Management System
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Preface

This regulatory document is part of the CNSC's Management system series of regulatory documents. The full list of regulatory document series is included at the end of this document and can also be found on the CNSC's website.

Regulatory document REGDOC-2.1.1, *Management System*, provides licensees and applicants with information on the CNSC's "management system" safety and control area (SCA), along with supplemental information on various and emerging issues related to management systems.

The CNSC's regulatory framework includes CNSC regulatory documents as well as national and international standards. Specifically, the Canadian Standards Association (CSA Group's) N-Series of standards provides an interlinked set of regulatory requirements for the management of nuclear facilities and activities. CSA standard N286-12 [1] provides an overall management framework and direction to develop and implement sound management practices and controls for the licensing basis. This regulatory document does not duplicate the generic requirements of CSA N286-12. However, it provides more specific direction for those requirements.

Guidance contained in this document exists to inform the applicant, elaborate further on requirements or provide direction to licensees and applicants on how to meet requirements.

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Management System

1.   Introduction

The Canadian Nuclear Safety Commission (CNSC) defines "management system" as "the framework of processes, procedures and practices used to ensure that an organization can fulfill all tasks required to achieve its objectives safely and consistently."[1] Management system requirements provide overall direction to the licensee organization for developing and implementing sound management practices and controls for the organization. An effective and well-implemented management system helps to assure the CNSC that licensees will conduct their licensed activities safely.

1.1 Purpose

The purpose of this document is to provide information:

- on management systems that are applicable to different types of CNSC licensees
- related to the Canadian Standards Association's (CSA Group's) CSA standard N286-12, *Management system requirements for nuclear facilities* [1]
- supplemental to specific topics that have been the subject of recent developments in management system standards, as well as those of recent regulatory interest with respect to management systems
- on radiation safety oversight related to nuclear substances, radiation devices and Class II nuclear facilities

1.2 Scope

The information in this document pertains to the following CNSC-licensed facility types that have management system as a licence condition:

- Class 1A power and non-power nuclear reactors
- Class 1B nuclear facilities
- uranium mines and mills
- radioactive waste management facilities

The following classes of licensees and facility or activity types do not have management system as a condition of their CNSC licences, but may also consult this document for information:

- nuclear substance and radiation devices
- Class II nuclear facilities and prescribed equipment
- dosimetry services
- packaging and transport of nuclear substances

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[1] REGDOC-3.6, *Glossary of CNSC Terminology*

1.3 Relevant legislation

The following provisions of the *Nuclear Safety and Control Act* (NSCA) and regulations made under the NSCA are relevant to this regulatory document:

- Paragraph 3(d) of the *Class I Nuclear Facilities Regulations* states that an application for a licence to operate a Class I nuclear facility shall contain "the proposed management system for the activity to be licensed … ".
- Subparagraph 3(b)(v) of the *Uranium Mines and Mills Regulations* states that an application for a licence in respect of a uranium mine or mill shall contain "the proposed management system for the activity, including measures to promote and support safety culture … ".
- The *General Nuclear Safety and Control Regulations,* General Application Requirements (section 3) and Application for Licence to Abandon (section 4), contain requirements that form the basis of a management system.
- The *Nuclear Substances and Radiation Devices Regulations* (sections 3 and 4) contain similar and more specific conditions that are fundamental to a management system.
- The *Class II Nuclear Facilities and Prescribed Equipment Regulations,* as follows:
  - For the construction of a Class II nuclear facility, paragraph 3(j) requires "the proposed quality assurance program for the design and construction of the nuclear facility", and for the operation of such a facility, paragraph 4(h) requires "the proposed quality assurance program".
  - For Class II prescribed equipment, "Licence to Service" (section 7) details the requirements that form the management system.
  - As per paragraph 11(n), the following information must be provided in order for the equipment to be certified: "the quality assurance program that was followed during the design of the equipment and that will be followed during the production of the equipment."
- The *Radiation Protection Regulations,* paragraph 18(b) requires "the proposed quality assurance program" for a licence to operate a dosimetry service.
- The *Packaging and Transport of Nuclear Substances Regulations, 2015,* paragraph 24(a), includes a requirement for a management system that is in accordance with IAEA regulations.

2.   Management system information

The CNSC expects licensees to adhere to all CSA N286-12 [1] principles as the basis of their management system and the corresponding core management processes. A management system implemented in accordance with these principles and requirements has features to assure safe operations. The requirements for a management system apply throughout the lifecycle of the licensed activity and extend to all safety and control areas (SCAs).

