



# Environmental Protection **Controlling Releases to the Environment**

---

REGDOC-2.9.2

March 2024



## **Environmental Protection: Controlling Releases to the Environment**

Regulatory document REGDOC-2.9.2

© His Majesty the King in Right of Canada, as represented by the Minister of Natural Resources, 2024

Cat. No. CC172-255/2024E-PDF

ISBN 978-0-660-70695-5

Extracts from this document may be reproduced for individual use without permission provided the source is fully acknowledged. However, reproduction in whole or in part for purposes of resale or redistribution requires prior written permission from the Canadian Nuclear Safety Commission (CNSC).

*Également publié en français sous le titre : Contrôle des rejets dans l'environnement*

### **Document availability**

This document can be viewed on the [CNSC website](#). To request a copy of the document in English or French, please contact:

Canadian Nuclear Safety Commission  
280 Slater Street  
P.O. Box 1046, Station B  
Ottawa, Ontario K1P 5S9  
Canada

Tel.: 613-995-5894 or 1-800-668-5284 (in Canada only)

Fax: 613-995-5086

Email: [cnscccsn@canada.ca](mailto:cnscccsn@canada.ca)

Website: [cnscccsn.gc.ca/](http://cnscccsn.gc.ca/)

Facebook: [facebook.com/CanadianNuclearSafetyCommission](https://facebook.com/CanadianNuclearSafetyCommission)

YouTube: [youtube.com/cnscccsn](https://youtube.com/cnscccsn)

Twitter: [@CNSC\\_CCSN](https://twitter.com/CNSC_CCSN)

LinkedIn: [linkedin.com/company/cnscccsn](https://linkedin.com/company/cnscccsn)

### **Publishing history**

March 2024

Version 1.0

## Preface

This regulatory document is part of the CNSC’s environmental protection series of regulatory documents, which also covers environmental principles, assessments, and protection measures. The full list of regulatory document series is included at the end of this document and can also be found on the [CNSC website](#).

Regulatory document REGDOC-2.9.2, *Controlling Releases to the Environment*, clarifies the CNSC’s requirements and provides guidance for controlling releases to the environment, through:

- applying the concept of best available technology and techniques economically achievable
- establishing and implementing licensed release limits and action levels for releases to the environment
- commissioning a treatment system and confirming system performance
- implementing adaptive management where required

This is the first published version of this regulatory document. It is meant to be used in conjunction with REGDOC-2.9.1, *Environmental Principles, Assessments and Protection Measures*.

These requirements and guidance apply to licence applications for proposed new nuclear facilities or activities and applications for licence renewals and amendments. This document will also be used to assess a licensee’s environmental protection measures when a potential for unreasonable risk has been identified and adaptive management is required.

Early engagement with CNSC staff is encouraged for facilities or activities with potential interactions with the environment or where there is uncertainty regarding the potential for interaction with the environment. CNSC staff can provide facility- or activity-specific guidance to assist applicants and licensees.

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 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.....	3
1.4	National and international standards.....	4
1.5	CNSC contact information.....	4
<b>2.</b>	<b>Background .....</b>	<b>5</b>
2.1	Tiered approach to regulation of releases .....	5
2.1.1	Overview of licensed release limits .....	6
2.1.2	Overview of action levels .....	6
2.1.3	Overview of upper value of normal operation .....	7
<b>3.</b>	<b>Environmental Control Measures .....</b>	<b>9</b>
3.1	Controlling releases to the environment (from all facilities and activities).....	14
3.2	New facility or activity, or existing facility or activity undergoing a major modification.....	15
3.3	Existing facility or activity under normal operation .....	15
<b>4.</b>	<b>Best Available Technology and Techniques Economically Achievable .....</b>	<b>17</b>
4.1	Requirements for conducting a BATEA assessment .....	17
4.2	Required elements of a BATEA assessment .....	17
4.3	Guidance for a BATEA assessment.....	18
4.3.1	Documentation of the BATEA assessment and results .....	20
<b>5.</b>	<b>Licensed Release Limits .....</b>	<b>22</b>
5.1	Requirements for establishing and documenting proposed release limits .....	23
5.2	Requirements for responding to licensed release limit exceedances .....	28
5.3	Requirements for revising licensed release limits.....	29
<b>6.</b>	<b>Action Levels for Environmental Protection.....</b>	<b>30</b>
6.1	Requirements for setting action levels.....	30
6.1.1	Contaminants and physical stressors .....	30
6.1.2	Other environmental controls .....	31
6.1.3	Documenting development of action levels.....	31
6.2	Requirements for responding to action level exceedances .....	31
6.3	Guidance for action levels .....	31

<b>7.</b>	<b>Commissioning a Treatment System.....</b>	<b>32</b>
<b>8.</b>	<b>Adaptive Management.....</b>	<b>34</b>
8.1	Requirements for adaptive management.....	34
8.2	Guidance for adaptive management.....	35
8.2.1	Components of an adaptive management plan .....	35
8.2.2	Components of an interim pollution prevention plan .....	35
<b>Appendix A: Role of Clearance Levels in the Graded Approach to the Application of the Environmental Protection Framework.....</b>		<b>36</b>
A.1	Basis for the calculation of generic conditional clearance levels .....	38
<b>Appendix B: Additional Information.....</b>		<b>47</b>
B.1	Optimization of Protection and Pollution Prevention.....	47
B.2	Environmental release targets, maximum predicted design release characteristics, licensed release limits, and action levels .....	49
<b>Appendix C: Establishing Environment Release Targets.....</b>		<b>52</b>
C.1	Introduction.....	52
C.2	Overview of the process .....	52
C.3	Identify final release points.....	53
C.4	Identify contaminants and physical stressors that require control .....	53
C.5	Calculate the proposed environmental release target.....	53
C.5.1	Exposure-based approach for nuclear substances.....	53
C.5.2	Exposure-based approach for hazardous substances .....	54
C.5.2.1	Dilution Factors .....	55
C.5.2.2	Releases to sewer.....	55
C.5.2.3	Releases into cooling water discharge.....	56
C.5.2.4	Example calculations of exposure-based environmental release targets for hazardous substances released to surface water using a simple mixing zone approach.....	56
C.5.3	Technology-based approach .....	57
C.6	Select the most restrictive environmental release targets .....	57
C.7	Document and justify the selection.....	57
<b>Appendix D: Guidance on Developing a Commissioning Plan and on Confirming Performance of a Treatment System.....</b>		<b>58</b>
D.1	Additional guidance for developing a commissioning plan for a treatment system .....	58
D.2	Additional guidance for confirming performance of the treatment system .....	60

**Glossary ..... 62**

**References..... 63**

**Additional Information ..... 65**

# Controlling Releases to the Environment

## 1. Introduction

### 1.1 Purpose

For nuclear facilities and activities, environmental protection is done in accordance with the *Nuclear Safety and Control Act* (NSCA) and the regulations made under it. The legislation includes provisions to ensure that licensees are meeting the CNSC's mandate to protect health, safety and security and the environment. Under the NSCA and its regulations, licensees are required to take all reasonable precautions to control the release of nuclear and hazardous substances to the environment from licensed facilities or activities.

As part of an application for a licence to construct, operate or decommission a nuclear facility, applicants and licensees are required to assess the effects on the environment and the health and safety of persons, and identify prevention or mitigation measures. In addition, the application must identify the:

- proposed location(s) of releases
- proposed maximum quantities and concentrations
- anticipated volume and flow rate of releases of nuclear and hazardous substances into the environment
- proposed measures to control releases of nuclear substances and hazardous substances into the environment

This regulatory document describes the requirements and guidance for controlling releases to the environment, through:

- applying the concept of best available technology and techniques economically achievable (BATEA)
- implementing licensed release limits and action levels for releases to the environment
- commissioning a treatment system and confirming performance
- implementing adaptive management where required

### 1.2 Scope

This document applies to nuclear facilities or activities that, under normal operation, release or are anticipated to release nuclear or hazardous substances to the environment. It applies to nuclear and / or hazardous substances directly released to air, surface water, sewer, or through the ground, including where natural or engineered barriers for control are proposed or incorporated. This regulatory document also applies to refurbishment and decommissioning facilities, and the normal operation of any treatment system(s) during refurbishment and decommissioning.

