



# Nuclear Substances and Radiation Devices **Radiation Protection Programs for Nuclear Substances and Radiation Devices Licences**

REGDOC-1.6.2

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August 2021



**Radiation Protection Programs for Nuclear Substances and Radiation Devices Licences**  
Regulatory document REGDOC-1.6.2

© Canadian Nuclear Safety Commission (CNSC) 2021  
Cat. No. CC172-236/2021E-PDF  
ISBN 978-0-660-39084-0

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*Également publié en français sous le titre : Programmes de radioprotection pour les permis de substances nucléaires et d'appareils à rayonnement*

**Document availability**

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**Publishing history**

August 2021

Version 1.0

## Preface

This regulatory document is part of the CNSC's nuclear substances and radiation devices 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-1.6.2, *Radiation Protection Programs for Nuclear Substances and Radiation Devices Licences*, provides guidance to nuclear substances and radiation devices licensees and applicants on the development, implementation, management and assessment of their radiation protection programs. REGDOC-1.6.2 also identifies the CNSC's considerations in assessing the adequacy of a radiation protection program.

REGDOC-1.6.2 is a new regulatory document meant to be used in conjunction with REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices*, which sets out requirements and guidance for nuclear substances and radiation devices licensees and applicants.

For information on the implementation of regulatory documents and on the graded approach, see REGDOC-3.5.3, *Regulatory Fundamentals*.

The words "shall" and "must" are used to express requirements to be satisfied by the licensee or licence applicant. "Should" is used to express guidance or that which is advised. "May" is used to express an option or that which is advised or permissible within the limits of this regulatory document. "Can" is used to express possibility or capability.

Nothing contained in this document is to be construed as relieving any licensee from any other pertinent requirements. It is the licensee's responsibility to identify and comply with all applicable regulations and licence conditions.

## Table of Contents

<b>1.</b>	<b>Introduction.....</b>	<b>1</b>
1.1	Purpose.....	1
1.2	Scope.....	1
1.3	Relevant legislation.....	2
<b>2.</b>	<b>Responsibility for Radiation Safety.....</b>	<b>2</b>
<b>3.</b>	<b>Radiation Safety Officer.....</b>	<b>3</b>
3.1	Duties.....	3
3.2	Authority of the RSO.....	4
3.3	Qualifications.....	4
	3.3.1 Refresher training.....	5
3.4	RSO staffing.....	6
	3.4.1 Alternate RSO.....	6
	3.4.2 Site RSO.....	6
	3.4.3 Consultant.....	6
<b>4.</b>	<b>Radiation Protection Program, Policies and Procedures.....</b>	<b>7</b>
4.1	Developing an RPP.....	7
4.2	Radiation safety manual.....	7
4.3	Management system.....	8
4.4	Policies and procedures.....	10
<b>5.</b>	<b>Implementing the Radiation Protection Program.....</b>	<b>10</b>
5.1	Fostering a healthy safety culture.....	10
<b>6.</b>	<b>Assessing the Radiation Protection Program.....</b>	<b>11</b>
6.1	Self-assessments.....	11
6.2	Independent assessments.....	12
6.3	Management reviews.....	12
	<b>Appendix A: Examples of RSO Duties.....</b>	<b>14</b>
	<b>Appendix B: Radiation Safety Committee.....</b>	<b>18</b>
B.1	Role and Responsibilities.....	18
B.2	Membership.....	18
B.3	Terms of Reference.....	19
B.4	Meetings.....	19

**Glossary ..... 20**

**References..... 21**

# Radiation Protection Programs for Nuclear Substances and Radiation Devices Licences

## 1. Introduction

As stated in section 4 of the *Radiation Protection Regulations*, all CNSC licensees are required to implement a radiation protection program (RPP). REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices* [1], also requires applicants to submit a proposed RPP with their licence application.

As CNSC licences for the use of nuclear substances and radiation devices vary in scope and associated risk, the content and level of detail of the RPP should be commensurate with these elements.

An RPP is submitted as part of the licence application and is the applicant's proposal on how it intends to comply with regulatory requirements. As such, the RPP is referenced in the licence appendix, and its implementation is verified during inspections by the CNSC. An RPP is typically developed, implemented and managed to suit the licensed activity, complexity and circumstances of the licensee.

The fundamental elements of an RPP are people and procedures. Sections 2 and 3 of this document describe the roles and responsibilities of the radiation safety officer (RSO), who is responsible for managing the RPP. Sections 4, 5, 6 and 7 provide information about the elements that should be considered when developing, implementing and assessing an RPP.

### 1.1 Purpose

This document provides guidance for nuclear substances and radiation devices licensees and applicants on how to develop, implement and assess an RPP as required by the *Radiation Protection Regulations*. It also provides guidance on how to meet requirements found in the *Nuclear Substances and Radiation Devices Regulations* and the CNSC's regulatory documents.

REGDOC-1.6.2 is meant to be used in conjunction with REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices* [1], which sets out requirements and guidance for licensees of nuclear substances and radiation devices. REGDOC-1.6.2 also gives examples of effective RPPs and related best practices, given the CNSC's considerations in assessing the adequacy of an RPP.

