provide meets established quality requirements. In many other sectors, it is common for organizations to adopt quality management systems, which can include QA activities, but have a broader focus on the organization's overall activities, not just those that produce the items and services they provide to their customers. Canadian nuclear operating organizations are required to develop and maintain management systems that cover a broad range of activities that encompass quality but extend to ensuring the organization's objectives are achieved in an efficient and effective manner [7].

This study reviews and analyzes existing nuclear management systems and QA practices and standards relevant to supply chain operations in Canada, internationally, and across comparable industries. The focus is to evaluate how these systems support safety, quality, and reliability throughout the life cycle—from design to decommissioning—of SMRs.

The objectives of this study are to:

- summarize and assess the applicability of existing standards, systems, and practices in addressing the safety, quality, and reliability demands related to nuclear supply chains for SMR projects;
- compare and assess the requirements of current management systems and QA standards applicable to the Canadian nuclear supply chain with those applied by suppliers to the nuclear sector in other jurisdictions and those used by suppliers of other (non-nuclear) safety-critical sectors;
- identify opportunities for adapting and enhancing standards to address SMR development and deployment; and
- address the role of standards-based solutions in supporting a robust, efficient, and scalable supply chain framework that upholds high standards of quality and safety for SMR projects.

Nuclear supply chains involve a network of participants, including operators who are assigned regulatory oversight, suppliers, and sub-suppliers who are bound by life-cycle services compliance verification. The objective of achieving quality across the supply chain encompasses many factors, including the establishment of requirements, procurement processes, knowledge and skill sets, communication and information sharing, scheduling, auditing, and standards. A review of the effectiveness of relevant CSA quality standards has been assessed in this study via a systems approach that considers the perspectives of the system's participants and the interrelated factors that affect and contribute to achieving quality across the supply chain.

# 2. Methodology

To evaluate and enhance the understanding of quality programs relevant to the SMR supply chain, a multi-faceted methodology was employed. This approach integrated a literature review, comparative analysis, and discussions with interested parties, ensuring a comprehensive assessment of current practices, challenges, and potential improvements.

## 2.1. Literature Review

The literature review provided a foundation for evaluating the nuclear supply chain, quality programs, and future trends relevant to SMR quality standards requirements. The review focused on:

- nuclear supply chain;
- Canadian nuclear quality structure;
- management systems and regulatory expectations, including an international scan;
- QA in the supply chain;
- evolution and modernization of standards;
- insights from non-nuclear industries; and
- quality management trends and future directions.

Key sources included academic literature, regulatory frameworks, industry guidelines, and standards. This review informed subsequent analyses, enabling the identification of key areas for improvement and alignment with future industry needs.

Technical and safety requirements must be met during the construction and operation of a nuclear reactor. A review was conducted to evaluate differences between the QA requirements for the nuclear industry and the non-nuclear industries that are required to meet similar requirements because of their potential impact on public safety. Six non-nuclear industries were evaluated for the relevance of their quality management to the nuclear energy sector: aerospace, oil and gas, rail transportation, automotive, pharmaceuticals, and defence. These sectors were evaluated by expert opinion across criteria, including safety, risk, modularity, regulatory requirements, industrial operations, and information availability. The result of this evaluation was the selection of aerospace and oil and gas as the most relevant industries for consideration within this study.

## 2.2. Standards and Systems Evaluation

A comparative analysis was conducted to evaluate quality program frameworks in six nuclear jurisdictions outside of Canada: Finland, France, Japan, Korea, the UK, and the U.S. These jurisdictions were selected for their established nuclear programs, regulatory structures, and potential to offer best practices that could benefit Canada, particularly in the context of SMR deployment. The goal of this comparison was to understand how these frameworks align with, or diverge from, Canada's approach, with a focus on identifying relevant insights that may support the evolving SMR supply chain.

To evaluate quality standards and management system frameworks across nuclear and non-nuclear industries, the CSA N299 series of standards and CSA N286 were used as the foundational benchmarks. These standards establish Canadian management systems requirements for nuclear power. The evaluation compared these standards with international frameworks, including ISO 9001, ISO 19443, SAE AS9100D, and ASME NQA-1, to assess the alignment, differences, and gaps in the requirements.

## 2.3. Interested Party Engagement

Meetings were conducted with interested parties from 10 organizations across nuclear and non-nuclear industries to capture diverse perspectives. All the participants, each with different backgrounds and interests, had some experience with the Canadian nuclear programs. Although there were prepared interview questions, the goal was to encourage the participants to share their experiences with the application of the Canadian programs, particularly the CSA N299 series.

Participants included:

- regulators (1);
- nuclear and non-nuclear quality experts (6);
- established nuclear manufacturers and suppliers of goods and services (4);




- nuclear operators (1);
- recent and prospective nuclear supply entrants (2); and
- prospective new operators (1).

These interviews explored participants' experience with QA standards in the nuclear industry and, where applicable, the focus was on SMR applications.

The limited number of interviews conducted provided constrained responses, which in turn restricted the depth and breadth of information available to support the observations and recommendations presented in this study.

### Thematic Analysis

The interview results were analyzed to identify recurring themes, such as challenges, opportunities, and priorities concerning the quality standards that impact the supply chain dynamics for SMR deployment. The feedback was categorized into 10 themes and then further grouped into three broader areas (see Section 5).

# 3. Literature Review

## 3.1. Nuclear Supply Chain

The nuclear supply chain encompasses the management of the operating organizations' procurement activities and the activities of external suppliers who provide the services, materials, and supplies necessary for the operator's activities, such as design, manufacturing, construction, assembly, commissioning, operation, and maintenance of nuclear facilities [8].

The complex and specialized nature of nuclear technology, combined with detailed regulatory demands, has resulted in national supply chains that often align with specific reactor technologies. Globally, the dominant reactor types in operation include i) light water reactors (LWRs), which are further subdivided into boiling water reactors and pressurized light water reactors, and ii) pressurized heavy water reactors (PHWRs) [9]. PHWR is the reactor type used in Canada's CANDU reactors. In many countries, codes and standards are tailored to the primary reactor

technologies in use. In Canada, the nuclear supply chain is primarily focused on CANDU technology, which is the only reactor type currently in operation domestically, although Canadian suppliers also provide expertise and components for LWR technology internationally. The Canadian nuclear supply chain has been shaped by the specialized requirements of CANDU technology and the diverse range of components and services necessary for the operation and maintenance of these nuclear power plants.

### 3.1.1. Key participants in the nuclear supply chain

The nuclear supply chain encompasses the operating organization (operator) and its network of suppliers. The operator, licensed by the regulatory authority, is ultimately accountable for safety and security at nuclear facilities [10], [11]. This responsibility includes overseeing procurement activities, setting technical and quality requirements for items and services, and assessing compliance across all tiers of the supply chain.

At the core of the supply chain are Tier 1 suppliers: nuclear-qualified organizations that have direct contractual relationships with the operator. Through established service agreements, these Tier 1 suppliers often provide supply chain support for plant operation, maintenance, and refurbishment on behalf of the operator. Tier 2, Tier 3, and other lower-tier suppliers supply parts, materials, components, and subcontracted technical or manufacturing services. These lower-tier suppliers are often contracted by Tier 1 firms, although some may work directly with the operator.

The nuclear supply chain has highly interconnected activities that demand relationships amongst several professionals, encompassing activities such as engineering, design, manufacturing, assembly, and site services critical to reactor operations. The flow of items and services—from engineering and design to materials and components, to manufacturing and assembly, to site services such as installation—is essential to maintain the quality and reliability of nuclear facilities. Roles within the supply chain are often fluid, meaning that suppliers can have interconnected customer and/or sub-supplier relationships with one another. This interconnection is common in complex projects, where suppliers often rely on one another to meet specified requirements.

The operator remains responsible for ensuring that all entities supplying items or services meet the requirements of the licence [12]. Any deviations in quality within the supply chain can have cascading impacts on project schedules and safety. These interconnected relationships emphasize the importance of collaboration and aligned quality expectations throughout the supply chain.

### 3.1.2. State of the industry and SMRs

The nuclear power industry supplies approximately 10% of the world's electricity, with 416 operational nuclear power reactors in 31 countries [9]. While there has been a significant expansion of the number of operating nuclear reactors globally, the majority of the new reactors built over the past 15 years have been in China, Russia, Korea, and India [13], [14]. In North America, the majority of nuclear reactors were built over 30 years ago, with the only new additions in recent years being the Watts Barr Unit 2 reactor in Tennessee in 2016 and the completion of two AP1000 projects in Georgia—Vogtle Units 3 and 4—the latest of which came online in 2024 [9], [14].

In addition to limited domestic projects in North America, the construction of North American–designed reactors has also declined in recent decades [8], [14]. These periods of low activity negatively impacted the supply chain, as suppliers with insufficient workloads might be inclined to let their nuclear certifications lapse and pursue supply opportunities for other sectors. In a recent U.S. Department of Energy report [8], *Nuclear Energy: Supply Chain Deep Dive Assessment,* this decline in the U.S. operations and maintenance supply chain is attributed to reduced exports of U.S. reactor technologies. The supply chain is constrained by skills and knowledge concentrated in a small number of players [8].

In Canada, the nuclear supply chain has been shaped by the operation and refurbishment of CANDU reactors. Major refurbishment projects at Darlington, Bruce, and Pickering stations began in 2016 and are

expected to continue until at least the mid-2030s [15]. These projects have increased supply chain activity, particularly in recent years, where concurrent refurbishment work has been underway at all three sites. This has allowed established supply chain players to begin to train new talent.