For nuclear facilities that do not have a licence condition for management system, the principles in CSA N286-12 can serve as guidance for establishing an effective management system. Further guidance on this matter is also found in other industry standards such as CAN/CSA-ISO 9001:16, *Quality Management Systems – Requirements* [2] and ISO 14001, *Environmental management systems* [3].

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CSA N286-12 structure and principles

CSA N286-12 [1] integrates requirements from other management system standards for quality, health and safety, environment, economics and security. It therefore provides a basis upon which a single management system may be implemented.

CSA N286-12 is based on a set of 12 principles described below. The first two principles are aimed at ensuring that safety is properly considered in all decisions and actions, and that licensees are expected to design, plan and control their activities in order to meet all requirements:

- safety is the paramount consideration guiding decisions and actions
- the business is defined, planned and controlled

As captured in the next three principles, to meet all requirements an organization must ensure that it is aligned with top management direction and able to establish, communicate and achieve the objectives and priorities it sets for itself:

- the organization is defined and understood
- resources are managed
- communication is effective

The remaining principles ensure that processes are established for managing activities consistently and for verifying that the desired objectives are achieved. Adherence to the following remaining principles can ensure that measures are in place to address deficiencies and to provide for continual improvement:

- information is managed
- work is managed
- problems are identified and resolved
- changes are controlled
- assessments are performed
- experience is sought, shared and used
- the management system is continually improved

CSA N286-12 is organized for ease of use for applicable facility types mentioned in the standard. The standard shows the generic requirements applicable to the facility types listed below, while each section thereafter applies to one or a group of facilities identified in the title. The table below shows the various facility types and corresponding sections containing CNSC management system requirements.

Table 1: Management system requirements for various facility types

Facility type	Applicable sections of CSA N286-12
Uranium mines and mills	4. Generic requirements for the management system 5. Specific requirements for uranium mines and mills
Uranium processing and fuel manufacturing facilities	4. Generic requirements for the management system 6. Specific requirements for uranium processing and fuel manufacturing facilities
High energy reactor facilities	4. Generic requirements for the management system 7. Specific requirements for high energy reactor facilities
Research and isotope processing facilities	4. Generic requirements for the management system 8. Specific requirements for research and isotope processing facilities
Radioactive waste management facilities	4. Generic requirements for the management system 9. Specific requirements for radioactive waste management facilities

The CSA's *Commentary on CSA N286-12, Management system requirements for nuclear facilities* (CSA N286.0.1-14) [4] provides background information concerning certain clauses and requirements in CSA N286-12. This background information can help the user clarify the context of CSA N286-12 requirements. Also, CSA N286.0.1-14 refers to research materials that were used during the formulation of some of the requirements in CSA N286-12. The clause headings and numbers used in CSA N286.0.1-14 correspond to those in CSA N286-12.

3.   Specific regulatory topics

3.1   Leadership

The role and behavior of leaders in an organization are fundamental to achieving excellence in safety. Through the development and implementation of an effective management system, the organization can better understand and promote a healthy safety culture.

CSA N286-12 [1] recognizes leadership in its scope and through requirements specific to top management. CSA N286-12 applies to top management, as defined in the standard, with overall accountability for the nuclear facility. Top management defines, plans and controls the business (licensed activities) through processes that define expectations for the organization and the means to monitor performance. Expectations of top management include making use of effectiveness reviews to continuously assess and improve its management system, as well as utilizing the latter to understand and promote a healthy safety culture.

Recently issued management system standards such as CAN/CSA-ISO 9001:16, *Quality Management Systems – Requirements* [2], and the IAEA's GSR Part 2, *Leadership and Management for Safety: General Safety Requirements* [5], have further elaborated on leadership expectations and requirements in recognition of the key role leaders have in an organization. These standards include requiring top management to demonstrate leadership and commitment to the management system by:

- taking accountability for the effectiveness of the management system
- ensuring the integration of the management system requirements into the organization's processes
- communicating the importance of effective management and of conforming to the management system requirements
- ensuring that the management system achieves its intended results
- engaging, directing and supporting persons in order to contribute to the effectiveness of the management system
- supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility
- establishing, advocating and adhering to an organizational approach to safety that stipulates that issues relating to safety receive the attention warranted by their significance
- acknowledging that safety encompasses interactions between people, technology and the organization
- establishing behavioral expectations and fostering a strong safety culture
- establishing the acceptance of personal accountability in relation to safety on the part of all individuals in the organization and ensuring that decisions made at all levels take account of the priorities and accountabilities for safety

3.2   Safety culture

The CNSC fully supports the concept that an organization that actively fosters a healthy safety culture can have a powerful influence on employee attitudes and behaviours, and consequently, on individual and corporate safety performance.