### 1.2 Scope

This document contains guidance for nuclear substances and radiation devices licensees and applicants for developing, implementing and assessing an RPP. It can also provide useful information for nuclear substances and radiation devices that fall under other classes of licences.

Some licences can have programs that are considered complex. For those licences, additional information may be needed in order to develop, implement, manage and assess their RPPs. When assessing a licence application for nuclear substances and radiation devices, the CNSC will

determine if a program is considered complex and inform licensees accordingly. The CNSC will take different factors into consideration, including:

- medium- and high-risk use types
- licences for the consolidated use of nuclear substances (use type 815)
- multiple licensed locations
- multiple licences issued at the same location
- multiple licences issued for the same organization

Appendix B provides information on the Radiation Safety Committee for licensees and applicants with complex programs, but could also be useful for other applicants.

### 1.3 Relevant legislation

The following provisions of the [Nuclear Safety and Control Act](#) (NSCA) and the regulations made under it are relevant to this document:

- NSCA, sections 24, 26 and 27
- [General Nuclear Safety and Control Regulations](#), sections 3–7, 10, 12, 15, 17, 27, 28, 29 and 31
- [Nuclear Security Regulations](#), sections 3, 4 and 5
- [Nuclear Substances and Radiation Devices Regulations](#), sections 3–9, 11, 16, 17, 18, 20, 22, 23, 24, 30–38 and Schedule 1
- [Packaging and Transport of Nuclear Substances Regulations, 2015](#), sections 19, 25, 26, 29, 37, 40 and 42
- [Radiation Protection Regulations](#), sections 3–16, 20-25

## 2. Responsibility for Radiation Safety

The licensee is accountable and responsible for radiation safety and for the conduct of all licensed activities that are authorized under its CNSC licence. The licensee assigns an applicant authority, who is an individual at the senior management level with sufficient authority – for both financial and human resources – for ensuring that an RPP is implemented in accordance with all regulatory requirements. The applicant authority has the full legal and financial responsibility for the licence and is ultimately responsible for the RPP.

The applicant authority can delegate duties for the day-to-day oversight of the RPP to an individual known as the radiation safety officer (RSO). However, the accountability for the RPP **cannot** be delegated.

The applicant authority is responsible for ensuring that sufficient resources are allocated to the RSO; for example:

- human resources to assist with managing and executing the required duties
- sufficient authority to meet regulatory requirements (see section 3.2)
- administrative assistance with correspondence, record-keeping requirements and document management associated with a CNSC licence
- financial resources to meet regulatory expectations and to address non-compliance, such as those for personnel training and for purchasing radiation monitoring equipment or other equipment

Further details on the responsibilities of the applicant authority and on guidance for allocating resources can be found respectively in REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices* [1], and *Welcome Package: Applicant Authority, Nuclear Substances and Radiation Devices Licences* [2].

### 3. Radiation Safety Officer

RSO is the designation commonly assigned to a radiation safety professional who, as a critical component of an RPP, administers the program on a day-to-day basis. As stated in section 15 of the *General Nuclear Safety and Control Regulations*, the applicant authority shall designate an RSO and complete the [Request to Appoint a Radiation Safety Officer or an Alternate Radiation Safety Officer: Nuclear Substances and Radiation Devices Licence](#) form. By signing this form, the RSO agrees to take responsibility for overseeing the implementation and management of the RPP and to communicate with the CNSC for all matters pertaining to it.

As described in REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices* [1], the RSO shall have the time, resources and authority to enforce policies and procedures established under the RPP in order to meet all regulatory requirements. Responsibilities of an RSO typically include:

- ensuring the health and safety of personnel, the public and the environment
- overseeing the daily aspects of the radiation safety program
- acting as the primary contact with the CNSC for licensing and compliance matters
- identifying radiation safety problems
- providing radiation safety advice to workers when requested
- implementing corrective actions
- verifying the implementation and effectiveness of the corrective actions
- ensuring compliance with CNSC regulatory requirements
- reporting regulatory non-compliance to the CNSC
- holding the authority to stop any unsafe work practices and any activity that might result in non-compliance
- developing procedures and policies related to radiation safety and training
- assessing the performance of the RPP and sharing the results with the applicant authority
- acting as the signing authority for CNSC licences

Depending on the structure and size of the licensed organization, an RSO could be designated to oversee RPP management at the corporate level, with assistance from other individuals (site RSOs) who oversee the program onsite to ensure that the RPP is effectively implemented and applied.

Note: All references to “shall” in the following subsections relate to regulatory requirements for applications for nuclear substance and radiation device licences, as outlined in REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices* [1].

#### 3.1 Duties

The RSO shall be given sufficient time to respond to day-to-day situations and to manage the RPP. The applicant authority is accountable for ensuring that the RSO has adequate ability and availability to manage the RPP, and that competing duties or priorities are not adjunct. The

applicant authority should also ensure that the RSO's assigned duties do not create a conflict of interest.