The North American nuclear supply chain remains concentrated on a small number of relatively large, long-term participants, providing items and services for the established LWR and PHWR technologies. Specialized skill sets and detailed security and nuclear-specific quality and code requirements contributed to creating a niche environment where this small group of suppliers met the needs of a stable industry that operated relatively independently (i.e., with limited interaction with other sectors). Recent increased activity levels due to refurbishment work, SMR technology development projects, and interest in nuclear as a low-carbon energy source are shifting the landscape of the nuclear supply chain. A high level of demand and the promise of growing needs in the sector are creating interest from new entrants.

SMR technologies encompass a wide breadth of new technologies that differ from the LWR and PHWR technologies. The Nuclear Energy Agency classifies SMRs into five categories based on their design and applications: fast spectrum, micro-reactors, molten salt, gas-cooled, and water-cooled [16]. Other sources distinguish some of the designs differently and also include salt-cooled and solid-core categories [17].

These different types of reactors have varying levels of technology readiness. Some are largely based on conventional reactor technologies and, therefore, existing codes and standards are mostly applicable and accident scenarios have been thoroughly evaluated, while others may include novel designs or have less mature technical features. For example, some advanced SMR technologies involve new materials and/or new applications for materials that will need to be qualified for high-temperature applications and exposure to radiation [18]. Alongside the need to verify these new designs and materials, the supply chain for these technologies is also still maturing. Many SMR designs incorporate passive safety systems that potentially reduce the impact of an event [19]. In the near term, however, concerns over the lack of operational experience in Canada and evidence of reduced risk could lead to higher quality requirements than necessary for SMR designs.

The emergence of SMRs is expected to place new demands on the existing nuclear supply chain. Unlike traditional reactors, SMRs are being designed for a wider range of applications beyond electricity generation, which may increase their global relevance [20]. The diversity of SMR technologies under development also opens the door for more flexible and varied deployment worldwide. Their compact size makes them particularly well-suited for smaller power grids, which could make them an attractive option for countries that are new to nuclear energy.

The process of modular design and construction, a key feature of the SMR concept, also enables centralized manufacturing for global distribution. Very small modular reactors or micro-modular reactors, a subset of SMRs, may be entirely factory-built, potentially even before a specific site or customer is identified for a given unit. Of course, these factory-built units do not address the equipment required at the output end of the reactor to use the heat produced, such as boilers and turbines, that often require a large footprint.

Currently, management system responsibilities rest primarily with the licence holder (the utility operator). In the future, SMR deployment could involve non-traditional ownership and operating structures, such as community-owned reactors or remote industrial applications involving ownership or partnerships with single or multi-user industrial corporations, potentially with separate operators [21]. In Canada, the requirement for licensees to ensure operational safety and related quality requirements is embedded in legislation. For example, REGDOC-2.3.2 [22] outlines compliance requirements regarding safety or REGDOC-2.1.1 [7] compliance for management systems.

To support the forecasted increasing demand for low-carbon energy, the nuclear industry will require new supply chain entrants.

## 3.2. Relation Between Canadian Regulatory Framework and Nuclear Management Systems

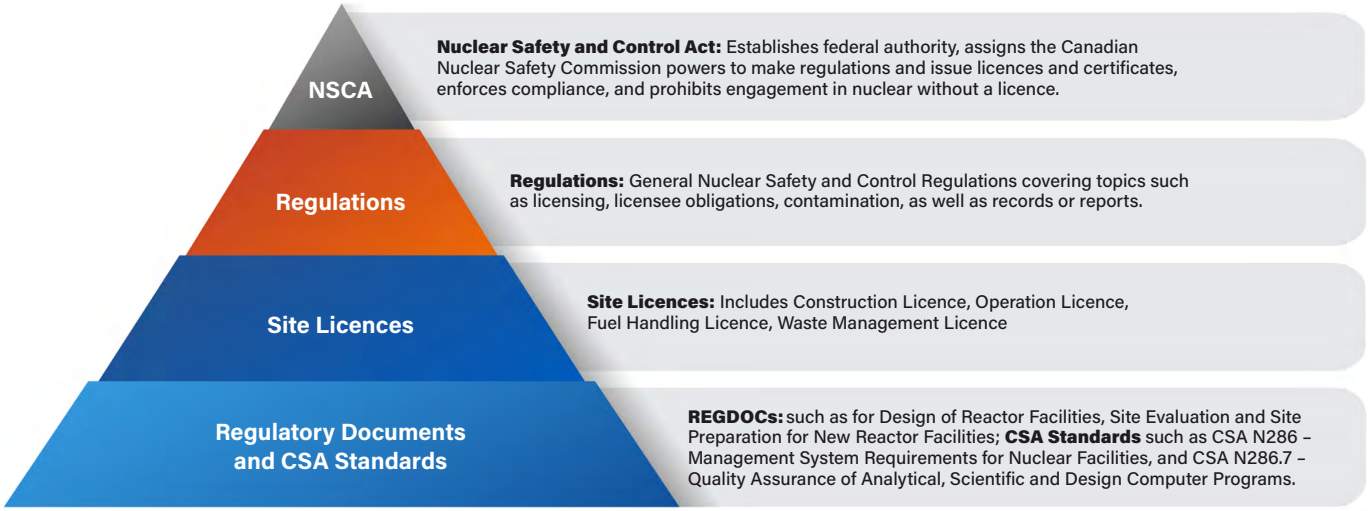
The Canadian nuclear quality structure operates within a hierarchical framework that begins with federal legislation and cascades down through regulations, licensing requirements, and standards. This structure allows for a consistent and transparent system for managing nuclear safety, regulatory compliance, and quality. Figure 1 illustrates this hierarchy.

As the regulatory authority for nuclear energy in Canada, the Canadian Nuclear Safety Commission (CNSC) develops regulatory requirements and license conditions and evaluates and enforces compliance at nuclear facilities in Canada. The Commission reviews and issues licences and approvals. CNSC REGDOC-2.1.1 [7] specifies the requirement for CNSC licensees to maintain a management system. While the regulation [7] does not mandate a standard, it indicates the expectation that the principles specified in CSA N286-12 [23] form the basis for the management system. CNSC licensees (i.e., the operators) develop a management system for their organization that fulfills the requirements of CSA N286-12, and CNSC staff review and evaluate the management system for the scope of the licensee's operation. It is important to note that it is possible to base a management system on a different standard, as long as the alternate standard meets the intent of the CSA N286-12 standard [24].

A management system is "a set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner" [25]. In Canada, CSA N286 [23] forms the foundation for a nuclear management system for the operators of nuclear facilities and establishes requirements that integrate health, safety, security, environmental, economics, and quality elements. The management system adopted in accordance with the requirements of the CNSC licence promotes accountability across all organizational levels, allowing for a cohesive approach to meeting the defined expectations [26].

The CSA N286 standard evolved from a set of QA standards into a comprehensive management system standard. CSA N286-12 [23] integrates quality, health, safety, security, and environmental considerations into a unified framework applicable to all life-cycle phases of nuclear facilities. The life-cycle, as defined in CNSC REGDOC-3.6 [27], includes all phases of a nuclear facility's life: site selection, site preparation, construction, commissioning, operations, and decommissioning or closure.

**Figure 1:** Nuclear reactor regulatory framework in Canada. [14]. (Image provided courtesy of March Consulting Associates Inc. © 2024. Reproduced with permission.)



The 12 principles of CSA N286 (Clause 4.1.2) listed below provide the foundation for safety, regulatory compliance, and continuous improvement across all operations:

1. Safety is the paramount consideration guiding decisions and actions.
2. The business is defined, planned, and controlled.
3. The organization is defined and understood.
4. Resources are managed.
5. Communication is effective.
6. Information is managed.
7. Work is managed.
8. Problems are identified and resolved.
9. Changes are controlled.
10. Assessments are performed.
11. Experience is sought, shared, and used.
12. The management system is continuously improved.

CNSC REGDOC-2.1.1 [7] further describes the expectation that licensees oversee the work conducted by contractors to ensure compliance with regulatory requirements, for which licensees are ultimately accountable. The CSA N286 standard contains requirements for management of suppliers by licensees; however, it does not specifically refer to or require a specific standard to govern the activities of suppliers. In practice, the Canadian nuclear utilities have adopted the requirements of the CSA N299 series of QA standards for the supply of items and services.

## 3.3. QA in the Supply Chain

### 3.3.1. QA programs

QA programs encompass a set of planned, coordinated, and controlled activities focused on achieving the design, fabrication, and delivery of quality products. QA programs introduce process controls and verification steps to identify and address non-conformance through corrective actions to confirm that each product meets specified requirements.

The CSA N299 series of standards were developed from the CSA Z299 series, which were initially developed to address the need for the commercial industry to provide quality products where they were required [3], [28]. The nuclear industry adopted this set of standards since they provided the necessary rigour required for the nuclear supply chain. The CSA Z299 series of standards was last updated in the 1980s and, during the same period, the features of these standards formed the basis for Canada's contributions to the development of the ISO 9001 quality management system standard [3]. Although the CSA Z299 standards were later withdrawn, the nuclear industry maintained their use until it became apparent that further development of the standards was required to address issues arising in the nuclear supply chain. These included counterfeit, fraudulent, and suspect items (CFSIs), foreign material exclusion, and use of experience. This led to the development of the CSA N299 series, which now addresses these issues [3], [28].

Like the CSA Z299 series, the CSA N299 series is structured as a series of four standards with increasingly more comprehensive categories of requirements for QA [3]. This provides for a graded approach to its application, depending on the safety significance and distinct properties or attributes of the supplied item or service, such as its complexity, uniqueness, design maturity, or the number of its critical and interrelated characteristics [3]. The standards outline four programs called categories: the Category 4 requirements (provided in CSA N299.4) are the least comprehensive, while the Category 1 requirements (provided in CSA N299.1) are the most comprehensive [3]. The categories are as follows:

- **Category 4:** Targets basic quality control for simpler items, distinguishing between conforming and nonconforming products or services [29].
- **Category 3:** Focuses on conformity verification at various production stages appropriate for items with moderate complexity [30].
- **Category 2:** Aims to prevent the recurrence of nonconformance applicable to high-technology items needing design verification and complex production processes [31].