The CSA N286-12 [1] safety culture requirement states the following: "Management shall use the management system to understand and promote a safety culture … ."[2] It is through the management system that organizations understand their prevailing culture. Top management communicates the vision and objectives of the organization while upholding the key principle that "safety is the paramount consideration guiding decisions and actions". Safety culture is understood and improved through key management processes such as assessments and continuous improvement.

For further information on the CNSC's approach to safety culture, refer to REGDOC-2.1.2, *Safety Culture* [6], which sets out specific requirements and guidance for assessing and fostering a healthy safety culture.

3.3   Supply chain

The specific requirements for a supply chain described in CSA N286-12 [1] apply to the supply of services as well as items. Licensees' supply chain management processes implemented in

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[2] See CSA N286-12, *Management system requirements for nuclear facilities,* (4.2)

accordance with CSA N286-12 are sufficiently robust to provide assurance that non-compliant items and services entering the supply chain are properly identified and dispositioned.

CSA standard N299, *Quality assurance program requirements for the supply of items and services for nuclear power plants* [7] was specifically developed for use by nuclear power plants for their suppliers. Therefore, this standard can also be used as guidance for the other classes of licensees with respect to the implementation of supply chain management processes and requirements for their suppliers.

3.3.1   Counterfeit, fraudulent and suspect items

While not mentioned in any specific section of CSA N286-12 [1], effectively implemented supply chain processes and adherence to the requirements of the management system can mitigate against the introduction of counterfeit, fraudulent and suspect items (CFSI) into the supply chain of a nuclear facility and/or activity. CFSI are items that:

- have been intentionally misrepresented as having met a code or standard when they have not
- have been intentionally misrepresented as having been certified when they have not
- are suspected of either of the above

The global supply chain is often long and complex, and the source of CFSI may be unknown. The risks presented by CFSI can be reduced by the effective implementation of a management system in accordance with CSA N286-12. The supply management processes include:

- audits of the supplier's management system to assess processes for the prevention, detection and removal of foreign material including CFSI
- selection of qualified, reputable and reliable vendors based on their ability to supply an acceptable product or service with adequate measures for the prevention, detection and removal of foreign material including CFSI
- identification of purchasing requirements including technical performance requirements; applicable codes, standards, and specifications; and inspection, test, and acceptance requirements that permit the identification and detection of CFSI during verification
- verification that the item received was fabricated, tested and inspected prior to shipment, in accordance with the applicable code, specification, purchase order (including technical performance requirements) or drawings
- provisions for extending applicable requirements to sub-suppliers for the prevention, detection and removal of foreign material including CFSI
- CFSI experience gained is identified and collected, reviewed for relevance and significance, incorporated into supply chain processes and used to initiate improvement

It is important to note that it is not only the supply chain that is affected by CFSI. Organizational functions such as engineering, maintenance and operations also need to be cognizant of CFSI issues and able to deal with them.

Additional CFSI information is available in IAEA TECDOC-1169, *Managing suspect and counterfeit items in the nuclear industry* [8]. The Electric Power Research Institute's (EPRI) report 1019163, *Plant Support Engineering: Counterfeit and Fraudulent Items – Mitigating the Increasing Risk* [9], provides information for the prevention, detection and mitigation of CFSI.

3.3.2   Management of contractors

The nuclear industry has recently increased the practice of engaging the services of contractors for a wide array of work, which includes not only the provision of lifecycle activities or specific one-time jobs, but also the conduct of routine processes such as maintenance. Managing contractors has taken on a new dimension that requires special attention to ensure that contractors:

- work in a safe environment
- possess the necessary qualifications and obtain the necessary training
- work in accordance with licensee requirements
- deliver products and services that meet regulatory requirements

Licensees are accountable for the work performed by contractors.

3.4   Configuration management

Adherence to a management system that meets the requirements of CSA N286-12 [1] will ensure that the configuration of a facility is maintained. However, there has been a recognized need for standardized processes and guidance to enhance the understanding of configuration management at high-energy reactor facilities. As a result, CSA standard N286.10-16, *Configuration management for high energy reactor facilities* [10], was issued to provide guidance on maintaining configuration throughout the full lifecycle of a facility.

CSA N286.10-16 provides information that may also be used by other nuclear facility licensees for maintenance and management of facility configuration.

3.5   Software quality assurance

CSA standard N286.7-16, *Quality assurance of analytical, scientific, and design computer programs* [11], applies to high energy reactor facilities as defined in CSA N286-12. The standard sets out the quality assurance requirements for software used in design, safety analysis, and supporting activities. CSA N286.7-16 provides guidance for other classes of licensees who use software programs for the purposes mentioned above, as well as for other operational needs.