This document is meant to be used in conjunction with REGDOC-2.9.1, *Environmental Principles, Assessments and Protection Measures* [1], which provides requirements and guidance for developing and implementing environmental protection measures to monitor and control releases to the environment, to perform an environmental risk assessment, and to develop and implement an environmental management system. This regulatory document provides requirements and guidance for additional environmental protection measures (such as action levels and licensed release limits) that are related to, affected by, and influence the environmental protection measures described in REGDOC-2.9.1 [1].

Applicants and licensees are expected to use these documents to develop or revise their environmental protection measures, or to develop additional environmental protection measures when adaptive management is required.

The CSA Group standards that are referenced in this regulatory document apply to Class I nuclear facilities and uranium mines and mills. For facilities or activities other than Class I nuclear facilities and uranium mines and mills, the CNSC reviews every licence application to verify that there are no significant interactions with the environment. If the CNSC's review of the application determines that the facility or activity would not interact with the environment, then only the CNSC's guiding principles for environmental protection (see REGDOC-2.9.1 [1]) are relevant as guidance for such facilities or activities.

For licence applications other than a Class I nuclear facility or uranium mine and mill, if the CNSC's review determines that the facility or activity has potential interactions with the environment and that additional consideration is warranted, the information in this document may be applied in a graded manner. The applicant or licensee may demonstrate that it meets the intent of this regulatory document as follows:

- for the control of nuclear substances, by comparing the proposed maximum quantities and concentrations to be released to the environment associated with the design of the facility or activity under normal operation:
  - to the exemption criteria or unconditional clearance levels specified under the *Nuclear Substances and Radiation Devices Regulations*, or
  - to the generic conditional clearance levels (CCLs) specified in appendix A:
    - for any radionuclide that exceeds the generic CCLs, the CNSC may establish practice-specific CCLs that are applicable to the type of facility or activity
    - for any radionuclide where the proposed maximum release is below the applicable CCLs (either generic or practice-specific), the CCLs are applied as the licensed release limits
    - for any radionuclide where the proposed maximum release exceeds the CCLs (generic or practice-specific), the balance of information in this document shall be applied
- for the control of hazardous substances, by comparing the proposed maximum quantities and concentrations to be released to the environment associated with the design of the facility or activity under normal operation:
  - to federal, provincial, territorial, or municipal environmental quality guidelines
  - where any proposed maximum release exceeds the environmental quality guidelines, the balance of information in this document shall be applied

Early engagement with CNSC staff is encouraged for facilities or activities with potential interactions with the environment or where there is uncertainty regarding the potential for interactions with the environment. CNSC staff can provide facility- or activity-specific guidance to assist applicants and licensees.

This regulatory document does not address the management of spills, fugitive emissions or uncontrolled releases.

The intent of this document is to not replace nor duplicate requirements in other federal, provincial, territorial, or municipal legislation. Meeting these other legislative requirements may be adequate for addressing the requirements of this regulatory document. In many instances, this regulatory document provides requirements and guidance to reduce regulatory duplication, where



possible, while continuing to apply the CNSC's mandate under the NSCA to ensure the control of the release of nuclear and hazardous substances.

### 1.3 Relevant legislation

The following provisions of the NSCA and the regulations made under it are relevant to this document:

- NSCA:
  - subsection 24(4)
  - subsection 24(5)
- *General Nuclear Safety and Control Regulations*:
  - paragraph 3(1)(f)
  - paragraphs 12(1)(c) and (f)
- *Class I Nuclear Facilities Regulations*:
  - paragraphs 3(e), (g), (h) and (j)
  - paragraphs 4(b), (c) and (e)
  - paragraphs 5(b), (i), (j) and (k)
  - paragraphs 6(h), (i), (j) and (k)
  - paragraphs 7(e), (f), (g), (h), (i) and (k)
  - paragraph 8(b)
- *Class II Nuclear Facilities and Prescribed Equipment Regulations*:
  - paragraph 3(p)
  - paragraphs 5(e), (f), (h) and (i)
- *Radiation Protection Regulations*:
  - paragraphs 4(a) and (b)
  - subsections 6(1) and (2)
  - subsection 13(1)
- *Nuclear Substances and Radiation Devices Regulations*:
  - paragraphs 3(1)(b), (g) and (i)
  - paragraph 12(1)(k)
- *Uranium Mines and Mills Regulations*:
  - subparagraph 3(a)(v)
  - subparagraphs 3(c)(ii), (iii), (v), (vi), (vii), (viii), (ix) and (x)
  - subparagraphs 3(d)(i) and (vi)
  - subparagraphs 4(1) and (2)

The CNSC also considers pertinent legislation from other government departments, including:

- *Impact Assessment Act*
- *Canadian Environmental Assessment Act, 2012*
- *Canadian Environmental Protection Act, 1999*
- *Fisheries Act*
- *Species at Risk Act*
- *Migratory Birds Convention Act, 1994*

## 1.4 National and international standards

Key principles and elements used in developing this document are consistent with national and international standards.

The following standards from CSA Group are relevant to this regulatory document:

- CAN/CSA ISO-14001, *Environmental Management Systems – Requirements with Guidance for Use* (2004 edition or successor editions)
- CSA N288.0, *Environmental management of nuclear facilities: Common requirements of the CSA N288 series Standards*
- CSA N288.1, *Guidelines for modelling radionuclide environmental transport, fate, and exposure associated with the normal operation of nuclear facilities* [2]
- CSA N288.3.4, *Performance testing of nuclear air-cleaning systems at nuclear facilities* [3]
- CSA N288.4, *Environmental monitoring programs at Class I nuclear facilities and uranium mines and mills*
- CSA N288.5, *Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills* [4]
- CSA N288.6, *Environmental risk assessment at Class I nuclear facilities and uranium mines and mills* [5]
- CSA N288.7, *Groundwater protection programs at Class I nuclear facilities and uranium mines and mills* [6]
- CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities* [7]

The International Atomic Energy Agency (IAEA) general safety guide GSG-9, *Regulatory Control of Radioactive Discharges to the Environment* [21], is also relevant to this regulatory document.

## 1.5 CNSC contact information

The applicant or licensee should engage with CNSC staff early in the planning process (before submission of a licence application) to identify the applicable regulatory documents and confirm an understanding of the CNSC's licensing process. To contact the CNSC, refer to the [CNSC's website](#).

## 2. Background

The CNSC requires the environmental effects of all nuclear facilities or activities to be considered and evaluated when licensing decisions are made. REGDOC-2.9.1, *Environmental Principles, Assessments and Protection Measures* [1], documents the environmental protection requirements along with additional guidance for a licensee’s overall environmental protection program. This regulatory document focuses on controlling releases to the environment under normal operations.

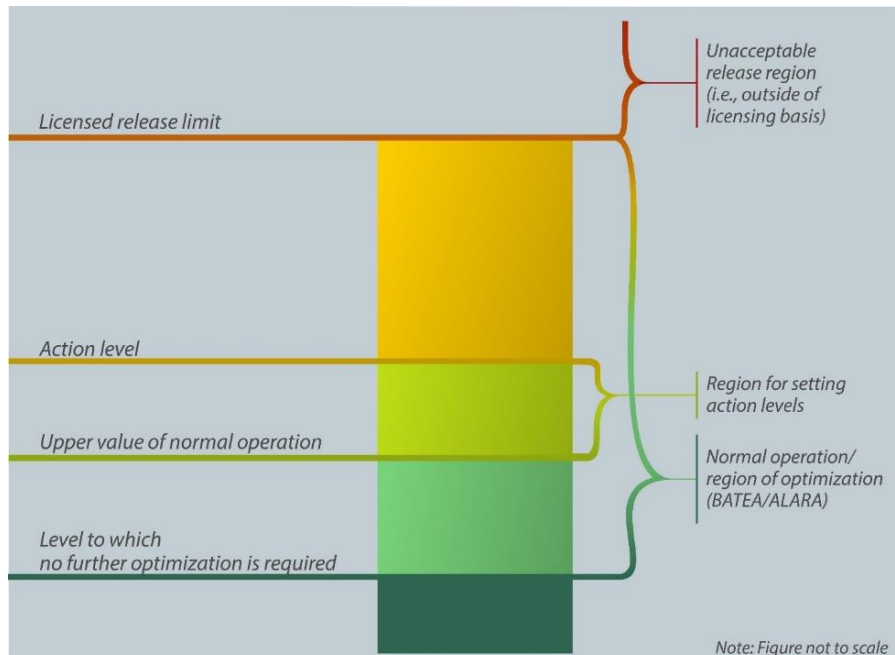
Paragraph 12(1)(f) of the *General Nuclear Safety and Control Regulations*, deals with “reasonable precautions” regarding control of releases. REGDOC-2.9.1 [1] specifies that reasonable precaution in the context of controlling releases involves the application of best available technology and techniques economically achievable (BATEA), and the application of the as low as reasonably achievable (ALARA) principle. Licensees are required to control releases to limits specified within regulation and demonstrate the application of BATEA and ALARA. Hereafter, the term BATEA is used when referring to both nuclear and hazardous substances, and the term ALARA is used when referring solely to nuclear substances. For requirements and guidance associated with the application of BATEA see section 4.