- **Category 1:** Designed for high-risk, high-complexity items where preventing nonconformities is paramount; suitable for custom-designed and first-of-a-kind technologies [3].

The categorization framework of the CSA N299 series of standards allows operators to specify the controls required for specific nuclear items and services, ensuring that the supply of complex or first-of-a-kind items and related services adhere to the requirements of the more comprehensive category, while items that require less detail can be supplied under a less comprehensive category. Suppliers can tailor their quality programs to a specific category level that aligns with their business activities.

The CSA N299 series of standards provide comprehensive requirements for quality management of all stages of a production process and contains 21 basic program elements:

- management review
- indoctrination, training, and qualification
- tender and contract review
- design
- documentation
- procurement
- verification planning
- verification activities
- verification status
- measuring and testing equipment
- identification and traceability
- handling and storage
- production
- special processes
- packaging and shipping
- records
- nonconformances
- corrective action
- customer-supplied items and services
- statistical techniques
- quality audits

In addition to the basic program elements, the CSA N299 series of standards contains specific requirements regarding safety culture, defined as the characteristics of a work environment that influence employee perceptions and attitudes on safety, use of experience, and CFSIs. The latest edition of CSA N299.1:19 [3] specifies an acceptable "dedication" process to procure an item or service that was originally produced in accordance with a non-nuclear QA program. The CSA N299 standards also provide non-mandatory guidance related to the development of QA program procedures, the design process, measuring and test equipment, and risk evaluation. Although some of these items were added in the most recent 2019 editions of CSA N299 standards [3], the 2016 editions [32], which contain most of these requirements, are also used within the industry.

For pressure-retaining systems and components, QA requirements are outlined in CSA N285.0 [33], a technical standard that also outlines requirements for their design, analysis, manufacturing, and inspection. It incorporates references to Section III of the ASME Boiler and Pressure Vessel Code (BPVC) [34] for requirements of the construction of nuclear components. In turn, CSA N285.0 mandates CSA B51 [35] for the provision of non-nuclear components designated as Class 6. Canada has traditionally relied on the ASME BPVC for the technical requirements for the construction of pressure-retaining components. Although ASME BPVC provides its own set of specific quality program requirements, CSA N299 standards can still be specified by customers in addition to the ASME requirements, especially when the pressure boundary component, such as a valve, has an actuator connected to the valve.

### 3.3.2. Conformity assessment of QA requirements

In Canada, it is the customer's responsibility to audit suppliers, "taking into account the complexity of the item or service" being provided by a supplier



**"In Canada, it is the customer's responsibility to audit suppliers, "taking into account the complexity of the item or service" being provided by a supplier."**

[3]. CSA N299 standards establish requirements for suppliers to conduct internal and external audits to verify compliance with QA program standards, with the audit frequency taking into account the status and importance of an activity [3].

One of the most significant aspects of CSA N299 auditing is the requirement that suppliers audit sub-suppliers if a QA program is required for supply, as per Clause 7.6.1.2, *Evaluation and Selection of Suppliers of the N299 standard* [3]. However, CSA N299.4 [29], which contains requirements for the least comprehensive CSA N299 QA program category, permits acceptance of an evaluation in place of an audit if the sub-supplier is already certified by another recognized accreditation body.

In Canada, Conexus, formerly CANDU Owners Group, facilitates joint nuclear industry QA audits through groups like:

- **CANDU Procurement Audit Committee (CANPAC):** Audits Tier 1 suppliers for multiple utilities, reducing duplication of audits across organizations, and
- **CANDU Industry Assessment Committee (CANIAC):** Performs audits for any tier of suppliers [36].

These collaborative processes allow companies to share audit results to reduce redundancy and duplication, streamline supplier approvals, and foster consistency in supply chain QA [37]. However, participation in the Conexus programs remains limited, and each customer is still responsible for evaluating and accepting audit results from shared audits [37].

In the US, an ASME NQA-1–compliant QA program of the facility for non-pressure boundary equipment can be audited by industry organizations like the Nuclear Procurement Issues Corporation (NUPIC) [38]—equivalent to CANPAC in Canada—which evaluates suppliers on behalf of utilities, while the Nuclear Industry Assessment Corporation (NIAC), which is similar to CANIAC in Canada, performs audits on behalf of suppliers for their sub-contracting needs [38], [39].

For ISO 9001 and ISO 19443, accredited certification bodies conduct regular audits to verify whether suppliers' quality programs meet standard requirements.

## 3.4. Leadership in Quality

The role of leadership in the management system and the successful implementation of the requirements for safety are defined in the IAEA Safety Guide GSR Part 2 [40]. The role of leadership is also addressed in most quality-related standards, including CSA N286, CSA N299, and ISO 9001 [3], [26], [41].

In Canada, the CNSC encourages leaders to integrate self-assessments, audits, and performance reviews to strengthen management systems, ensuring alignment with strategic objectives and regulatory compliance [42].

# 4. Standards and Systems Evaluation

## 4.1. International Regulatory Structures and Standards

Nuclear power plant operation requirements are globally regulated by governments through laws, regulations, licensing frameworks, and standards. While all regulatory frameworks aim to ensure safety and reliability, they vary in specificity, flexibility, and reliance on international standards.

Table 1 provides a high-level comparison of the regulatory structures and quality program requirements for operators and Tier 1 supply chains in Canada, Finland, France, Japan, Korea, the UK, and the U.S. These jurisdictions were selected as relevant to the Canadian nuclear industry supply chain. Table 1 outlines governing regulatory bodies, key legislative and quality documents, and practices that influence owners, operators and suppliers.

Nuclear regulatory frameworks across reviewed jurisdictions illustrate different approaches to QA and management systems. Many jurisdictions integrate international standards, tailoring their practices to address specific regulatory and operational needs. This section highlights key practices and their relevance to advancing nuclear safety and quality.

Finland's nuclear framework is governed by the Radiation and Nuclear Safety Authority (STUK) under the *Nuclear Energy Act and Nuclear Energy Decree* [63], [64]. STUK mandates compliance with its Regulatory Guides on nuclear safety (YVL), including YVL A.3 [46] – *Leadership and Management for Safety,* which outlines requirements for management systems. Operators and suppliers typically adopt ISO 9001 [41] and ISO 19443 [47], which satisfy the principles of YVL A.3 [46]. STUK's YVL Guides serve as the authoritative framework, ensuring alignment with Finnish regulatory expectations [64].

France's nuclear sector is regulated by the *National Safety Authority (ASN) under the Act on Transparency and Security in the Nuclear Field,* referred to as the TSN Act [48], [65]. ASN Guide No. 22 [49] establishes core quality management system requirements, which operators and suppliers typically meet by adopting ISO 9001 [41] and ISO 19443 [47]. The French system incorporates additional safety culture and traceability elements beyond ISO standards, emphasizing nuclear-specific considerations like CFSI and enhanced risk management [49].

Japan's Nuclear Regulation Authority (NRA) enforces quality requirements under the *Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors* [66]. The NRA requires operators to adhere to JEAC-4111 [51], a QA code that uses principles from ISO standards [51], [67]. JEAC-4111 also incorporates provisions from International Atomic Energy Agency (IAEA) safety standards, including General Safety Requirements (GSR) Part 2 [40], ensuring that Japan's quality management system approach aligns with both national and international best practices [51].

Korea's Nuclear Safety and Security Commission (NSSC) regulates quality under the *Nuclear Safety Act* [52], [54] . The Act mandates compliance with the Korean Electric Power Industry Code (KEPIC) standards, including KEPIC-QAP, R*equirements for Quality Assurance Programs for Nuclear Facilities,* which is based on ASME NQA-1 [55]. KEPIC-QAP, along with QAO, which is specific to the operations phase of a nuclear facility, applies to both operators and suppliers, emphasizing detailed QA practices while incorporating ongoing efforts to align with ISO 19443 for enhanced global compatibility [56].

In the UK, the Office for Nuclear Regulation (ONR) oversees the industry under the *Energy Act* and *Nuclear Installations Act* [68], [69]. ONR's Technical Assessment Guides (TAGs), including TAG NS-TAST-GD-077 [58], which provides requirements for supply chain management, outlines quality management systems requirements for operators and suppliers [16]. While ISO 9001 and ISO 19443 are not explicitly mandated, they often satisfy TAG requirements, offering flexibility for operators and suppliers to adopt internationally recognized standards [58].