The allocated time will be estimated by the licensee or applicant, taking into consideration the number of workers, the magnitude of operations and the geographic disparity of sites within the organization. It may be necessary to delegate the duties to a full-time RSO to oversee a complex program. For other programs, the RSO could manage the RPP on a part-time basis while assuming other duties. Depending on the organizational size and geographic disparity of sites, additional support may be required, as described in section 3.4.2.

The RSO typically provides day-to-day administrative oversight of radiation safety. As a best practice, the RSO should be provided with a description of duties and the number of hours to be dedicated to them. The ability of the RSO to manage the RPP should be evaluated by the applicant authority at defined intervals, in order to identify where additional time or other assistance is needed.

A non-exhaustive list of examples of duties is provided in appendix A.

### **3.2 Authority of the RSO**

The RSO is responsible for the day-to-day administration and control of the radiation protection program on behalf of the licensee.

In particular, the RSO shall have the necessary authority to:

- implement the RPP
- identify problems or issues that could lead to non-compliance with regulatory requirements
- initiate corrective actions and verify their implementation and effectiveness
- immediately stop any work, task or undertaking that they consider unsafe for workers or that may contravene requirements of the NSCA and its regulations or of the CNSC licence, regardless of the stoppage's potential impact on the organization's operations
- communicate directly with the applicant authority
- act as signing authority on all matters of radiation safety, the CNSC licence and the obligations of the licensee
- implement and enforce any changes to any work, task or undertaking which are necessary to ensure that the licensee remains compliant or returns to compliance
- modify any policy and procedure, and ensure that the changes are properly documented and communicated to workers

### **3.3 Qualifications**

The RSO shall have sufficient knowledge to effectively manage activities with nuclear substances and radiation devices in accordance with the NSCA and its relevant regulations. The details of the RSO's qualifications shall also be included in the licence application, and a copy of the RSO's training course certificate shall be submitted to the CNSC.

The RSO's qualifications could vary according to the responsibilities assigned to the RSO and the complexity of the licensee's use of nuclear substances, but should include knowledge and/or experience related to:

- fundamental radiation protection principles

- radiation safety
- safe use of nuclear substances and radiation devices authorized under the CNSC licence
- dosimetry
- radiation instrumentation
- licensed activities and its conventional hazards
- conditions of the CNSC licence
- applicable CNSC regulatory documents
- CNSC licensing and compliance verification programs
- authorities and responsibilities of the position

Additional knowledge and/or experience, based on the proposed licensed activities, could include:

- source recovery activities, for industrial radiography licences
- transportation of dangerous goods, for those shipping or receiving nuclear substances and radiation devices
- contamination control and spill management techniques, for those using unsealed nuclear substances
- safe management and use of the nuclear substances and radiation devices, including any special considerations (e.g., confined spaces, biohazardous materials)

The CNSC does not endorse or recommend any specific RSO training organization, but offers an online [list of service providers](#) to licensees for information only.

### **3.3.1 Refresher training**

RSOs shall maintain their qualifications by undertaking refresher training. This should include a review of the fundamentals of protection and safety; information on any changes to safety standards, equipment, policies and procedures; and an overview of any changes in regulatory requirements.

Refresher training should be provided at least every 3 to 5 years and when safety issues, or changes to regulatory requirements or licence conditions, occur. Refresher training should also be delivered to RSOs after a long-term absence, such as those listed in section 3.4.1. The frequency and extent of the refresher training should be defined and documented in the RPP.

Licensees or applicants can set the frequency of refresher training to match other mandatory training programs. For example, many CNSC licensees hold refresher training every 3 years, at the same time as Transport Canada's Transportation of Dangerous Goods training.

Refresher training should be determined based on an evaluation of the complexity, importance and frequency of the tasks assigned. A training needs analysis should be conducted when any changes are made to the RSOs' activities or responsibilities.

As part of the refresher training, RSOs should review their knowledge of CNSC regulatory requirements. RSOs should be made aware of any changes to regulatory requirements that may impact the licensed activities authorized under the CNSC licence. More details on radiation safety training programs can be found in appendix A of REGDOC-2.2.2, *Personnel Training* [3].

### **3.4 RSO staffing**

If the RSO cannot be at the site of the licensed activity or reasonably be able to attend to the site of licensed activity, other persons can be assigned RSO duties to ensure continuous oversight of the RPP at the site, such as alternate RSOs, site RSOs or consultants.

Any person replacing or assisting the RSO should have similar levels of training and knowledge on the licensed activities and the regulatory requirements.

#### **3.4.1 Alternate RSO**

An alternate RSO is designated during the RSO's absence, in order to carry on the licensed activities and to ensure continuous oversight of the RPP. The alternate RSO can also be involved with the day-to-day management of the RPP as an assistant to the RSO.

In the case of long-term absences, such as parental leave, extended assignment to other duties, severe illness or injury, the licensee shall notify the CNSC of the replacement. This can be done by completing the [Request to Appoint a Radiation Safety Officer or an Alternate Radiation Safety Officer: Nuclear Substances and Radiation Devices Licence](#) form.

#### **3.4.2 Site RSO**

When an application is submitted to conduct licensed activities in multiple geographical locations, each location should have a site RSO in order to ensure direct oversight of the RPP. The site RSO should maintain a presence in the workplace by periodically observing work practices to implement and manage the RPP. The site RSO can be designated by the RSO.