### 2.1 Tiered approach to regulation of releases

A tiered approach has been established to ensure the protection of human health and the environment, and to demonstrate pollution prevention through the application of BATEA. The tiers are substance-specific and consist of the licensed release limits, action levels, the upper values of normal operation and the clearance level (where no further optimization is required).

Figure 1 is conceptual and not necessarily to scale. The actual range between the values depends on the site-specific design and operation of the facility or activity, and on the expected variability in effluent and/or emission quality under normal operations.

**Figure 1: Conceptual relationship between an upper value of normal operation for a nuclear or hazardous substance, an action level, and a licensed release limit.**



The CNSC uses regulatory instruments, such as licensed release limits and action levels, to monitor whether the licensee is operating within its licensing basis.

### 2.1.1 Overview of licensed release limits

As part of the CNSC's regulatory framework, licensed limits may be applied to different safety and control area programs and/or control measures. A licensed limit is part of the licensing basis and, if exceeded, represents a loss of control of part of the licensee's program(s) or control measure(s). Exceeding a licensed limit indicates that the licensee is operating outside their licensing basis for normal operation, but does not necessarily imply an unreasonable risk to the environment, to the health and safety of persons or to national security. Exceeding a licensed limit is a non-compliance and triggers a requirement for the licensee to take specific action.

**Note:** The licensed limits may include any limits specified in the licensing basis.

Licensed release limits are a subset of licensed limits, that are specific to releases to the environment, and are part of the licensing basis. If these limits are exceeded, this represents a loss of control of part of the licensee's environmental protection program(s) or control measure(s). Exceeding a licensed release (that is, a red light) limit indicates that the licensee is operating outside their licensing basis for normal operation, and represents a clear loss of control of the environmental protection program and/or control measure(s). A release outside of the licensing basis indicates a major failure of control systems and is subject to enforcement action. It does not necessarily imply an unreasonable risk to the environment or to the health and safety of persons. Exceeding a licensed release limit is a non-compliance and triggers a requirement for the licensee to take specific action.

Implementing licensed release limits ensures that:

- human health and the environment are protected
- the licensee applies appropriate control measures (including abatement strategies) for pollution prevention, demonstrating optimization through the application of BATEA and ALARA
- the licensee is operating within the licensing basis for normal operation

The applicant or licensee proposes release limits as part of the licence application. When approved by the CNSC, these become licensed release limits and form part of the licensing basis for the facility or activity. Since licensed release limits are based on either the accepted design of the facility or those identified within federal/provincial/territorial regulation, they rarely change over time. If there is a major modification to the nuclear facility and/or activity or the regulation, the licensing basis and licensed release limits would be updated to reflect the modification.

Licensed release limits are often site-specific or subsector-specific, as design characteristics vary across the nuclear industry, and each facility or activity has a unique environmental protection program or control measures. Licensed release limits are values for releases over a specified period and are not typically applied to any individual sample.

For more information, see section 5 on licensed release limits.

### 2.1.2 Overview of action levels

Action levels for environmental protection provide the licensee with a tool to demonstrate adequate control of their environmental protection program. Action levels are typically set below

licensed release limits and above the upper value of normal operation in order to serve as an early warning indicator.

Exceeding an action level (that is, a yellow light):

- indicates a potential loss of control of the licensee's environmental protection program
- signals a potential reduction in effectiveness of the environmental protection program or of the control measures
- indicates a possible deviation from normal operation
- triggers a requirement for specific action to be taken by the licensee

Action levels are proposed by the licensee and submitted for review and approval by the CNSC.

Action levels are operationally/performance-based, are derived using the current upper value of normal operation, and lie within the maximum upper-end of normal operation (that is, licensed release limit). Action levels for existing facilities are based on the most recent (for example, 5-year) monitoring results that correspond to a licensee's effluent and emissions monitoring program and are reflective of the current operation (that is, current state of the facility such as care and maintenance or refurbishment, current production rates, current ore body quality, etc.).

Since action levels lie within the upper end of normal operation they are expected to be periodically reached, and if reached, may indicate a potential loss of control of part of the environmental protection program and/or control measure(s). Licensed release limits on the other hand, are established at the upper end (that is, maximum) of normal operation, and are not expected to be reached, unless there is a clear loss of control of the environmental protection program and or control measure(s).

Action levels are periodically reviewed (at a minimum of every 5 years in accordance with CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities* [7]) to be reflective of current operations, and therefore may change over time, either increasing or decreasing. The operation of the facility must fall within the licensing basis. Licensed release limits on the other hand, do not change over time, unless there is a major modification to the operations of the facility, which results in a change to the release characteristics.

Exceeding an action level signals a potential loss of control (that is, a yellow light) or reduction in the effectiveness of the program and/or control measure(s), and may indicate a deviation from normal operation. Exceeding a licensed release limit indicates a clear loss of control (that is, a red light), and that the facility is operating outside of its approved facility design, and hence its licensing basis. For more information on action levels, see section 6.

### **2.1.3 Overview of upper value of normal operation**

The upper value of normal operation is based on the predicted or current operating conditions, and is typically determined using either:

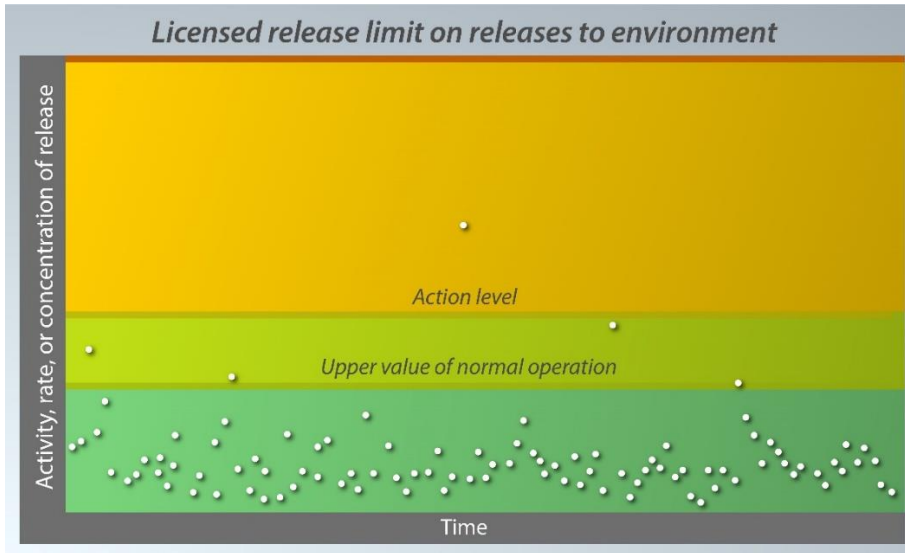
- a prospective approach for a new facility or activity, based on the approved design and other relevant information
- a retrospective approach for an existing facility or activity, using all available performance data (including historical data)

The applicant or licensee may also use the upper value of normal operation as internal control levels, or to inform internal control levels (also commonly known as internal investigation levels

or administrative levels). Exceeding the upper value of normal operation typically triggers internal action by the licensee; however, use of internal control levels are not a regulatory requirement. Their use is at the discretion of the licensee.

Figure 2 shows operational performance data that demonstrates the relationship between the upper value of normal operation, the action level, and the licensed release limit.