**Table 1:** Regulatory structures and referenced standards applicable to operators and Tier 1 suppliers of nuclear plants by country

| Country | Regulatory Body | Key Legislative Document | Owner/Operator Management System Requirements | Supply Chain QA Requirements | Comments |
|---|---|---|---|---|---|
| **Canada** | CNSC – Canadian Nuclear Safety Commission | *Nuclear Safety and Control Act* SC 1997, c.9 [43] | Operators typically adopt CSA N286 [26] | CSA N299 [3] is acceptable but not required by the regulator | CSA N286 and CSA N299 are adopted as standard practice but not explicitly mandated by legislation |
| **Finland** | STUK – Finnish Radiation and Nuclear Safety Authority | *Nuclear Act* (990/1987) [44] and *Nuclear Energy Decree* (161/1988) [45] | STUK YVL A.3 [46]; the owner/operator typically adopts ISO 9001 [41] and ISO 19443 [47] | ISO 9001 [41] and ISO 19443 [47] are acceptable but not specifically required by the regulator | Finnish operators and suppliers must meet STUK YVL guides unless alternatives are approved by the regulator |
| **France** | ASN – National Safety Authority | *Act on Transparency and Security in the Nuclear Field,* 2006 [48] | ASN Guide No. 22 [49]; the owner/ operator frequently relies on ISO 9001 [41] and ISO 19443 [47] | ISO 9001 [41] and ISO 19443 [47] are often supplemented with traceability and risk management enhancements | ASN integrates additional safety culture and risk management elements into an ISO-based quality management system |
| **Japan** | NRA – Nuclear Regulation Authority | *Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors, 1957* [50] | JEAC-4111 [51] | JEAC-4111 [51], based on ISO-9001 [41] | JEAC-4111[51] also incorporates provisions from IAEA document GSR Part 2 [40], [51] |
| **Korea** | NSSC – Nuclear Safety and Security Commission, KINS – Korea Institute of Nuclear Safety [52] | *Atomic Energy Act, 2010* [53] and the *Nuclear Safety Act,* 2022 [54] | KEPIC-QAP, 2018 – Korean Electric Power Industry Codes aligned with ASME NQA-1 [55] | KEPIC-QAP plus QAO specifically for the operations phase, which uses ANSI/ANS 3.2 as a reference standard [55] | There are ongoing efforts to align KEPIC-QAP with ISO 19443 [56] |
| **UK** | ONR – Office for Nuclear Regulation | *Energy Act, 2013* [57] | TAG NS-TAST-GD-077 [58]; the owner/operator often relies on ISO 19443 [47] | ISO 9001 [41] and ISO 19443 [47] | UK quality management system requirements are licence-dependent, tailored to each site's needs |
| **U.S.** | NRC – Nuclear Regulatory Commission | *Atomic Energy Act, 1954* [59] | 10 CFR 50 Appendix B, [60] and ASME NQA-1 [61] | ASME NQA-1 [61] and 10 CFR Part 21 [62] | 10 CFR Part 50 Appendix B mandates QA requirements, with NQA-1 recognized as an acceptable compliance method |



In the U.S., the Nuclear Regulatory Commission (NRC) enforces quality requirements under the *Atomic Energy Act* [59], [70]. Operators must comply with 10 CFR Part 50, Appendix B [60], which establishes QA criteria for nuclear power plants and fuel reprocessing facilities [70]. The NRC recognizes ASME NQA-1 as a standard that meets the foundational requirements of 10 CFR Part 50 Appendix B [71]. It has primarily evolved to address conventional LWR designs. Advanced reactor vendors can navigate the existing regulatory framework through built-in flexibility and an exemption process to license new technologies.

To address these challenges, an initiative is underway to establish a new regulatory framework, 10 CFR Part 53 [72] – *Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors.* This framework is designed to offer an optional, technology-inclusive pathway for licensing advanced nuclear reactors, using risk-informed and performance-based evaluation methods [72]. The development of this framework is important from a quality perspective, as an assessment of the safety risk of reactor components is an important component of the QA requirements under ASME NQA-1. Recognizing that many emerging nuclear technologies lack operating experience, the NRC requires that advanced designs provide at least the same level of protection as current-generation LWRs. 10 CFR Part 53 is being developed to accommodate these technologies while ensuring compliance with safety standards. A goal of this initiative is to streamline the licensing process for advanced reactor technologies, which include many types of SMRs. This effort is expected to facilitate and encourage the adoption of innovative nuclear technologies for the benefit of the industry and the public [72]. As of early 2025, the NRC continued to hold public meetings and solicit comments online about this proposed regulatory initiative [72].

## 4.2. Relevant Nuclear Industry Documents

Based on the comparative analysis, the international documents most relevant for this project's QA and management system comparison were identified, as presented in Table 2. These standards and best practices documents address important aspects of nuclear safety and quality.

**Table 2:** Key quality standards, regulations and documents used in the nuclear industry

| Relevant Document | Purpose |
|---|---|
| **CSA N286 - Management system requirements for nuclear facilities [23]** | Applies to the operator (licensee) of the nuclear power plant and can apply to a delegated organization (e.g., supplier) that the operator contracts to perform life-cycle activities. However, the operator retains accountability to ensure that the requirements are met. Specifies management system requirements for life-cycle phases of nuclear facilities, emphasizing safety and integration. Specifies management program system requirements. |
| **CSA N299 series of standards – Quality assurance program requirements for the supply of items and services for nuclear power plants [3]** | Applies to the supply chain. Specifies QA program requirements, focusing on the graded approach for nuclear supply chain quality management. |
| **10 CFR Part 50 Appendix B – Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants [62]** | Applies to the operator (licensee) of the nuclear power plant and can apply to a delegated organization (e.g., supplier) that the operator contracts; however, the operator retains accountability to ensure that the requirements are met. Establishes QA program requirements mandated by the U.S. NRC [70]. Specifies criteria to be met for an acceptable QA program. |
| **ASME NQA-1 – Nuclear Quality Assurance [61]** | Primarily applies to the supply chain. Developed to meet the requirements of 10 CFR Part 50 Appendix B. Defines QA program requirements to ensure compliance with U.S. regulatory criteria for nuclear facilities and supply chains. |
| **ISO 9001 – Quality Management Systems – Requirements [41]** | Primarily applies to the supply chain. Provides the foundation for effective management systems across industries, emphasizing customer satisfaction and continual improvement. Specifies quality management system and/or QA program requirements. |
| **ISO 19443 – Quality management systems in the nuclear sector [47]** | Primarily applies to the supply chain. Extends ISO 9001 requirements to address nuclear-specific quality management needs, focusing on safety, traceability, and supplier qualification. |
| **INPO 14-005 – Principles for Excellence in Nuclear Supplier Performance [73]** | Provides guidance primarily applicable to the supply chain. Establishes principles for supplier performance in alignment with quality management systems to enhance reliability and safety [73]. Specifies principles related to a quality management system. |
| **IAEA GSR Part 2 – Leadership and Management for Safety [40]** | Primarily applies to the operator (licensee) and regulators. Provides a high-level guide to principles of leadership and management for safety. Defines requirements for leadership and continuous improvement in management systems to maintain nuclear safety. Establishes requirements for assessing, sustaining, and continuously improving effective leadership and management for safety. |
| **IAEA-TECDOC-1910 – Quality Assurance and Quality Control in Nuclear Facilities and Activities [74]** | Provides guidance for the operator (licensee) of the nuclear power plant and can apply to a delegated organization (e.g., supplier) that the operator contracts. Provides insights and states good practices and lessons learned for implementing QA and quality control in nuclear facilities. |

## 4.3. Comparison of CSA Standards with Other Relevant Nuclear Quality Documents

### 4.3.1. Comparison of ASME NQA-1 and CSA N299 standards

A broad analysis was performed to assess and compare each standard or reference document against CSA N299.1 and CSA N286. CSA N299.1 was used as the basis for comparison, as it specifies the most comprehensive QA program requirements of the four CSA N299 series of standards. Due to the cumulative structure of the CSA N299 series, each standard within the series was developed with distinct objectives and foundational approaches. Some focus on process performance, while others are based on prescriptive criteria. Consequently, direct comparisons between individual CSA N299 standards and other QA and quality management standards may not provide a fully accurate assessment.

ASME NQA-1 was developed to provide requirements for meeting the general QA principles of the 10 CFR Part 50, Appendix B [62] regulatory requirement in the U.S. for QA programs used in the nuclear industry. ASME NQA-1 provides a QA framework that was developed to help ensure that items and services supplied to the nuclear sector effectively support the safe, reliable, and efficient operation of nuclear facilities. In addition to nuclear power generation, ASME NQA-1 applies to spent fuel fabrication, storage, reprocessing, waste management, and nuclear research, covering activities such as siting, design, procurement, and software development, to fabrication, construction, operation, maintenance, and decommissioning [61].

Designed for application at any stage of a nuclear facility's life cycle, ASME NQA-1 employs a graded approach, allowing organizations to tailor the level of QA controls based on safety, reliability, and operational importance. The factors accounted for in the graded approach are: i) relative importance to nuclear safety; ii) magnitude of involved hazard; iii) facility or item life-cycle stage (e.g., design, construction, operation, decommissioning); iv) function of a facility; v) characteristics of the facility or item; vi) relative importance to radiological or nonradiological hazards; and other relevant factors that might be important for assessing safety and risk [75]. In the U.S., ASME NQA-1 is widely adopted by commercial nuclear power plants to meet the 10 CFR Part 50 Appendix B regulatory requirements and is used both by plant operators and suppliers. Certain provisions of ASME NQA-1, particularly Part 1 and select sections of Part 2, are also mandated for ASME nuclear pressure boundary equipment and components. The standard has undergone multiple revisions, with ASME NQA-1:1994 [76] still in active use by most U.S. operating plants, while some operators have transitioned to ASME NQA-1:2008/2009 [77]. Recent U.S. nuclear projects have been built under ASME NQA-1:2015 [62]. The latest edition was published in 2024 [75].

ASME NQA-1 and the CSA N299 series both serve as nuclear QA standards, but they differ significantly in scope, application, and prescriptive detail. Table 3 outlines key differences between NQA-1 and CSA N299.1 across QA elements. An important distinction is that ASME NQA-1 applies to both operators and suppliers, whereas Canada has separate standards: the CSA N286 management system standard for operators and the CSA N299 QA standards for suppliers. This does not mean that ASME NQA-1 encompasses the scope of both Canadian standards; it is a QA standard only. American operators are not mandated to have a management system, which is a requirement in Canada's CNSC REGDOC-2.1.1. While CSA N286 is intended to address overall direction to management, there is no U.S. equivalent standard to CSA N286.

### 4.3.2. Comparison of ISO 9001 and ISO 19443 with CSA N299 standards

ISO 9001 is an internationally recognized quality management system standard that provides requirements that are applicable across numerous industries and sectors. Given its generic nature, several sectors have developed industry-specific accompanying standards that are meant to be used in conjunction with ISO 9001 to address requirements that are unique to that sector. ISO 19443 is the companion standard to ISO 9001 for the nuclear sector.