The site RSO should report to the RSO on all radiation protection matters. The roles and responsibilities and the lines of authority for the site RSO should be clearly defined. It should be clear that the RSO remains the person responsible for managing the overall RPP and is the main liaison with the CNSC.

#### **3.4.3 Consultant**

If there are no qualified or available personnel to assume the role of the RSO, it is acceptable to temporarily contract an independent consultant to serve as the RSO or site RSO. The licensee or applicant shall ensure that the consultant can spend enough time at the licensed location to oversee the RPP, even if that individual is managing several programs simultaneously.

In terms of licensed activities and regulatory requirements, the consultant should have a similar level of knowledge and training that would be expected of an RSO.

It is important to remember that the applicant authority remains accountable for the implementation of the RPP.

## 4. Radiation Protection Program, Policies and Procedures

### 4.1 Developing an RPP

The overall objectives of the RPP are:

- to protect workers, the general public and environment by ensuring that radiation doses are kept as low as reasonably achievable (ALARA)
- to ensure that regulatory requirements and licence conditions are met
- to describe the organizational structure and the roles and responsibilities of management and personnel
- to ensure that proper training and instruction delivered to workers includes:
  - radiation protection
  - knowledge of emergency procedures
  - knowledge on the licensed activities and the regulatory requirements

The RPP is normally developed by the licensee in collaboration with the RSO, specialists and other relevant staff. Licensees or applicants may also involve their occupational health and safety committee, since they play a similar role in the protection of workers and the public. To ensure radiation safety and compliance with the relevant requirements, a typical RPP includes operating policies and procedures that demonstrate its effectiveness and that describe how it will be maintained. Further information can be found in REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices* [1].

The specific details of the RPP are usually documented in a radiation safety manual.

### 4.2 Radiation safety manual

As a good practice, the radiation safety manual should be signed and dated by the RSO and applicant authority to confirm that the published version of the manual was reviewed and approved. It is recommended that the RPP be reviewed periodically and updated as necessary, to reflect any changes to policies, procedures and regulatory requirements. The frequency of reviews should be determined, defined and documented. It is important to note that the licensee is to inform CNSC licensing staff, and to submit any changes to them for review and approval, before implementing the new version of the radiation safety manual. Prior to implementation, the updated version will be referenced on the licence. It is important to ensure that revisions to the radiation safety manual also include documented version control.

Pursuant to section 12 of the *General Nuclear Safety and Control Regulations*, workers shall be informed of all changes and modifications made to any policies and procedures within the radiation safety manual. This can be done through different means, such as training sessions, emails or weekly meetings, as long as this is documented by the licensee to prove that workers have received the updated information. The preferred process to inform workers should be documented in the RPP.

### **4.3 Management system**

A management system is the framework of processes, procedures and practices that enable the organization to complete all work activities to achieve success.

The management system helps define how licensed activities are managed in order to meet objectives and requirements consistently and safely. The RPP should be developed and aligned with management system principles that are incorporated into key management processes.

#### **Management system principles**

##### **a) Safety is the paramount consideration guiding decisions and actions**

Risk and safety are considered in all decision making and actions; this is promoted throughout the organization as a key driver for a healthy safety culture.

##### **b) The licensed activities are defined, planned and controlled**

Objectives and plans are established including all relevant requirements. Risks to objectives are identified and controlled. Results are measured and monitored to ensure that planned results are achieved.

##### **c) The organization is defined and understood**

Authorities, accountabilities, line of communications and responsibilities of positions are communicated and understood by everyone. This is reflected in the organization structure.

##### **d) Resources are managed**

Resources including infrastructure, equipment, tools, material, manpower, competency and qualification of personnel are identified and provided.

##### **e) Communication is effective**

Processes are in place to ensure that workers know what is expected of them, and that they understand the relevance and importance of their work.

##### **f) Information is managed**

Information is provided in a timely manner to those who need it. Documents and records are maintained and controlled.

##### **g) Work is managed**

Work is identified, planned and conducted using controlled documents, software, tools, items, processes and practices. Work is verified to ensure that it is completed correctly.

##### **h) Problems are identified and resolved**

Problems are identified, controlled, documented and evaluated for significance. Corrective actions are reviewed for effectiveness.

**i) Changes are controlled**

Required changes, including those for organization, design, engineering, process and documentation, are identified, justified, controlled and reviewed for effectiveness.

**j) Assessments are performed**

Self-assessments, independent assessments and management review and oversight are conducted to assess that the licensed activities are meeting performance objectives and planned results.

**k) Experience is sought, used and shared**

Lessons learned internally or externally arising from experience gained from problems, events, or improvements, from similar or different activities, are collected, shared and used.

**l) The management system is continually improved**

Management continually improves the management system. This includes resolving problems, learning from assessments and identifying improvement opportunities.

**m) Processes are applied appropriately and there is accountability for the management system**

Management processes are applied to all work associated with licensed activities, including design, procurement, construction, commissioning, operations, maintenance and decommissioning.