**Figure 2: Release performance data for a quantity or concentration of a sample nuclear or hazardous substance over time**



Action levels are compared to the environmental releases (effluent and/or emissions) monitoring program results (for example, daily or weekly grab or composite sample concentrations, daily or weekly or monthly loading rate) that correspond to a licensee’s effluent and/or emission monitoring program, designed in accordance with CSA N288.5, *Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills* [4].

### 3. Environmental Control Measures

Figure 3 on the following page shows the life-cycle process for establishing environmental control measures for:

- a new facility or activity
- an existing facility or activity in normal operation
- an existing facility or activity that is undergoing a major modification

A major modification is one that requires a change in the licensing basis for the facility or activity. Some examples of major modifications are:

- changes to the licensed physical facility, or to facility or activity processes, that have the potential to change the nature of the effluents and/or emissions and the resulting risks to receptors (for example, commissioning a treatment system)
- a response to adaptive management
- a result of a periodic safety review (PSR)

#### **Environmental management system**

An organization's environmental policy, documented in the environmental management system (EMS), includes the organization's commitment to continuous improvement, pollution prevention and other specific areas, which may include sustainable development and adaptive management. These principles are the core components in controlling releases to the environment to ensure the application of ALARA and BATEA.

The EMS includes clearly defined release targets and objectives. The scope of these targets and objectives may include the following elements, which are described in this regulatory document:

- design related items such as environmental release targets (see section 4)
- licensed release limits (see section 5) and action levels (see section 6)
- other performance indicators (for example, continuous improvement initiatives) (see section 8)
- pollution prevention initiatives (see section 8)

A loss of control of the environmental protection program occurs if releases are outside the bounds established in the licensee's licensing basis (that is, the licensed release limits).

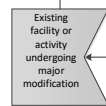
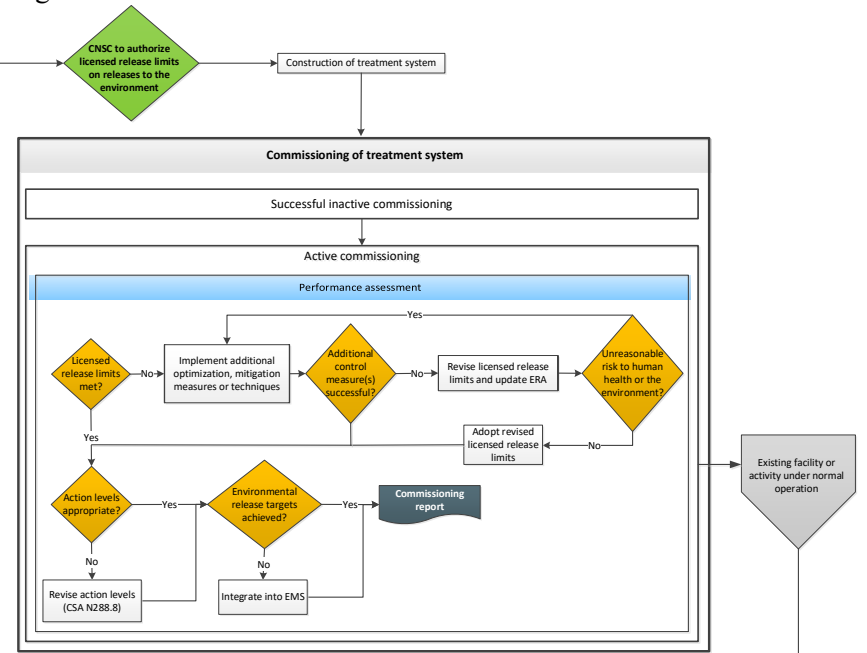
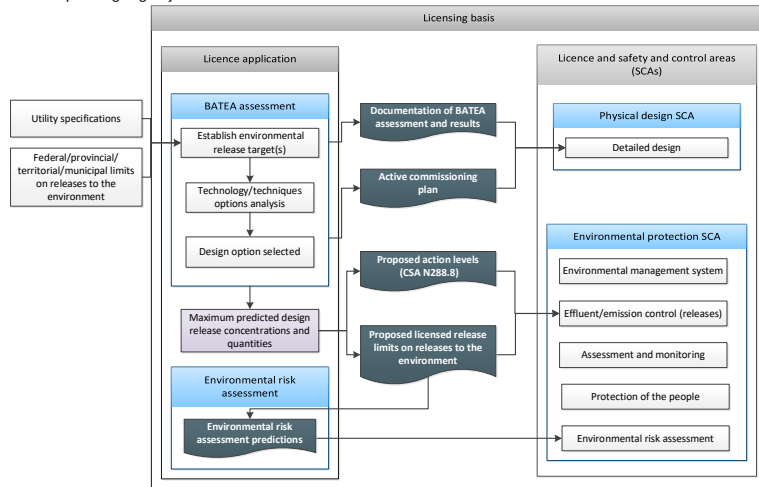
In normal operations, the licensing basis sets bounds on releases through the maximum quantities and concentrations contained within the licensee's licensing basis documentation.

The predictions of environmental effects are submitted as part of a licence application and forms part of the licensing basis. This may be supported with the predictions of environmental effects as described in the approved environmental risk assessment (ERA) or similar documentation submitted in support of a licence application.

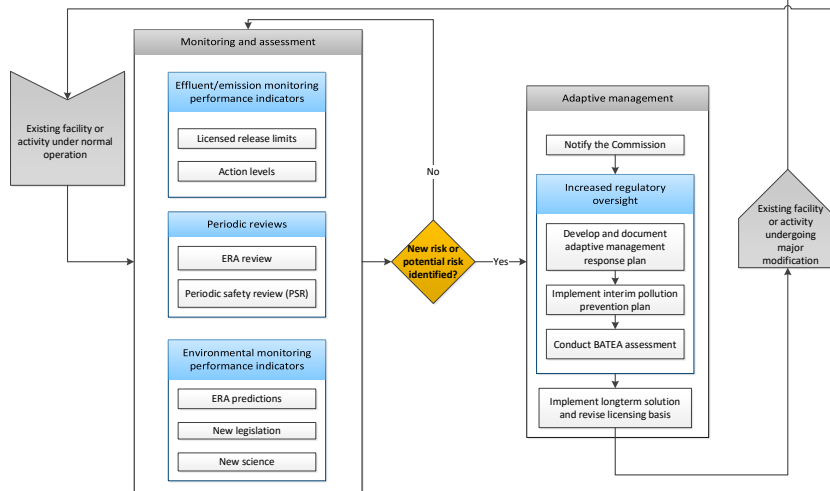
**Figure 3: Simplified overview of the integrated process for establishing and implementing control measures on releases to the environment**

**Note:** The following figures 3a, 3b and 3c show the details of each subsection of figure 3.

New nuclear facility or activity  
Or facility undergoing major modification



Existing nuclear facility or activity under normal operation  
Monitoring and assessment with adaptive management





**Figure 3a: Information on control measures for releases to the environment to be submitted for a new facility or activity applying for a licence to construct, or an existing facility undergoing a major modification and requiring a licence amendment**