4.   Radiation safety oversight: Nuclear substance licensees, radiation device licensees and Class II nuclear facility licensees

Nuclear substance licensees, radiation device licensees, and Class II nuclear facility licensees have the primary responsibility for safety of the licensed activities. Licensees are expected to demonstrate that they are qualified to undertake the proposed activities and have made adequate provision for the health and safety of persons and protection of the environment. This includes demonstrating that they can manage and control the licensed activities. Licensees must provide effective management support, including both human and financial resources, to properly implement and maintain their radiation safety programs, meeting all of the programs' regulatory obligations. This includes addressing the requirements of section 4 of the *Radiation Protection Regulations*.

When implementing safety and control measures, licensees should take into account the management system principles outlined in section 2 of this regulatory document, recognizing that measures should be appropriate to their unique structure and governance framework. Program

oversight should be comprehensive and integrate the roles and responsibilities of the applicant authority, the radiation safety officer and the radiation safety committees, as applicable. Oversight activities include assessing the effectiveness of the safety and control measures, identifying opportunities for improvement and resolving any problems.

Licensees may have an existing system of controls and processes that govern their overall operations. In such cases, radiation safety programs should be integrated within the licensees' existing management system.

The elements of leadership outlined in section 3.1 of this regulatory document should be employed by licensees' top management. Furthermore, the principles underpinning a healthy safety culture, as described in section 3.2 of this document, should be considered by licensees when implementing their safety and control measures.

Glossary

For definitions of terms used in this document, see REGDOC-3.6, *Glossary of CNSC Terminology*, which includes terms and definitions used in the *Nuclear Safety and Control Act* and the regulations made under it, and in CNSC regulatory documents and other publications. REGDOC-3.6 is provided for reference and information.

References

1. CSA Group, CSA N286-12, *Management system requirements for nuclear facilities*, Toronto, 2012.

2. CAN/CSA-ISO 9001:16, *Quality Management Systems – Requirements*, Toronto, 2015.

3. International Organization for Standardization, ISO 14001, *Environmental management systems*, Geneva, 2015.

4. CSA Group, CSA N286.0.1-14, *Commentary on CSA N286-12, Management system requirements for nuclear facilities,* Toronto, 2012.

5. IAEA GSR Part 2, *Leadership and Management for Safety: General Safety Requirements,* Vienna, 2016.

6. Canadian Nuclear Safety Commission, REGDOC-2.1.2, *Safety Culture*, Ottawa, 2018.

7. CSA N299 standard series, *Quality assurance program requirements for the supply of items and services for nuclear power plants,* Toronto, 2016.

8. International Atomic Energy Association, IAEA-TECDOC-1169, *Managing suspect and counterfeit items in the nuclear industry*, Vienna, 2000.

9. Electric Power Research Institute, Inc. (EPRI), 1019163, *Plant Support Engineering: Counterfeit and Fraudulent Items - Mitigating the Increasing Risk*, Palo Alto, 2014.

10. CSA Group, CSA N286.10-16, *Configuration management for high energy reactor facilities,* Toronto, 2016.

11. CSA Group, CSA N286.7-16, *Quality assurance of analytical, scientific and design computer programs*, Toronto, 2016.

Additional Information

The following documents contain additional information related to management systems.

- Canadian Nuclear Safety Commission (CNSC), REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants,* version 2, Ottawa, 2016.

- CNSC, S-106, *Technical and Quality Assurance Requirements for Dosimetry Services*, *Revision 1*, Ottawa, 2006.

- CSA Group, CSA N290.12, *Human factors in design for nuclear power plants*, Toronto, 2014.

- IAEA TECDOC 1740**,** *Use of a Graded Approach in the Application of the Management System Requirements for Facilities and Activities*, Vienna, 2014.

CNSC Regulatory Document Series

Facilities and activities within the nuclear sector in Canada are regulated by the Canadian Nuclear Safety Commission (CNSC). In addition to the *Nuclear Safety and Control Act* and associated regulations, these facilities and activities may also be required to comply with other regulatory instruments such as regulatory documents or standards.

Effective April 2013, the CNSC's catalogue of existing and planned regulatory documents has been organized under three key categories and twenty-five series, as set out below. Regulatory documents produced by the CNSC fall under one of the following series:

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         1.2   Class IB facilities
         1.3   Uranium mines and mills
         1.4   Class II facilities
         1.5   Certification of prescribed equipment
         1.6   Nuclear substances and radiation devices

2.0 Safety and control areas

Series   2.1   Management system
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         2.4   Safety analysis
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         2.13   Safeguards and non-proliferation
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3.0 Other regulatory areas

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