Senior management is accountable for the effectiveness and implementation of the management system.

**n) Other**

The management system sets expectations for and supports human performance and safety culture. It does this by providing the mechanisms by which an organization can plan, do, assess and correct its activities to meet requirements and improve on performance (see section 5.1 for more information).

Numerous standards typically refer to core management processes; for example: planning, resource and competency management, document management, change control, work management, corrective actions in case of non-conformance, monitoring and measurement, internal audits and assessments, management review, and continuous improvement.

The following documents contain more information on management systems:

- REGDOC-2.1.1, *Management System* [4], provides information on management system principles.
- CSA N286-12, *Management System Requirements for Nuclear Facilities* [5], describes the generic requirements for each of the principles.

#### **4.4 Policies and procedures**

The RPP includes procedures that inform and direct persons who use or oversee the use of nuclear substances and radiation devices. Depending on the complexity and risk inherent in the RPP and the organization's structure, the policies and procedures can be submitted to the radiation safety committee (RSC) for review and/or approval before implementation. Further information on the RSC can be found in appendix B.

For good practices in writing technical procedures, see:

- *Procedure Writers' Manual* [6]
- *Procedure Process Description* [7]
- *Guidance for Preparing Standard Operating Procedures* [8]

### **5. Implementing the Radiation Protection Program**

In addition to the access to resources, communications are key to effectively implementing the RPP, ensuring safety and meeting regulatory requirements. The applicant authority should transmit information coming from management to the RSO and to workers. Workers and the RSO should also be able to communicate to management through the applicant authority.

For successful implementation of the RPP, workers and management should have access to the RPP, understand its implications and be able to communicate when changes are required.

As described in the following section, safety culture is supported by ensuring the implementation and oversight of radiation safety, by minimizing the likelihood of safety-related events and by mitigating the potential impact of such events.

#### **5.1 Fostering a healthy safety culture**

An organization that actively fosters a healthy safety culture can have a powerful influence on employee attitudes and behaviours, and maintaining the safety of workers, the public and the environment.

As described in REGDOC-2.1.2, *Safety Culture* [9], the CNSC defines safety culture as the characteristics of the work environment, such as the values, rules, and common understandings that influence workers' perceptions and attitudes about the importance that the organization places on safety.

A healthy safety culture evolves from the development and application of a questioning attitude at all levels of the organization. Understanding an organization's safety culture, as well as perceptions and attitudes of both workers and management, is vital to maintaining and improving radiation safety. This relies equally on the shared commitment of the applicant authority, RSOs and workers to promote, foster and sustain that culture.

Licenseses or applicants may foster a healthy safety culture by:

- promoting the commitment to protection and safety at all levels of the organization
- ensuring a common understanding of the key principles of the safety culture within the organization

- providing the means by which the organization supports individuals and teams in carrying out their tasks safely and effectively, taking into account the interactions between individuals, technology and the organization
- providing a safe work environment that enables reporting without fear of reprisal
- encouraging workers to participate in the development and implementation of policies, rules and procedures that deal with protection and safety
- ensuring the accountability of the organization and of individuals at all levels for protection and safety
- encouraging open communication about protection and safety within the organization and other relevant parties
- encouraging a questioning attitude to challenge prevailing assumptions with respect to the planning and execution of work
- providing the means by which the organization continually seeks to better understand, develop and strengthen its safety culture

Information and guidance on how to assess and improve safety culture can be found in REGDOC-2.1.2, *Safety Culture* [9].

## 6. Assessing the Radiation Protection Program

As stated in section 3 of the *Nuclear Substances and Radiation Devices Regulations*, the RPP shall include means to periodically assess the performance of the program. This may be performed through self-assessments, independent assessments or management reviews. The RPP should define the type(s) of assessment(s) to perform, the frequency and the method(s) to be used. **Note:** An inspection performed by a CNSC inspector is not considered an assessment activity.

The results of these assessments should be documented and shared with the applicant authority and with the RSC, if one has been established. A follow-up of the deficiencies identified and their corrective actions should be conducted to ensure the items of non-compliance are properly resolved and verified for effective implementation.

Assessments ensure that the RPP is adequate, effective, up to date and implemented in accordance with the ALARA principle. The information collected during assessments may be used to improve any weaknesses identified for continuous improvement.

Although the RPP should be reviewed at least every five years, the frequency of the assessments will depend on the complexity of the RPP and the risk associated with the licensed activity. The frequency and the chosen method(s) should be defined and documented in the RPP. The basis of the assessments may need to be expanded to account for different use types, associated hazards and mitigating controls. The RPP should be reviewed following changes in operations or regulatory requirements.

These assessments can be carried out using checklists, document reviews, observations of actual work being performed against procedures and staff interviews.

### 6.1 Self-assessments

Self-assessments are conducted periodically by all levels of management in their areas of responsibility (e.g., RSOs, site RSOs, site representatives, coordinators, supervisors, managers, etc.). These assessments are performed to evaluate work or processes, to identify opportunities for

improvement, and to confirm that the work being performed that has an impact on the licensed activities is meeting RPP requirements. Self-assessments are less stringent than independent assessments and may be informal, planned, unplanned or ad hoc when deemed necessary.