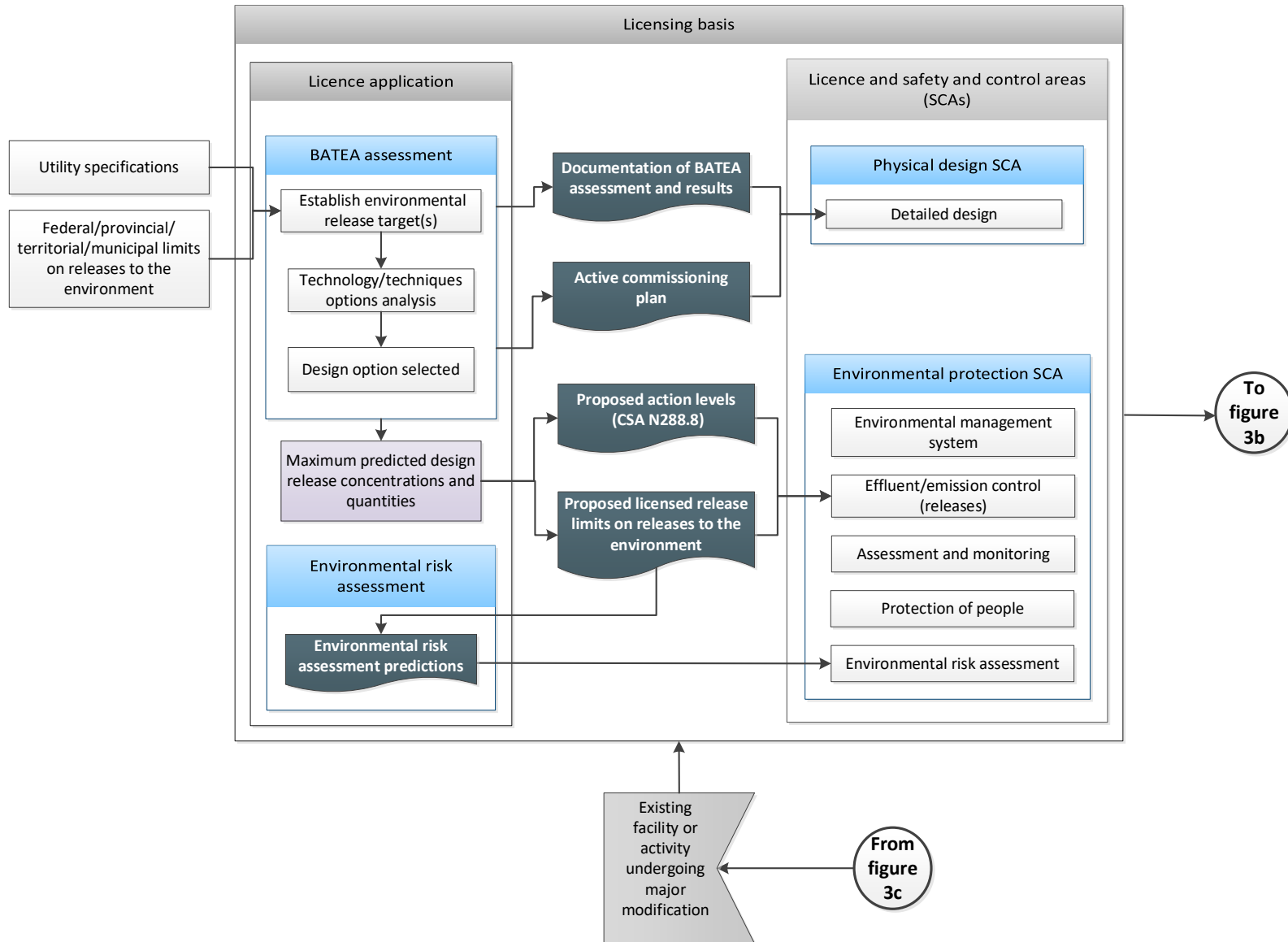
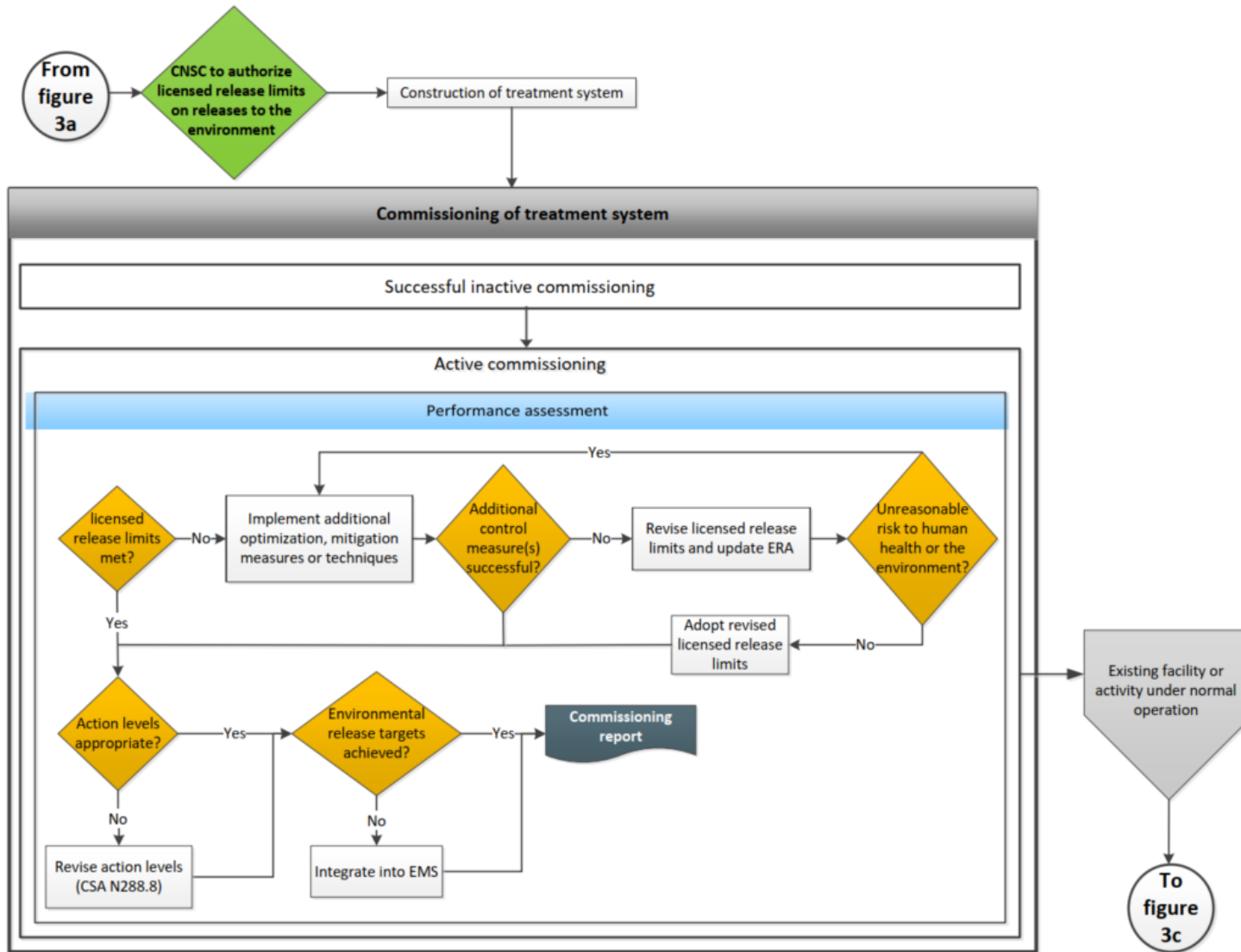
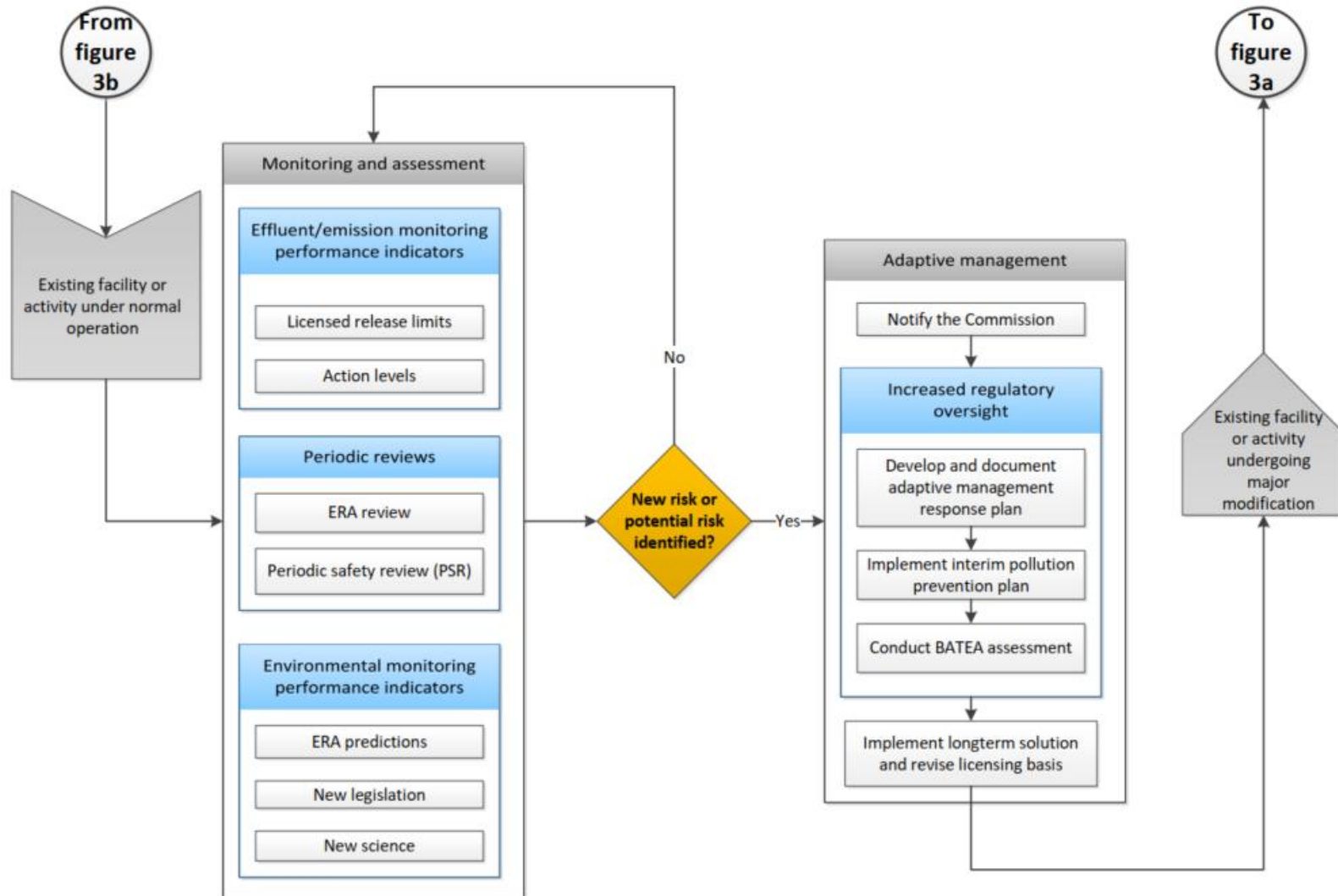