**Table 3:** Comparative analysis of ASME NQA-1 and CSA N299.1

| QA Element | CSA N299.1 Requirements [3] | ASME NQA-1 Requirements [61] | Key Differences |
|---|---|---|---|
| **Scope and Application** | Supplier-focused QA program for nuclear component manufacturers and service providers | Facility-wide framework covering all phases of a nuclear facility's life cycle, including design, procurement, operation, and decommissioning. | CSA N299.1 applies mainly to suppliers, while ASME NQA-1 applies to operators and suppliers |
| **Measuring and Test Equipment** | Detailed calibration procedures, unique equipment ID, traceability, and reassessment if out of calibration | More extensive calibration verification, environmental monitoring, and record retention | Both enforce calibration controls, but ASME NQA-1 is more detailed on environmental monitoring and record retention |
| **Non-Conformances (NCR) and Corrective Action** | Structured NCR process, root cause analysis, corrective action verification, trend analysis, and management review | Adds segregation and disposition evaluation, project-wide trending, and enhanced verification | ASME NQA-1 introduces enhanced procedural oversight, broader trend tracking, and more rigorous verification controls |
| **Procurement categorization** | One of four categories of QA are determined using specific prescribed evaluation methods based on safety and business risks | A graded approach to the application of specific elements for individual procurements; eight example factors for consideration are given | With CSA N299, specific categories of QA are selected using prescribed methods, while with NQA-1, the rigour required for each QA requirement may be determined based on the amount of control and verification required for a procurement |
| **Procurement** | Supplier qualification and QA compliance program oversight at procurement | Extends oversight to contractors/subcontractors, requires audits before/after procurement, and higher traceability for high-risk components | CSA N299.1 focuses on supplier QA controls; ASME NQA-1 expands scope to subcontractors with more extensive audits and traceability |
| **Packaging, Shipping, Handling, and Storage** | Packaging/storage per customer requirements, environmental controls, and periodic reinspection | Adds detailed environmental monitoring, pre-shipment inspections, and handling protocols for high-risk materials | ASME NQA-1 includes additional prescriptive environmental and handling requirements |

It was developed to address the quality management needs of suppliers in the nuclear industry. Building upon ISO 9001, it incorporates additional nuclear-related quality and safety requirements. These requirements address the scrutiny and assurance needed for items and services significant to nuclear safety. ISO 19443 provides a standardized approach to qualifications and QA, supporting consistency across international markets while aligning with ISO's overarching quality management philosophy [41], [47].

Key ISO 19443 requirements include:

- safety culture integration;
- counterfeit and fraudulent item prevention; and
- operational experience tracking.

While ISO 19443 adds nuclear-specific elements, it remains less prescriptive than CSA N299 standards or ASME NQA-1, meaning:

- It lacks the full scope of QA controls required for high-risk nuclear components.
- It does not mandate detailed requirements for traceability and verification.

The NRC has previously explored the application of ISO-based systems through its SECY-03-0117 report [78], which examined the feasibility of using ISO 9001 as a pathway to meet 10 CFR Part 50 Appendix B requirements. The report concluded that such an approach would require additional quality provisions to ensure alignment. No information was found on whether the additional provisions in ISO 19443 fully address these concerns. The concern that quality programs based on ISO 9001 combined with ISO 19443 may not provide sufficient detail to fully address nuclear QA was also raised during discussions with interested parties. In the opinion of some, it would be challenging to independently develop the detailed QA requirements needed for nuclear supply using the ISO 9001 and ISO 19443 standards in the absence of a QA program based on a nuclear QA standard (such as ASME NQA-1 in this instance).

Adoption of ISO 9001 and ISO 19443 as part of nuclear supplier programs aligns with the broader global trend toward ISO-based quality management systems. This trend reflects the flexibility of ISO standards to be adapted to various regulatory environments and the value their application brings to global supply chains by harmonizing quality expectations.

In several jurisdictions outside of North America, ISO 9001 and ISO 19443 are required quality management system standards for suppliers in the nuclear sector. In Canada, however, suppliers are expected to establish a QA program based on the CSA N299 standards. A summary of the key differences between ISO 9001, ISO 9001 combined with ISO 19443, and CSA N299 standards is highlighted in Table 4 below. Although this table compares a quality management system standard with a QA standard, the comparison is justified, as it illustrates the alignment and differences in quality program requirements for international nuclear suppliers to those of Canadian suppliers.

## 4.4. Relevant Non-Nuclear Industry Documents

Across industries such as aerospace and oil and gas, quality management system, QA, and quality control standards provide foundational frameworks for operational reliability, safety, and regulatory compliance. These industries largely rely on ISO 9001 [41] as a widely adopted framework for quality processes, risk management, and continual improvement. Building upon ISO 9001, specialized standards have been developed to address industry-specific needs and challenges. Table 5 provides a high-level overview of key non-nuclear industry documents relevant to this analysis.

**Table 4:** Comparative analysis of ISO 9001 + ISO 19443 and CSA N299 standards

| QA Element | CSA N299.1 Requirements [3] | ISO 9001 and ISO 19443 Requirements [41], [47] | Key Notes |
|---|---|---|---|
| **Scope and Application** | Prescriptive nuclear product-oriented QA program with strict supplier controls | Broad management system approach; ISO 19443 adds nuclear safety focus | ISO standards focus on performance/customer satisfaction, while CSA N299.1 is prescriptive and product-oriented for the nuclear industry |
| **Design** | Covers planning, interfaces, inputs/outputs, verification, plus specific requirements for design stages, software, and documentation | Covers planning, interfaces, inputs/outputs, verification, and validation with testing | Both address core design process, but CSA N299.1 contains detailed stage/documentation requirements; ISO contains design validation |
| **Procurement** | Detailed supplier evaluation, QA program selection, subcontract control, inspection, and audit | Limited to contract review; no supplier selection/control requirements | Procurement is a major focus of CSA N299.1, but it is not addressed in ISO 9001/19443 |

| QA Element | CSA N299.1 Requirements [3] | ISO 9001 and ISO 19443 Requirements [41], [47] | Key Notes |
|---|---|---|---|
| **Measuring and Test Equipment** | Fifteen detailed requirements, including calibration procedures, acceptance criteria, and traceability | Four high-level calibration requirements without procedural detail | CSA N299.1 provides prescriptive traceability and procedural controls; ISO covers calibration only generally |
| **Non-Conformances (NCR) and Corrective Action** | Structured NCR process with root cause analysis, corrective action verification, and management review | Requires control and documentation but minimal prescriptive guidance | CSA N299.1 mandates structured processes; ISO leaves process details to the organization |
| **Packaging, Shipping, Handling, and Storage** | Customer-specific storage conditions, environmental controls, periodic reinspection, and contamination prevention | General "preservation" requirement with suggested prevention methods | ISO relies on general practices; CSA N299.1 enforces strict nuclear-specific controls |
| **Quality Audits** | Requirements for both internal/external audits with detailed execution, reporting, re-audit, and qualifications | Internal audits only; limited to planning, execution, and corrective actions | CSA N299.1 requires both internal and external audits and provides more detailed requirements. |

**Table 5:** Non-nuclear industry quality management system standards and documents relevant for nuclear industry

| | Standard | Description | Relevance to Nuclear Industry | Quality Program Elements Applicable to Nuclear |
|---|---|---|---|---|
| **All** | ISO 9001 [41] | International standard for quality management systems | Foundational framework is adaptable to nuclear practice | Process-based approach, continual improvement, and customer satisfaction |
| **Aerospace** | SAE AS9100D [79] | Internationally recognized quality management system standard tailored for aerospace organizations | Risk management, safety-critical supply chains, and counterfeit part prevention; complex supply chains, high reliability, and counterfeit part prevention | Configuration control, traceability, and counterfeit prevention; risk management, configuration control, and part reliability |
| | SAE AS9120B [80] | Quality management system for distributors in the aerospace industry | Traceability, inventory control, and counterfeit prevention for distributors | Preventing counterfeit parts; documented traceability |
| **Oil and Gas** | API Spec Q1 [81] | Quality management system for manufacturing organizations | Applicable to safety-critical manufacturing in nuclear | Emphasis on defect prevention, traceability, and material quality |
| | API Spec Q2 [82] | Quality management for service supply organizations | Risk-based approaches for nuclear operations require specialized services | Maintenance and service quality, defect prevention, and risk management |
| | ISO 29001 [83] | Sector-specific quality management system for petroleum, petrochemical, and natural gas | Advanced risk management and defect prevention applicable to nuclear | Risk mitigation, safety compliance, and traceability |

The documents listed in Table 5 highlight relevant quality management system and QA elements such as traceability, counterfeit prevention, risk management, and defect prevention. They are intended to address aspects that are similar to the quality demands of the nuclear industry's supply chain, which shares operational and safety challenges with aerospace and oil and gas. For example, SAE AS9100D [79] integrates comprehensive controls for counterfeit parts and risk management, while API Spec Q2 [82] emphasizes service quality and risk-based approaches for safety-critical operations.

By studying documents identified in Table 5, the nuclear industry, especially in the context of SMR deployment, can identify transferable practices that enhance supply chain quality management, modularity, and scalability. These insights also contribute to the development of more robust QA/quality control systems tailored to the unique challenges of nuclear operations.

SAE AS9100D [79], SAE AS9120B [80], and ISO 29001 [83] are closely aligned with the needs of the nuclear industry, specifically regarding safety-critical supply chain management, traceability, risk management, and prevention of counterfeit components.