Self-assessments are important in evaluating the implementation and effectiveness of the RPP. They can be done through management walk-arounds; observation of the work being performed to ensure they are aligned with procedures and training; periodic meetings; or use of checklists, internal audits or inspections. Self-assessments of the RPP are generally conducted by the site RSO to assess the work practices against requirements established in the RPP and to identify opportunities for improvement.

The RPP should describe the self-assessment methods used and when it should take place. Self-assessment results may be used as inputs for the independent assessments.

The list of examples of [Type II inspection worksheets](#) on the CNSC's website can be useful when developing a self-assessment policy and procedure.

## **6.2 Independent assessments**

Independent assessments, which may also be referred to as internal or external audits, are planned and carried out at set frequencies by qualified auditors, on behalf of the applicant authority or top management. The primary objective of the independent assessment of radiation safety is to confirm that the documented RPP meets the requirements and that its implementation is effective.

The RPP should describe the frequency of the independent assessments and describe the elements that will be assessed. The frequency should be determined based on the complexity of the licensed activities and the results of previous assessments, with specific regard to deficiencies identified. Based on best practices, independent assessments should be performed at least annually, or in response to significant changes in the organization's licensed activities, following identification of weaknesses in safety, or after substantive changes to work practices have been implemented.

The personnel performing the assessment should not have been involved in any aspects of the work, processes or topic being audited. The assessments can be completed by someone internal or external to the organization, but are generally conducted by the corporate RSO, alternate RSO or site RSOs.

The results of self-assessments and independent assessments are reported to the applicant authority, RSC or to the management level with authority and accountability to resolve noted deficiencies.

## **6.3 Management reviews**

Management reviews are conducted by the applicant authority at a set frequency as an oversight activity, to assess the effectiveness of the RPP and to proactively make improvements as required.

The frequency of management reviews should be defined in the RPP and should be based on the complexity of the licensed activities, changes to the licensed activities or as a result of event investigations.

The results of self-assessments and independent assessments should form the basis for decisions and actions at management review meetings. Management reviews should be documented and communicated to the appropriate management and staff, and to the RSC if there is one in place. Problems identified should be tracked and the appropriate corrective actions for follow-up should be established, as described in the RPP.

The CAN/CSA- ISO 9001: 16, *Quality Management Systems – Requirements* [10], can be useful guidelines to follow for conducting management review.

## **Appendix A: Examples of RSO Duties**

The duties of the RSO may vary depending on the licensed activity. The following list includes examples of tasks that may be required of the RSO, in collaboration with the applicant authority and workers, and is organized by safety and control area (SCA). SCAs are the technical topics used by the CNSC to assess, review, verify and report on regulatory requirements and performance across all regulated facilities and activities.

### **Conventional health and safety**

This SCA covers the implementation of a program to manage workplace safety hazards and to protect workers.

- Stop unsafe work practices.
- Take into consideration all health and safety hazards that may be present where the licensed activity is conducted.

### **Emergency management and fire protection**

This SCA covers emergency plans and emergency preparedness programs for emergencies and for non-routine conditions. It also includes any results of participation in emergency exercises.

- Coordinate or participate in emergency responses to events involving nuclear substances and radiation devices.
- Investigate all unusual occurrences, determine the cause, identify corrective actions and implement such actions.

### **Environmental protection**

This SCA covers programs that identify, control and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities.

- Determine whether additional measures are required due to a release of nuclear substances into the environment.

### **Fitness for service**

This SCA covers activities that impact the physical condition of structures, systems and components to ensure that they remain effective over time. This includes programs that ensure all equipment is available to perform its intended design function when called upon to do so.

- Ensure that sealed sources are leak tested at the required frequency and in accordance with the regulatory requirements.
- Ensure that radiation-monitoring instruments are calibrated in accordance with the regulatory requirements.
- Maintain a sufficient supply of radiation monitoring instruments that are capable of detecting the nuclear substances in use.

### **Human performance management**

This SCA covers activities that enable effective human performance through the development and implementation of processes that ensure that a sufficient number of licensee personnel are in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.

- Ensure that workers who are required to use nuclear substances and radiation devices are adequately trained in radiation safety and radiation protection procedures.
- Authorize qualified workers to use nuclear substances or radiation devices.
- Ensure that the certification of exposure device operators is valid.
- Ensure that auxiliary personnel (e.g., clerical, janitorial, security) whose duties may occasionally expose them to nuclear substances and radiation devices receive appropriate training in radiation safety.
- Provide refresher training.

### **Management system**

This SCA covers the framework that establishes the processes and programs required to ensure an organization achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture.

- Ensure that the licensed activity complies with regulatory requirements.
- Ensure that all records and reports are prepared, maintained and submitted in accordance with licence conditions and regulatory requirements.
- Propose or initiate any revisions to policies or procedures and changes to equipment or room design, and submit licence amendments, as required.
- Prepare and implement corrective actions to address any deficiencies identified.
- Conduct assessments of the RPP.

### **Operating performance**

This SCA includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.