Figure 3b: Commissioning treatment system(s)



**Figure 3c: The part of the overall process for establishing control measures that is specifically for a nuclear facility or activity under normal operation**



### **Effluent and emission monitoring and control**

The effluent and emission monitoring measures are used to:

- inform the development of action levels and licensed release limits
- demonstrate compliance with those action levels and licensed release limits

### **Environmental risk assessment**

The results of an environmental risk assessment (ERA) can be used to identify any contaminants or physical stressors that may require mitigation including implementation of additional controls on releases to the environment. An ERA may also:

- identify nuclear and hazardous substances that merit action levels or licensed release limits
- identify supporting information about mixing zone models, or detailed environmental transport and pathway exposure models, that can be used:
  - in the calculation of exposure-based environmental release targets for new facilities or existing facilities undergoing a major modification
  - to demonstrate that technology-based environmental release targets are acceptable
- identify the receptors and associated exposure scenarios used to determine appropriate benchmark value criteria (that is, to determine the release and exposure benchmarks that define the “limiting” release scenario)
- demonstrate that the licensed release limits are protective of people and the environment

The ERA also provides information that will be used in any decisions regarding adaptive management.

### **3.1 Controlling releases to the environment (from all facilities and activities)**

The following requirements and guidance apply to all facilities and activities. For additional requirements and guidance for controlling releases to the environment:

- from a new facility or activity, or an existing facility or activity that is undergoing a major modification; see section 3.2
- from an existing facility or activity under normal operation; see section 3.3

### **Requirements**

The applicant or licensee shall:

- describe the control measures that will be taken for the protection of the environment, including the pollution control and abatement technologies and techniques
- demonstrate that reasonable precautions have been taken:
  - to prevent or mitigate physical disturbances and releases of nuclear or hazardous substances
  - to prevent or minimize any effects associated with those disturbances and releases
- demonstrate that the principles of ALARA and BATEA have been incorporated (based on the approved design; see section 4) to:
  - minimize controlled releases and prevent uncontrolled releases of nuclear and hazardous substances to the environment
  - mitigate physical effects such as impingement and entrainment of biota
  - reduce exposures of radiation
- ensure that releases are not acutely lethal

For more information, see REGDOC-2.9.1, *Environmental Principles, Assessments and Protection Measures* [1].

### **Guidance**

The description of the control measures should include:

- a list of all structures, systems and components that are important control measures (for example, engineered barriers, wastewater treatment systems, air pollution control technology systems, liquid waste monitoring equipment and stack monitoring equipment)
- the maintenance program established to ensure the sustained operational performance of preventive and control measures
- any alarm systems to be installed to respond to failure of control measures
- the methods to be used:
  - to prepare, store and retain records of releases that will be made routinely from the site
  - to compare those records of releases to available performance indicators (for example, internal investigation levels, administrative levels, and other environmental monitoring objectives and targets)
- identification of the measures that will be taken to make appropriate information available to the authorities and the public (for more information, see REGDOC-3.2.1, *Public Information and Disclosure* [8])

### **3.2 New facility or activity, or existing facility or activity undergoing a major modification**

#### **Requirements**

As part of the licence application for a new facility or activity, or for an existing facility or activity that is undergoing a major modification, the applicant or licensee shall:

- conduct a BATEA assessment to determine the maximum predicted design release characteristics (see section 4)
- establish the proposed release limits (see section 5)
- establish the action levels (see section 6)
- conduct an ERA in accordance with REGDOC-2.9.1, *Environmental Principles, Assessments and Protection Measures* [1]
- establish a commissioning plan and implement commissioning of the treatment system and control measures (see section 7)

### **3.3 Existing facility or activity under normal operation**

For an existing facility or activity under normal operation, a BATEA assessment is not required unless a new risk (see section 8.1) has been identified in the ERA that merits adaptive management.

#### **Requirements**

For an existing facility or activity under normal operation, and in line with its environmental protection program, the licensee shall:

- conduct routine effluent and/or emission and environmental monitoring as described in the licensee's approved environmental protection program

- assess effluent and/or emission monitoring results against the licensed release limits and action levels
- assess the environmental monitoring results against:
  - the predictions in the ERA
  - any new or changes in legislation
- update the site-specific ERA and characterize the risks to the environment (as per ERA periodic update requirements)
- upon completion of the ERA, notify the Commission if a previously unmanaged risk is identified in the ERA, and adaptive management is required to restore the effectiveness of the environmental protection program
 

**Note:** Some examples of unmanaged risks are those identified as the result of new science or new legislation, or evidence of a significant increase in magnitude or spatial extent of a previously known risk to an extent likely to have a measurable impact on ecological or biological health, as identified in the ERA.

Where adaptive management is required, the licensee shall:

- develop and document an adaptive management response plan (see section 8)
  - implement an interim pollution prevention plan, as applicable (see section 8)
  - conduct a BATEA assessment to determine the maximum predicted design release(s) characteristics (MPDRCs) and update proposed release limits to be used in the new or revised ERA (see section 4)
  - submit the information for the proposed revision to the licensing basis to the CNSC
  - as applicable, implement the long-term solution arising from the BATEA assessment (see section 8)
- Note:** Once an adaptive management plan is established, it can be integrated into the facility's routine monitoring and reporting program.

## Guidance

New science or the application of adaptive management may provide evidence to support the removal of a licensed release limit. A licensee may submit a request to the CNSC for the removal of a licensed release limit as part of the periodic review of its environmental protection program.

The implementation of BATEA during operations is part of a licensee's commitment to pollution prevention and to continuous improvement, as part of its environmental policy and as managed through the EMS. As with the ALARA principle, the licensee should apply the BATEA concept throughout the lifecycle of the facility or activity. Best practice for licensees is to periodically re-evaluate the adequacy of their technology and techniques: for example, when managing the aging of structures, systems, and components, or making improvements to an existing facility or activity that could affect releases to the environment. For more information, see section 4.