ISO 29001 is a quality management system developed to address the specific operational and safety needs of the oil, gas, and petrochemical sectors. It builds on ISO 9001 by introducing industry-specific requirements such as enhanced risk management, traceability and non-conformity management, with a focus on mitigating operational risks and controlling environmental impact. Some elements of ISO 29001 include:

- continuous risk assessment and corrective action protocols for high-risk activities like drilling and refining;
- emphasis on supplier management and the need for detailed documentation to ensure the traceability and quality of critical equipment and materials; and
- formal reviews and verifications to help reduce risks of non-compliance and environmental harm.

The standard [83] integrates performance evaluation and customer satisfaction monitoring into operational planning, encouraging continuous improvement in line with safety and environmental priorities. These provisions make ISO 29001 particularly relevant for managing complex supply chains in high-risk industries. Conformity is assessed through accredited third-party certification bodies, providing independent verification of compliance. However, it does not fully align with the categorization framework of the CSA N299 standards.

SAE AS9100D and SAE AS9120B are aerospace-specific quality management standards developed by the International Aerospace Quality Group (IAQG) [84]. Both standards are built on ISO 9001, incorporating additional requirements tailored to the unique needs of the aerospace, space, and defence industries, including risk management, traceability, configuration control, and counterfeit prevention.

SAE AS9100D applies broadly across the aerospace supply chain, covering manufacturers, suppliers, and service providers. It introduces provisions for product safety, non-conformity management, and supplier evaluation. Features such as First Article Inspection (FAI) ensure product conformity, while detailed configuration management safeguards regulatory compliance and product specifications.

SAE AS9120B, designed specifically for distributors, focuses on the handling, storage, and tracking of safety-critical materials. It emphasizes inventory control, detailed documentation, and traceability measures to prevent counterfeit parts from entering the supply chain. Like SAE AS9100D, it includes customer satisfaction monitoring and non-conformance management to ensure continuous improvement.

The shared principles between SAE AS9100D and SAE AS9120B address challenges such as managing complex supply chains and ensuring the integrity of critical materials and components. While SAE AS9100D targets broader operational needs across manufacturing and supply chains, SAE AS9120B zeroes in on the unique risks faced by distributors.

ISO 29001, SAE AS9100D, and SAE AS9120B offer proven frameworks for managing safety-critical supply chains, helping ensure traceability and mitigating risks in industries with high-reliability requirements. However, when compared to CSA N299 standards and CSA N286, they do not provide comparable coverage required for nuclear-specific elements, such as a graded QA approach, safety culture integration, and the comprehensive life-cycle management needed for SMR projects.

## 4.5. Comparison of Specific QA Program Elements Among Standards

### 4.5.1. Graded approach

Table 6 provides highlights of how quality categories are selected for CSA N299 and how a graded approach is applied in ASME NQA-1. Related activities outlined in ISO 9001 and ISO 19443 are also included.

The CSA N299 categorization framework for QA of items and services supplied to the nuclear facility is designed to provide QA requirements that are graded based on the potential impact of the item or service on the nuclear facility's level of safety or business operation risks. The QA category selection process requires expertise across multiple disciplines, including safety, engineering, design, and procurement. An initial selection analysis may be performed by the nuclear facility operator or a higher-tier supplier who is contracted to procure on behalf of the operator. Suppliers subsequently perform categorization selections for sub-suppliers they are contracting for products or services.

ASME NQA-1–compliant organizations can implement requirements for QA programs and QA requirements for nuclear facilities applications according to guidance outlined in ASME NQA-1 Part III, or they can develop their own implementation process, which allows nuclear

**Table 6:** Approaches to quality category selection/graded approach from selected standards

| Standard | Graded Approach | Graded Approach – Key Features |
|---|---|---|
| **ISO 9001 [41]** | Implemented based on risk evaluation | Serves as a general quality management system standard, focusing on organizations' performance and continuous improvement. |
| **ISO 19443 [47]** | No graded approach | Introduces some nuclear-specific enhancements, such as counterfeit item detection and safety culture provisions.<br><br>Adds a limited graded approach to QA; specifies that consideration must be given to the complexity and importance to nuclear safety of an item to appropriately grade the application of requirements related to quality management, documentation, monitoring, and measurement. |
| **CSA N299 series** | Grading reflected by a four tier QA categorization framework; each category imposes progressively more comprehensive requirements based on factors such as safety risk, design complexity, and operational impact [3] | Defines two methods for determining the applicable QA category [3]:<br><br>**The Analytical Method –** A qualitative assessment where suppliers answer a structured series of questions related to quality controls and business risk.<br><br>**The Factor Rating Method –** A numerical rating system based on six key factors: safety, design complexity, design maturity, production complexity, item characteristics, and business risk. Values that get assigned to each factor are then summed to determine the appropriate category assignment.<br><br>Analysis is performed using both methods, and the higher rating is used to define the quality level for supply of the item or service. |
| **ASME NQA-1 [61]** | Risk-informed, scalable approach | ASME NQA-1 specifies a process to assess the quality in two steps. In practice, in commercial nuclear, it is usually the utility that has the primary responsibility for this process. |




facility subject matter experts to use their professional judgment along with documented justification when determining whether the supplier's QA program meets the level of quality required for nuclear facility safety and operation. This determination may consider the history of supply of a specific item from a specific supplier. Note that in Canada, where ASME NQA-1 is invoked for the supply of a nuclear pressure boundary item, the QA requirements of CSA N299 are typically also mandated.

### 4.5.2. Audit requirements

Audit requirements vary across standards. CSA N299 standards mandate internal and external audits but do not impose specific audit frequency, while ASME NQA-1 enforces a defined baseline frequency, including internal audits recommended annually and external audits required every three years. ASME NQA-1 non-mandatory Part II suggests that pre- and post-audit conferences, risk-based audit grading, and continuous improvement evaluations may allow suppliers to reduce the implementation effort associated with these audit requirements [61].

ISO 9001 certification relies primarily on external certification audits conducted by third-party accredited conformity assessment bodies, with internal audits occurring at planned intervals. Unlike CSA N299 and ASME NQA-1, ISO 9001 does not require supplier audits unless contractually mandated [47]. SAE AS9100D builds its audit requirements on ISO 9001 and mandates structured supplier risk assessment, thorough supplier oversight, and compliance verification specific to the aerospace industry [79].

For nuclear suppliers, ISO 19443 extends the requirements of ISO 9001 by adding nuclear-specific safety and traceability requirements, including risk-based supplier audits, nuclear safety culture verification, and material traceability audits to prevent CFSIs from entering the nuclear supply chain [85].

Table 7 provides compares these audit requirements across CSA N299, ASME NQA-1, ISO 9001, SAE AS9100D, and ISO 19443.

**Table 7:** Audit requirement comparison across relevant standards

| Element | CSA N299 standards [3] | ASME NQA-1 [61] | ISO 9001 [41] | SAE AS9100D [79] | ISO 19443 [47], [85] |
|---|---|---|---|---|---|
| **Audit Approach** | CSA N299.4 requires no audits; others require internal/ external audits, but with no set frequency and minimal risk/ supplier focus; there is more detail in higher categories | Structured audit process (Req. 18) with pre/post-audit meetings, formal planning, and optional risk-based methods; applicable to suppliers, with strong documentation and follow-up expectations | Risk-based audits; supplier audits only if in contract | Process compliance focus; tiered audits by supplier risk | Nuclear-specific, risk-based supplier audits with reliability and traceability requirements |
| **Auditor Training and Qualification** | No explicit requirements; references ISO 19011 | Requires auditor training and qualification; auditors must be competent in technical, quality management systems, and audit methods | No auditor qualification requirements | Requires auditors with compliance/ risk expertise | Requires nuclear safety training and supplier safety culture assessment |
| **Audit Requirements** | Internal and external audits required (except in CSA N299.4), but frequency is not defined | Baseline cycle enforced; clear scheduling, notification, and consistency; may be risk-based | Internal audits required | Required audits for aerospace compliance and risk | Supplier qualification plus risk-based audits for nuclear safety compliance |
| **Internal Audit Requirements** | Frequency per program need | Annual, extendable to 2 years; includes improvement tracking | Planned intervals to check quality management system compliance | Focus on aerospace safety/quality compliance | Focus on nuclear safety principles and quality management system compliance |
| **External Audit Requirements** | Frequency per program need | Every three years; includes product effectiveness and operational experience reviews | Three-year certification cycle with surveillance audits | Tiered by supplier risk/ compliance | Adds material traceability and nuclear safety supplier evaluations |
| **Supplier Evaluation and Sub-Supplier Audits** | Sub-supplier audits required; qualified suppliers list mandated; certification can replace audit in CSA N299.4 | Risk-based grading adjusts scope/ frequency; purchaser retains responsibility | Supplier audits only if contractually required | Structured supplier evaluation with risk/ traceability | Supplier evaluation for nuclear risk and full material traceability |
| **Corrective Action Requirements** | Supplemental audits for non-conformance; detailed plans and follow-up | Continuous improvement evaluations to enhance quality management system and supplier performance using audit results | Corrective actions and continual improvement required | Tracks corrective actions and supplier quality improvement | Corrective actions must integrate nuclear safety culture |

| Element | CSA N299 standards [3] | ASME NQA-1 [61] | ISO 9001 [41] | SAE AS9100D [79] | ISO 19443 [47], [85] |
|---|---|---|---|---|---|
| **Supplier Traceability and Risk Mitigation** | Not defined | Prioritizes high-risk suppliers to focus oversight | No mandate for traceability audits | Risk-based oversight with traceability | Mandatory material traceability audits to prevent counterfeit items |
| **Configuration and Change Management Audits** | Not defined | Requires change management compliance audits for modifications | Not required | Requires documented control of process changes | Requires that modifications maintain compliance with nuclear industry safety requirements |

# 5. Experts engagement results

Using a systems approach, comments from the interviews were organized into nine themes grouped into three main topics, provided in Table 8. Because the systems approach considers the interrelated factors that affect and contribute to achieving quality across the supply chain, it is acknowledged that these themes address both the requirements of the standards and how the requirements are understood and applied by various participants in the system.