- Monitor, and advise and consult on issues related to the handling of nuclear substances and radiation devices in accordance with licence conditions and regulatory requirements.
- Develop, implement and assess an RPP that is consistent with the scope of the licensed activities to ensure compliance with regulatory requirements.
- Review requests for authorization to purchase or use nuclear substances and radiation devices, in order to ensure that the proposed handling and location of storage are acceptable and comply with the RPP, licence conditions and regulatory requirements.
- Develop and implement programs to inspect and review licensed activities, the locations of nuclear substance and radiation devices and the adequacy of worker training, safety procedures and the work environment.
- Investigate all reports of overexposure to ionizing radiation, as well as accidents and losses involving nuclear substances and radiation devices, determine pertinent facts or confirm events, and recommend appropriate actions to mitigate the consequences or prevent recurrences.
- Ensure that the events and the results of related investigations are reported to the CNSC and other relevant authorities in accordance with licence conditions and regulatory requirements.

- Maintain a presence in the workplace by periodically observing work to promote good work practices and prevent non-compliance.
- Administer or control the distribution, use and maintenance of personnel radiation monitoring equipment.
- Maintain open communication with all workers and management.
- Act on behalf of the licensee in communicating with the CNSC.
- Advise workers on decontamination methods and techniques.

### **Packaging and transport**

This SCA covers programs for the safe packaging and transport of nuclear substances to and from the licensed facility.

- Ensure that packaging and transport of nuclear substances and radiation devices comply with the *Packaging and Transport of Nuclear Substances Regulations, 2015*

### **Physical design**

This SCA relates to activities that impact the ability of structures, systems and components to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account.

- Ensure that a design assessment form is submitted and approved for each room, area or enclosure in which nuclear substances and radiation devices will be used or stored.

### **Radiation protection**

This SCA covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations*. The program shall ensure that contamination levels and radiation doses received by individuals are monitored, controlled and maintained ALARA.

- Provide appropriate personal radiation detection equipment to workers.
- Design and implement appropriate personnel monitoring programs.
- Review the occupational radiation exposures of workers.
- Recommend measures to reduce occupational radiation exposures in accordance with ALARA.
- Provide information to nuclear energy workers in accordance with the *Radiation Protection Regulations*.
- Design and implement a radiation survey and contamination monitoring program, and assess the results.
- Establish internal administrative and action levels.

### **Safeguards and non-proliferation**

This SCA covers the programs and activities required for the successful implementation of the obligations arising from the Canada/International Atomic Energy Agency (IAEA) safeguards agreements, as well as all other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.

- Ensure compliance with the regulatory requirements for safeguards and non-proliferation.

**Safety analysis**

This SCA includes maintenance of the safety analysis that supports the overall safety case for the facility. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and considers the effectiveness of preventive measures and strategies in reducing the effects of such hazards.

- Evaluate potential hazards and preventive measures.
- Manage safety issues (including research and development programs).

**Security**

This SCA covers the programs required to implement and support the security requirements.

- ensure that measures are in place for the physical security of sealed and unsealed sources
- ensure appropriate access control measures are in place for designated areas
- maintain and submit information to update the Sealed Source Tracking System

**Waste management**

This SCA covers internal waste-related programs that form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. This area also covers the planning for decommissioning.

- Arrange for the safe storage of nuclear substances and radiation devices.
- Ensure the safe handling and disposal of any radioactive waste in compliance with the local, provincial and federal authorities.
- Provide support in decommissioning tasks.

## Appendix B: Radiation Safety Committee

Licenseses and applicants with complex programs are advised to establish a radiation safety committee (RSC), which may have corporate responsibilities for radiation safety, or it may simply have an advisory or evaluation role. The information in this appendix should be considered when developing a complex RPP with an RSC.

### B.1 Role and Responsibilities

The RSC may be tasked with providing advice or direction on radiation safety matters and with ensuring the implementation and oversight of the RPP. Such committees are usually established or retained with the approval of the applicant authority. The RSC should work in collaboration with the health and safety committee.

The RSC works with the applicant authority and the RSO to define, plan and control the implementation of the RPP, in order to ensure that the RPP is aligned and integrated with the core business objectives of the licensed activity. As such, the RSC should be involved in establishing policies and procedures for managing the RPP. The role of the RSC may include the following:

1. overseeing the RPP and radiation safety matters
2. advising on radiation safety matters, including the safe use of nuclear substances and radiation devices during licensed activities
3. ensuring that radiation exposures for all nuclear energy workers and general public are maintained as low as reasonably achievable
4. review proposed uses of nuclear substances and radiation devices and determine whether they comply with the RPP and regulatory requirements
5. assessing the adequacy and the effectiveness of the training programs
6. reviewing the results of RPP assessments
7. discussing positive and negative operational experiences to determine where improvement is needed
8. reviewing any reports concerning events or unusual occurrences
9. recommending corrective measures or improvements when the review or assessment identifies deficiencies
10. recommending measures or improvements to prevent the reoccurrence of any events
11. advising the applicant authority of any need for additional resources to establish, maintain or improve the RPP

The RSC should maintain written records of its meetings, as detailed in section B.4.