Evaluation of the adequacy of the licensee's technologies involves consideration of component lifecycle upgrades and other cost-effective refinements to the existing facility or activity. These considerations are often already considered as continuous improvements and documented within the EMS or integrated management system. For nuclear power plants, the periodic evaluation of major pollution prevention and control treatment systems and measures should be addressed as part of the PSR. For more information, see:

- REGDOC-2.3.3, *Periodic Safety Reviews* [10]
- REGDOC-2.6.3, *Aging Management* [11]

#### 4. Best Available Technology and Techniques Economically Achievable

A best available technology and techniques economically achievable (BATEA) assessment does not apply to nuclear facility technology (for example, reactor technology, mining and/or milling technology and/or techniques). However, this type of assessment does apply to treatment and/or control technologies and techniques applied to untreated pollutant sources being released from a nuclear facility.

For a BATEA assessment, the applicant or licensee reviews new and existing technology and techniques to:

- determine an adequate design of pollution control technologies and techniques to reduce releases to the environment, to ensure that:
  - appropriate control measures (including abatement strategies) for pollution prevention are applied
  - risks are mitigated to protect human health and the environment
- identify the maximum predicted design release(s) characteristics (MPDRCs) to:
  - set licensed release limits
  - develop action levels (for new facilities)

In accordance with the *Class I Nuclear Facilities Regulations* and the *Uranium Mines and Mills Regulations*, the MPDRCs include the proposed location of the points of release, the proposed maximum quantities and concentrations, and the anticipated volume and flow rate of nuclear and hazardous substances expected to be released to the environment, including their physical, chemical and radiological characteristics. The MPDRCs correspond to the residual release: that is, the remaining release of a nuclear or hazardous substance, after accounting for all treatment and mitigation through the application of BATEA.

##### 4.1 Requirements for conducting a BATEA assessment

For facilities and activities that are new or are undergoing major modifications that have the potential to increase or change the nature of releases to the environment and the resulting risks to receptors, the applicant or licensee shall conduct an assessment to identify the best available technologies, or the best available techniques for control, that have been demonstrated on an industrial scale to reduce the release of contaminants or physical stressors to the environment.

**Note:** Demonstration of a technology or technique as a best practice in a similar industry or activity may indicate that the technology or technique is economically achievable. The applicant or licensee may decide to assess the use of emerging technologies, with justification that a similar or better outcome is achieved.

The applicant or licensee shall document the BATEA assessment and results and shall submit them to the CNSC (see figure 3a). This document may form part of the licensing basis for the facility or activity.

##### 4.2 Required elements of a BATEA assessment

A BATEA assessment shall contain the following elements:

- characterization of pollutant source or sources
- identification of contaminants and physical stressors that will require control
- establishment of environmental release targets
- analysis of options for technology and techniques

- identification of the maximum predicted design release characteristics
- analysis of benefits
- selection of best BATEA option

### **4.3 Guidance for a BATEA assessment**

The applicant or licensee should use a systematic approach to conduct a BATEA assessment.

The BATEA assessment includes the optimization process that was used to identify the adequate design of pollution control technologies and techniques. Appendix B provides additional information on the role of radiation protection principles such as optimization and dose constraints relative to BATEA assessments and the setting of release limits for nuclear substances.

#### **Characterization of pollutant sources**

Characterization of the pollutant sources includes identifying the expected nature, quality, and quantity to be treated prior to release to the environment from the facility or activity.

Some examples of pollutant sources are process waters, untreated collection waters, gaseous releases, and other waste streams.

The quantity should be calculated using the average and maximum predicted influent concentrations over the operating lifecycle of the facility or activity.

#### **Identification of contaminants and physical stressors**

A screening assessment identifies the contaminants and physical stressors that will require control (that is, treatment or management).

The contaminants and physical stressors that require control include the pollutant sources that are:

- nuclear substances identified as exceeding conditional clearance levels established by the CNSC (see appendix A)
- subject to existing federal, provincial, territorial, or municipal requirements applicable to releases
- identified as potentially exceeding applicable and most scientifically defensible federal, provincial, territorial, or municipal environmental quality guidelines, objectives, standards, or criteria, before consideration of treatment
- identified within the ERA as requiring control, where an unreasonable risk or potential unreasonable risk to human health and the environment has been identified

#### **Establishment of environmental release targets**

Environmental release targets (ERTs) are not licence limits; rather they are evaluation criteria used as the basis of the design of the treatment technologies and techniques being appraised as part of the BATEA assessment. Two basic types of ERTs may be used:

- dose constraints, concentrations, or total loadings identified in federal and/or provincial regulations as applicable to the substance and type of release (emission/effluent) being evaluated
- risk based ERTs based on receiving environment quality criteria (for example, dose constraints, Canadian Council of Ministers of the Environment Environmental Quality



Guidelines, Federal Environmental Quality Guidelines, Canadian Ambient Air Quality Standards)

Due to the complexities and trade-offs associated with optimizing treatment design for complex releases (multiple waste stream characteristics and compositions) and the limits of technology, not all ERTs may be achievable. The BATEA assessment identifies the optimal design composition (technologies and techniques) which:

- achieves any ERTs specified as limits within federal or provincial regulations, and
- achieve the most comprehensive suite of receiving environment ERTs.

**Note:** Due to the wide range of potential ERTs and the many differences in their derivation and site-specific application, detailed discussion and examples are provided in appendix C on establishing environmental release targets and their role in the BATEA assessment and the final development of licensed release limits.

### **Analysis of options for technology and techniques**

Analysis of the technology options identifies:

- available technologies
- their performance in reducing source contaminants and physical stressors (that is, treatment efficiencies and expected concentrations)
- their associated benefits and drawbacks

A techniques analysis identifies areas of optimization that may have a direct effect on reducing releases to the environment. A techniques analysis should include:

- the engineering aspects of applying various types of control techniques
- different configurations of a technology
- the processes employed and the process changes
- human factors
- management oversight and process
- water management
- management of greenhouse gases
- how contaminants and physical stressors are released to the environment
- trade-offs associated with applying a given technique (for example, energy requirements, air pollution and greenhouse gases, waste generation, worker exposure and public exposure)
- other site-specific factors, as appropriate to the facility or activity

The analysis should review top-performing similar facilities or activities to identify technologies and techniques that should be considered as part of the BATEA assessment. The analysis should demonstrate that the selected technologies and techniques represents an optimized design to achieve the environmental release targets.

The analysis should consider the potential impacts the technology and/or techniques will have on climate change. The identification of the technology and/or techniques that are BATEA should consider the minimization of greenhouse gases released to the environment.

Treatment systems should be designed to accommodate the potential for extreme weather events and should consider the future impacts of climate change on those events (for example, 1-in-100-years weather event).

This analysis may be supported by any bench-scale, laboratory-scale, or pilot project-scale testing to confirm treatment efficiencies and expected treated effluent and/or emission concentrations.

Licensees of nuclear facilities emitting radioactive particulates and radioiodines should consider the use of CSA N288.3.4, *Performance testing of nuclear air-cleaning systems at nuclear facilities* [3] for the design, commissioning, and maintenance of air pollution control systems.

Some examples of techniques are:

- improved procedures for changing filters
- faster mixing using diffusers
- discharging into fast- versus slow-moving water bodies
- limiting or preventing discharge during environmentally sensitive time periods
- use of high stack height and/or reduced diameter for the stack
- improvement in the chemical reagents used
- increased certainty in orebody concentrations
- minimizing human errors through improvement in the training programs
- optimizing operating conditions

### **Identification of the maximum predicted design release characteristics**

For the combination of technologies and techniques under consideration, determination of the MPDRCs includes the concentration and quantities expected to be released from the facility or activity.

When determining the MPDRCs, the applicant or licensee should consider:

- the maximum expected influent characteristics
- the anticipated treatment efficiencies for full-scale operations
- a margin of operational flexibility

### **Analysis of benefits**

An analysis of benefits (for example, cost-benefit analysis, or a multi-value criteria analysis) supports the selection of an appropriate technology or technique.

### **Selection of most applicable BATEA option**

Based on the assessments described above, the applicant or licensee should select the most applicable BATEA option for the facility or activity.