The topics covered in these themes had varying levels of emphasis and prevalence amongst interested parties. To the extent possible, counterpoints are provided within the themes to summarize the diverse perspectives of supply chain participants.

## 5.1. Overarching Themes

### 5.1.1. Understanding and application of standards by suppliers

Interviewees acknowledged that the CSA N299 series provides a structured and robust framework for managing supplier product quality, particularly for Tier 1 suppliers delivering safety-critical components. The clear traceability, audit expectations, and documentation requirements were described as well-aligned with the safety needs of nuclear power plants.

Interviewees specified that procedural expectations around procurement and software QA were among the most difficult to apply because they are very detailed. Interviewees emphasized the need for more support for consistent implementation. Specific recommendations for updates to the CSA N299 standards included improved guidance for interpreting Annex A grading criteria, further discussed in Section 5.2.1, and clearer procedural expectations for procurement and software controls. A risk-informed approach was suggested to ensure that effort and oversight remain proportional to component safety significance and supplier capability. Other suggested implementation resources are discussed in Section 5.3.1.

### 5.1.2. Challenges with nuclear supplier qualification

Interviewees representing suppliers, utilities, and regulators consistently pointed to challenges that affect broader participation in the nuclear supply chain. For organizations not historically involved in nuclear projects, the expectations embedded in the CSA N299 standards were described as difficult to implement without quality manufacturing experience in operating in a highly regulated environment. Interviewees commented on the difficulty of qualifying under CSA N299-based procurement specifications.

**Table 8:** Thematic categorization of comments collected via interviews

| Type | Theme |
|---|---|
| **Overarching** | Understanding and application of standards by suppliers |
| | Challenges with nuclear supplier qualification |
| | Equivalency and compatibility with other nuclear standards |
| | Transitioning from non-nuclear industries to CSA N299 |
| | Performance-based CSA N299 grading approach |
| **Element-specific** | QA category selection |
| | Execution of audits |
| **Supporting Tools** | Education, training, and knowledge retention |
| | Digital tools integration |

Some participants expressed that, while product quality could be met, compliance with procedural and documentation requirements within a highly regulated environment often required support from consultants due to the complexity and perceived ambiguity of the requirements in the standard.

Specific implementation areas, such as procurement controls and grading, have proven to be challenging for suppliers that are unfamiliar with the expectations of the nuclear industry. The difficulties are often compounded by a perception that the administrative and procedural burden is not always commensurate with the actual safety significance of the item or service being procured, especially in the case of non-pressure-retaining components. To address this, operators permit alternatives to the CSA N299.4 standard for procurement of non-pressure boundary items—including components and piece parts—provided the requirements comply with an acceptable QA program, such as ISO 9001 or equivalent [86]. This flexibility in the choice of QA program allows for risk-informed application of quality requirements, helping to reduce unnecessary barriers for suppliers while maintaining safety and compliance.

While the option of using different QA programs, along with alignment and harmonization of QA frameworks, could help reduce these burdens, it is equally important that CSA N299 requirements are understood by potential suppliers before they enter the nuclear market. Understanding the effort and resources required to meet CSA N299 enables suppliers to make informed business decisions and supports a high level of preparedness and QA across the nuclear supply chain.

### 5.1.3. Equivalency and compatibility with other nuclear standards

Interviewees stressed the importance of alignment with international standards to reduce duplication and support broader supplier participation, particularly given that many SMR designs and supply chains are international in nature. A recurring theme was the operational challenge of navigating multiple QA frameworks across jurisdictions, with particular concern about the lack of a clearly defined pathway for suppliers operating under ISO-based quality systems to align with CSA N299 requirements.

Suppliers working internationally reported that complying with both CSA N299 standards and other frameworks, such as ISO 9001, ISO 19443, and ASME NQA-1, often results in multiple audits. This was described as resource-intensive, particularly for companies for whom nuclear projects represent only a portion of their overall business.



> "A key theme that emerged from the engagement with interested parties was the challenges faced by suppliers transitioning from non-nuclear sectors, such as aerospace and oil and gas, in becoming a supplier for the nuclear industry."

### 5.1.4. Transitioning from non-nuclear industries to CSA N299

A key theme that emerged from the engagement with interested parties was the challenges faced by suppliers transitioning from non-nuclear sectors, such as aerospace and oil and gas, in becoming a supplier for the nuclear industry. Interviewees identified best practices from aerospace and oil and gas industries outlined in standards listed in Table 5 as a possibility to be incorporated into the application of CSA N299 standards, particularly practices for supplier management, digital integration, and modular QA approaches.

### 5.1.5. Performance-based CSA N299 grading approach

During the interviews, some respondents noted that the ASME NQA-1 standard provides a prescriptive framework that outlines processes to achieve specified outcomes, offering clarity around QA requirements implementation.

In contrast, one challenge identified with the use of the CSA N299 standard series is its implementation of a performance-based approach. While CSA N299 defines the expected outcomes, it does not prescribe the process for achieving them. This approach offers flexibility for suppliers to develop processes aligned with their own systems and experience. However, interviewees noted that this flexibility can be a barrier for potential suppliers, particularly those without an established quality management system and experience in developing compliant processes independently.

Interviewees emphasized the importance of updating the standards in general to better support more proportionate, risk-informed applications. This could enhance accessibility for a wider range of suppliers without compromising safety or quality objectives.

## 5.2. Element-Specific Themes

### 5.2.1. QA category selection

A key component of QA program categorization or grading under CSA N299 and ASME NQA-1, respectively, is the consideration of the findings from safety risk methodologies used by nuclear facility design authorities. Interviewees advocated that industry should ensure that a strong link be maintained between the safety significance assigned to an item and the risk assessments done by the nuclear facility design authorities.

Interviewees pointed to the ASME NQA-1 framework as being more easily applied to a broader range of procurements, due to its more flexible graded approach, from highly specialized nuclear safety-critical components to commercial-grade items. They also said that international suppliers tend to prefer this approach, citing that it appears to be simpler and easier to interpret. Conversely, some interviewees raised concerns about potential inconsistencies in

application of ASME NQA-1 requirements through its graded approach, because it could result in different interpretations of the requirements across different projects, organizations, and auditors.

While the CSA N299 categorization framework offers a structured approach in terms of the application of QA rigour, interviewees noted several challenges in its application. Interviewees felt that categorization decisions in CSA N299 necessitate personnel with expertise across various disciplines that they may not have easy access to, which could potentially hinder the consistent application of rating criteria.

Another identified challenge was a fragmentation of expertise among the procurement teams, engineering groups, and quality personnel of many supplier companies. Interviewees described the categorization framework as complex and difficult to navigate, especially for smaller suppliers that may lack the necessary in-house knowledge.

Interviewees felt that the subjective interpretations of category selection criteria by different subject matter experts, even within the same organization, can result in inconsistencies. To address this issue, some interviewees recommended the development of supplementary guidance on how to apply the factor rating method uniformly across projects. Without guidance, organizations may inadvertently apply varying levels of QA rigour to similar components, potentially leading to inefficiencies in procurement and compliance.

### 5.2.2. Execution of audits

A consistent theme across interviews was the perceived lack of consistent execution of nuclear audits, with many interviewees highlighting variability in how audits are conducted, the subjectivity of auditor interpretations, and the inefficiencies caused by redundant auditing requirements.

#### 5.2.2.1. Compliance assessment

Interviewees noted that while the wording of CSA N299 is highly specific, inconsistent interpretations, particularly during audits, lead to differences in how compliance is assessed. Several study participants emphasized the need for additional auditor training and implementation guidance (i.e., materials that explain the CSA N299 requirements and outline practical steps for compliance) to reduce interpretation variability and avoid misinterpreted expectations being required of suppliers. Some of the interviewed suppliers reported a seeming lack of understanding from auditors of how suppliers' QA manuals function in practice.

Challenges were noted to be pronounced in specialized areas, such as software verification and procurement, where auditors may not have the expertise to assess the effectiveness of controls beyond compliance checks. Interviewees suggested that additional training and certification programs would help to develop audit personnel with the technical knowledge necessary to conduct meaningful evaluations.

#### 5.2.2.2. Audit effectiveness and equivalencies

CSA N299 audits were perceived as resource-intensive, requiring extensive documentation. Several interviewees felt that this level of detail is burdensome without a clear understanding of the added value. One interviewee discussed requirements being added to their quality program that were perceived to be as a result of an auditor's interpretation of the requirements rather than a valuable or significant change to their QA program.

Suppliers operating in multiple jurisdictions indicated they are often audited to different frameworks, such as CSA N299 standards, ASME NQA-1 [61], and ASME BPVC Section III [34]. As discussed earlier, many of the elements among these standards overlap, and preparing and conducting these audits can be confusing, resource-intensive, and time-consuming, without a perceived corresponding increase in QA value.

#### 5.2.2.3. Audit criteria

Some interviewees advocated for incorporating historical supplier performance data into audit evaluations similar to ASME NQA-1, which recognizes these data as a method of acceptance per paragraph 200 of Requirement 7 [61]. This practice can reduce the audit burden for established suppliers with a proven history of compliance. It was also suggested that performance data could be used to guide and tailor areas of audit scrutiny.

#### 5.2.2.4. Centralized auditing system

There was strong support among the interviewees for a centralized and standardized auditing framework, which could streamline compliance, reduce duplication, and enhance consistency. The NUPIC model in the U.S., which has been developed for the owners of a nuclear facility, was mentioned as an example. It consolidates audits for multiple customers, reducing the audit burden on suppliers while ensuring audit consistency. Canada has similar programs, with the key difference of CANPAC being used by utilities and CANIAC being used by supply chain participants. While NUPIC audits are executed according to the requirements of ASME NQA-1 by audited utilities with participation from other utilities who form a team, CANPAC secures a team of auditors who execute audits according to CSA N286 and CSA N299 standards.