### B.2 Membership

RSCs should include members selected or appointed because of their expertise or involvement in radiation safety matters. Collectively, these members should advise their managers and RSOs on radiation safety matters in general and on the RPP effectiveness within the organization in particular. RSC members may participate on a full-time or part-time basis.

The RSC should comprise members from multiple disciplines. An RSC should include at least the RSO and site RSOs, an authorized user from each type of licensed activity, a representative of the auxiliary personnel (e.g., clerical, janitorial, security), a representative of the nursing service where applicable (therapeutic nuclear medicine licence) and a management representative. The RSC may also include physicians, physicists, and corporate interest group representatives such as managers (senior staff

members), workers or specific user units. It should also include a representative of the health and safety committee. Every department with employees who receive occupational doses or that has an impact on radiation exposure or safety should also be represented.

When selecting a chairperson for the committee, several factors should be considered, such as knowledge of radiation safety and leadership abilities. The chairperson should have sufficient time to devote to this position in addition to other responsibilities. In general, the RSO should not be appointed chairperson of the RSC, since this person is responsible for the day-to-day oversight of the RPP and may be too closely involved in the licensed activities to be objective.

The RSO's participation is essential, as is that of a site RSO from each authorized location. Any decision made by the RSC should be communicated to the applicant authority before being carried out.

### **B.3 Terms of Reference**

The RSC's terms of reference depend on individual circumstances, such as management decisions, procedures, available resources, licence requirements and the magnitude, diversity or complexity of the licensed activities. The terms of reference should contain the following:

1. decision-making system
2. quorum requirements
3. membership
4. roles and responsibilities (refer to section B.1)
5. members' roles and responsibilities
6. meeting agenda items
7. meeting frequency
8. examples of circumstances leading to non-routine meetings

The terms of reference should be part of the RPP.

### **B.4 Meetings**

Meetings are vital to the effective functioning of the RSC and its ability to provide oversight on matters pertinent to radiation safety. They are necessary for decision making, problem solving, discussion of issues, and review and approval of policies and procedures that form the radiation safety program. The RSC should meet as necessary, but at least annually

A quorum should ensure a minimum participation. Quorum can be a majority, but has to be defined according to the committee's needs and purposes.

Written minutes and any associated actions should be maintained for future reference and circulated to all RSC members. Minutes should include the meeting date, the members present and absent to demonstrate that quorum was respected, and a summary of discussions, recommendations and any decisions made during the meeting.

The RSC relies on the RSO's experience with the details of the RPP and applicable regulatory requirements, as members may not have the same level radiation safety knowledge.

## 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

The CNSC may include references to information on best practices and standards such as those published by CSA Group. With permission of the publisher, CSA Group, all nuclear-related CSA standards may be viewed at no cost through the CNSC Web page “[How to gain free access to all nuclear-related CSA standards](#)”.

1. Canadian Nuclear Safety Commission (CNSC), [REGDOC-1.6.1, Licence Application Guide: Nuclear Substances and Radiation Devices](#), Ottawa, Canada, 2017.
2. CNSC, [Welcome Package: Applicant Authority, Nuclear Substances and Radiation Devices Licences](#), Ottawa, Canada, 2020.
3. CNSC, [REGDOC-2.2.2, Personnel Training](#), Ottawa, Canada, 2016.
4. CNSC, [REGDOC-2.1.1, Management System](#), Ottawa, Canada, 2019.
5. CSA Group, CSA N286-12, [Management System Requirements for Nuclear Facilities](#), Mississauga, Canada, 2012.
6. Procedure Professionals Association (PPA), [Procedure Writers' Manual](#), PPA AP-907-005, USA, 2016.
7. PPA, [Procedure Process Description](#), PPA AP-907-001, USA, 2016.
8. United States Environmental Protection Agency, [Guidance for Preparing Standard Operating Procedures](#), EPA QA/G-6, USA, 2001.
9. CNSC, [REGDOC-2.1.2, Safety Culture](#), Ottawa, Canada, 2018.
10. International Organization for Standardization, [ISO 9001: 2015, Quality management systems - Requirements](#), 2015.

## CNSC Regulatory Document Series

Facilities and activities within the nuclear sector in Canada are regulated by the 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.

CNSC regulatory documents are classified under the following categories and series:

### 1.0 Regulated facilities and activities

- Series
- 1.1 Reactor facilities
  - 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
  - 2.2 Human performance management
  - 2.3 Operating performance
  - 2.4 Safety analysis
  - 2.5 Physical design
  - 2.6 Fitness for service
  - 2.7 Radiation protection
  - 2.8 Conventional health and safety
  - 2.9 Environmental protection
  - 2.10 Emergency management and fire protection
  - 2.11 Waste management
  - 2.12 Security
  - 2.13 Safeguards and non-proliferation
  - 2.14 Packaging and transport

### 3.0 Other regulatory areas

- Series
- 3.1 Reporting requirements
  - 3.2 Public and Indigenous engagement
  - 3.3 Financial guarantees
  - 3.4 Commission proceedings
  - 3.5 CNSC processes and practices
  - 3.6 Glossary of CNSC terminology

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