## 5.3. Supporting Tools

### 5.3.1. Education, training and knowledge sharing

As addressed in several other themes, understanding, interpreting, and applying nuclear QA standards was identified as a challenge for new suppliers, especially those transitioning from other industries.

Transferring knowledge and strengthening industry capacity—such as enhancing workforce skills, developing training resources, and maintaining organizational readiness needed to meet CSA N299 requirements—were identified as key areas for overcoming the challenges of implementing CSA N299 standards. Improved access to training programs on QA standards was cited by interviewees as an opportunity that could help suppliers fulfill nuclear QA expectations more effectively. Other suggested developing implementation resources such as guidance documents, online learning modules, or case-based examples.

### 5.3.2. Digital tools integration

Interviewees noted that the nuclear industry remains slow to adopt digital tools to support QA programs, although this is not impacted by the CSA N299 standards. Interviewees from other industries noted that digital tools for automated compliance tracking and electronic record-keeping offer benefits that can enhance the efficiency, traceability, and effectiveness of QA programs.

Interviewees pointed to the success of digital tools in other industries, such as aerospace, where automated compliance and AI-driven analysis have streamlined quality management. However, in nuclear QA, digitalization remains in its early stages. Interviewees suggested that gradual integration, combined with regulatory engagement, would be necessary to ensure digital tools align with compliance expectations.

# 6. Recommendations and Considerations

## 6.1. Challenges with CSA N299 Application

Based on the analysis of relevant literature and interviews with interested parties, several recurring challenges have been identified with the application and interpretation of CSA N299. The following summarizes the more significant issues and the reasons they pose obstacles:

- **Application of the standards:** The CSA N299 standards' results-based approach is intended to offer flexibility but can be a barrier for suppliers that lack mature quality management systems, as they may struggle to independently develop compliant processes.
- **Transition pathways:** Support for a growing SMR market will require the entry of non-nuclear and more international suppliers that will be transitioning from non-Canadian QA programs and management systems. There is no Canadian guidance document that addresses the differences between Canadian and other international standards.
- **Auditing inconsistency:** Interviewees reported variability in audit outcomes, which is exacerbated by the number of audits required for suppliers. The lack of standardized auditor training and qualification criteria might contribute to this challenge.



## 6.2. Lessons Learned from Aerospace and Oil and Gas

Based on the analysis of interviews with interested parties and comparison of QA standards for different industries, several practices from the aerospace and oil and gas sectors were identified as particularly relevant to the maintenance of CSA N299 standards. These insights reflect implementation experience and observations shared by industry participants, which can be considered to enhance the usability and alignment of CSA N299 standards. The following examples illustrate practices from other industries that could inform CSA N299 implementation, particularly in areas where additional guidance, examples, or tailored approaches may be beneficial.

- **Modular construction practices:** In oil and gas, modularization involves the off-site fabrication of large, repeatable units under controlled conditions, which allows for more consistent quality oversight, streamlined inspection processes, and earlier defect detection. For example, large-scale liquified natural gas facility modules are fabricated in purpose-built yards, using standardized weld procedures and quality records that travel with each module to the site [87], [88]. SMR designs, which also rely on prefabricated, repeatable modules, share similar characteristics. These modular production environments could be better addressed in CSA N299 standards by adding guidance on topics such as off-site inspection protocols, supplier documentation transfer, and integration of modular QA records into final plant records. While not yet explicitly covered in the current standards, these aspects could be integrated through implementation guidance to help align CSA N299 practices with both ISO-based requirements and proven modular quality management strategies.
- **Risk-based supplier management models:** SAE AS9100D [79], the aerospace quality standard, applies a risk-informed approach to supplier management, where the depth and frequency of oversight are scaled to the supplier's demonstrated capabilities and the risk level of the supplied product or service. This contrasts with the current CSA N299 structure of four graded QA requirements standards, where supplier requirements are determined primarily by category. Adopting more flexible, risk-based implementation practices—either within the existing categorization framework or as supplementary guidance—could improve audit efficiency, reduce supplier burden, and better align with international supply chain management strategies. Such an approach could be supported by guidance materials that explain how to incorporate supplier performance history, criticality of the work, and past audit results into determining the level of oversight required.

## 6.3. Recommendations for Enhancing the CSA N299 Standards and Supporting Nuclear Supply Chain Resources

The following recommendations are derived from an analysis of interview data, a literature review, and a comparative assessment of relevant national and international standards and practices. They reflect common implementation challenges and evolving needs within the nuclear supply chain. These recommendations are presented without any implied prioritization.

Addressing the items outlined below, either through updates to the CSA N299 suite of standards or through the development of supplemental supply chain resources, has the potential to enhance the clarity, consistency, and overall utility of the CSA N299 standards for all users within the nuclear sector.

### 6.3.1. Recommendations for potential updates to the CSA N299 standards

#### 6.3.1.1. Audit requirements

The CSA N299 standards would benefit from more clearly defined requirements related to auditor qualifications and training. Additionally, incorporating guidance to support performance-based and risk-based audit evaluations would improve the consistency and effectiveness of audit practices.

- **Recommendation:** Incorporate a formal definition of "Quality Auditor" in Clause 2 of the standards to support consistent understanding and application across the supply chain.
- **Recommendation:** Introduce a new clause outlining a transparent and structured process for the resolution of audit-related disputes.

#### 6.3.1.2. Categorization framework

Clarification of roles and responsibilities in the application of product and service categorization, as outlined in CSA N299 Annex A, is necessary to support consistent interpretation and implementation. Enhanced guidance would assist users in applying grading criteria effectively.

Moreover, the introduction of an alternative categorization framework—incorporating risk-informed decision-making factors such as safety significance, potential consequences of failure, supplier capability, and historical performance—would enhance the applicability of the standards, particularly for SMR projects.

- **Recommendation:** Clarify the recommended technical disciplines in CSA N299 Annex A that should be consulted, at a minimum, during the categorization framework selection process.
- **Recommendation:** Include a new clause in CSA N299 Annex A addressing the potential use of an alternative, risk-informed categorization framework.
- **Recommendation:** Include a new clause in CSA N299 Annex A establishing a formal process for the resolution of categorization-related disputes or misinterpretations.

#### 6.3.1.3. SMR-specific considerations

To align with evolving construction practices, particularly those related to SMRs, the standards should explicitly confirm the allowability of modular and offsite fabrication processes, including the consideration of the following:

- off-site inspections;
- transfer and validation of supplier documentation; and
- integration of modular QA records into final plant documentation.

### 6.3.2. Recommendations for supporting resources and systems across the nuclear supply chain

#### 6.3.2.1. Audit practices

Standardized training programs and supplemental resources for auditors—particularly those representing utilities, vendors, and sub-suppliers—would promote audit consistency and competency. In addition, formal recognition of third-party certifications as partial or full evidence of conformance, supported by defined gap-closure procedures, could broaden supplier participation across jurisdictions.

- **Recommendation:** Develop standardized auditor training programs for utilities, vendors, and sub-suppliers.
- **Recommendation:** Establish a formal third-party certification pathway for demonstrating CSA N299 conformance.
- **Recommendation:** Implement a streamlined dispute resolution process within the audit framework to address issues arising during or after QA audits.

#### 6.3.2.2. Categorization resources

The development of dedicated resources is recommended to support the effective and consistent application of categorization criteria. These may include guidance documents, decision-support tools, and practical examples.

- **Recommendation:** Develop and distribute supplemental materials to aid in the application of categorization processes in accordance with CSA N299 Annex A.
- **Recommendation:** Incorporate a structured support and dispute resolution mechanism for addressing categorization challenges within the broader QA system.

#### 6.3.2.3. Additional supporting materials

The availability of practical implementation tools—such as decision trees, educational modules, case studies, and interpretive guidance—would contribute to consistency and knowledge sharing across the nuclear supply chain.

In addition, developing a transition framework to map CSA N299 requirements to internationally recognized standards would support harmonization efforts and facilitate the integration of new or international suppliers.

#### 6.3.2.4. Awareness of standards development processes

Enhancing awareness of the CSA standards development and interpretation processes could support more consistent application of the standards and foster greater industry engagement.

- **Recommendation:** Develop targeted communications or training materials to inform users how to:
  - propose revisions to CSA standards; and
  - request official interpretations of specific clauses or terminology.

## 7. Summary and Conclusions

This report presents the challenges and opportunities associated with CSA N299 standards for advancing SMR adoption, based on a review of relevant literature, interviews with interested parties, comparative analysis of related QA standards, and practical implementation observations. The findings reflect consistent themes and operational insights shared across a range of industry participants. The challenges identified through interviews with interested parties—particularly regarding auditing practices and categorization framework — indicate areas where improvements can be made.

Many of the challenges identified by interviewees are not reflective of deficiencies in the standards. Instead, the challenges described stem from varying interpretations of intent, inconsistent implementation practices, and a lack of shared understanding among auditors, suppliers, and operators. These factors contribute to duplicated effort, barriers to nuclear qualification for suppliers from other industries, and challenges with the consistent and effective application of the standards. Addressing these challenges could involve developing resources, such as additional guidance and training, that could aid all participants in the system in achieving a common understanding, in turn supporting compliance, efficiency, and resilience in Canada's SMR supply chain.

Overall, this analysis demonstrates that the CSA N299 standards are applicable as QA standards for the SMR supply chain. While certain implementation challenges exist, they are largely related to interpretation and application rather than inherent gaps in the standards themselves. With targeted improvements, such as enhanced guidance, training, and clarification of expectations, CSA N299 can serve as an effective foundation for ensuring QA, supporting regulatory compliance, and strengthening the overall performance and reliability of the SMR supply chain in Canada.

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