#### **4.3.1 Documentation of the BATEA assessment and results**

The applicant or licensee should document the following information about the BATEA assessment and results:

- a summary of the results of the characterization of pollutant sources, including:
  - the nature of the source
  - the average and maximum predicted influent concentrations
  - quantities to be treated
- the established environmental release targets and the methodology used in their derivation

- a summary of the results of the technology options analysis, including a list of the technologies assessed and their expected performance (that is, the expected treatment efficiency) in treating identified contaminants and physical stressors
- a description of the techniques to be applied
- if applicable, a summary of the results of the cost-benefit analysis, or the multi-value criteria analysis
- the final proposed design and its justification as the BATEA option
- the predicted treatment efficiencies, MPDRCs, and a comparison to the established environmental release targets

For more information on how the CNSC considers cost-benefit information, refer to REGDOC-3.5.3, *Regulatory Fundamentals* [12].

## 5. Licensed Release Limits

Licensed release limits apply to releases to the environment from the licensed facility or activity and are applied to the final point of control. For radioactive nuclear substances, where there are multiple release points, facility- and/or activity- wide licensed release limits may be authorized.

In establishing licensed release limits, the objective is to constrain the quantity or concentration of contaminants and physical stressors that may be released into the environment. In line with this objective, a licensed release limit is based on the proposed maximum quantities or concentrations that could be released during normal operation, in other words the maximum predicted design release concentrations (MPDRCs). These MPDRCs are based on the facility design, include a margin of operational flexibility as discussed in section 4.3, and form part of the licensee's design basis documentation submitted in support of their licence application. Therefore, exceeding a licensed release limit indicates that there is a loss of control of part of the environmental protection program or control measure(s), and that the licensee is operating outside the licensing basis.

The implementation of licensed release limits ensures:

- the application of acceptable control measures (including abatement strategies) for pollution prevention
- the protection of human health and the environment
- that the licensee is operating within the licensing basis for normal operation for that facility or activity

As licensed release limits represent the upper-end (that is, maximum) on acceptable releases during normal operations, it is necessary to ensure that these releases do not pose an unreasonable risk to the environment or to the health and safety of persons. This can be demonstrated through a site-specific ERA.

For new facilities, or existing facilities undergoing major modifications that require an amendment to the licence, the proposed release limits are submitted as part of a licence application and are approved by the Commission. Any changes to the licensed release limits for an existing facility would require approval by the CNSC.

When a licence is issued, the licensee is authorized to release to the environment in accordance with the licensed release limits. Authorization to release must be received from all applicable jurisdictions prior to any releases:

- authorization under other jurisdictions does not constitute authorization from the CNSC
- authorization from the CNSC does not constitute authorization under other jurisdictions

The CNSC will work with other jurisdictions to ensure that, to the extent possible, authorizations are acceptable to all applicable jurisdictions. Section 5.1 identifies procedures for harmonizing CNSC licensed release limits with those currently in federal/provincial/territorial regulations that apply to the licensed activity. Licensed release limits are only applicable to normal operation. During emergency events, licensed release limits do not apply – emergency management procedures take effect until normal operation is restored. During this period, CNSC staff are in on-going communications with the licensee and apply enhanced regulatory oversight.

Exceeding a licensed release limit demonstrates a lack of compliance with requirements and is subject to enforcement action. Enforcement action, which is commensurate with the level of release, associated risks to human health and the environment, and prior compliance history, may include any of the CNSC's graduated enforcement tools. For more information, see [the CNSC's approach to compliance verification and enforcement](#).

**Note:** Licensed release limits are set at a level that ensures no unreasonable risk to human health and the environment, and as a result are protective of human health and the environment. The implementation of licensed release limits, which includes how to respond to a licence limit exceedance and those actions taken to restore the effectiveness of the environmental protection program, accomplish this protection.

### 5.1 Requirements for establishing and documenting proposed release limits

The applicant or licensee shall submit to the CNSC:

- the locations of the proposed controlled release points
- for radioactive nuclear substances, either:
  - the proposed release limit(s) associated with each proposed controlled release point for each contaminant, or
  - the proposed release limit(s) for the facility and/or activity for each contaminant
- for hazardous substances, the proposed release limit(s) associated with each proposed controlled release point for each contaminant and/or physical stressor
- the methodology used to establish the proposed release limit(s)

**Note:** For new facilities, proposed release limits for radioactive nuclear substances should be specific to each release point.

The site-specific proposed release limit(s):

- shall be at or below any applicable release limits found in existing legislation
- are subject to approval by the Commission (and therefore become part of the licensing basis; that is, licensed release limits)

For contaminants and physical stressors that do not have established limits on releases, the applicant or licensee shall use the MPDRCs to establish appropriate proposed release limits.

For all nuclear substances released from the facility or activity, the applicant or licensee shall demonstrate that, based on the proposed release limit(s), the maximum predicted annual total effective dose to a member of the public is less than the regulatory public dose limit.

To establish the proposed release limit(s), the applicant or licensee shall:

- identify the controlled release points where proposed release limit(s) will apply
- identify the MPDRCs
- identify each contaminant and physical stressor that requires a release limit
- establish the proposed release limit(s)
- demonstrate that the proposed release limits respect the radiological regulatory public dose limit, and do not pose an unreasonable risk to human health or the environment

## Guidance

The applicant or licensee should use a systematic, structured process to establish the proposed release limits.

### **Identify the controlled release points where proposed release limit(s) will apply**

The list of proposed controlled release point(s) should be in alignment with the facility design and with those controlled release points established in the effluent and/or emissions monitoring program. For nuclear substances, where there are multiple release points, facility- and/or activity-wide licensed release limits may be applied.

In alignment with the prohibition on dilution as an internationally accepted best practice, controlled release points where licensed release limits apply should be prior to combining with water or any other effluent for the purpose of diluting effluent before it is released (for example, cooling water discharge).

### **Identify the maximum predicted design release characteristics**

Identify the MPDRCs for each proposed controlled release point:

- for a new facility or activity, or for an existing facility or activity that is undergoing major modifications, this information is documented as part of the BATEA assessment and results
- for an existing facility or activity under normal operation:
  - this information may be documented in the approved design documentation for normal operation
  - otherwise, the MPDRCs should be established by using historical performance data for each controlled release point
  - for nuclear substances, facility-wide and/or activity-wide MPDRCs can be established through the following methodology:
    - i. for each radionuclide/radionuclide group, identify a level that represents the maximum facility- and/or activity-wide release(s) during normal operation based on historical performance data
    - ii. calculate the total effective dose to the representative person (or critical receptor) using the maximum release values obtained in step i
    - iii. calculate the dose corresponding to the MPDRCs by applying a factor to the dose calculated in step ii, to account for operational flexibility based on an understanding of the anticipated operation of the facility and/or activity, and professional judgement
    - iv. for each radionuclide/radionuclide group, determine their fraction of contribution to the total effective dose identified in step iii
    - v. for each radionuclide/radionuclide group, back calculate from the dose corresponding to the MPDRCs, and multiply by its fraction contribution to the total dose identified in step iv, to obtain a facility-wide and/or activity-wide MPDRC

The applicant or licensee may use the methodology described in CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities* [7], such as a retrospective approach. This approach could use a percentile that represents the upper value of normal operation and apply a factor to represent the maximum predicted design release. This should be informed by site-specific knowledge and professional judgement.

For those licensed nuclear facilities where, due to the nature of the operation (for example, research and development, providing services for nuclear industry), releases are dependent on the

type of active work, which may change over time, an appropriate margin for operational flexibility should be factored into the MPDRCs to account for anticipated operations throughout the lifecycle of the facility.

### **Identify each contaminant and physical stressor that requires a licensed release limit**

All contaminants and physical stressors that require a licensed release limit should be identified:

- i. that are subject to existing federal, provincial, territorial, or municipal requirements on releases; or
- ii. where the MPDRC exceeds applicable, to the facility and/or activity, and most scientifically defensible federal, provincial, territorial, or municipal environmental quality guidelines, objectives, standards, or criteria not covered by i; or
- iii. by reviewing the ERA and considering contaminants and physical stressors that pose an unreasonable or potentially unreasonable risk, or require mitigation in the case where due to the precautionary approach, mitigation measures have been recommended in the ERA.

The applicant or licensee should demonstrate that a review has been completed of existing legislation, regulation, and associated limits or controls applicable to the facility or activity that should be considered when proposing release limits.

**Note:** this review is already required for a licensee's environmental management system.

A licensed release limit may not be required where the applicant or licensee can demonstrate that, for controlled releases under all foreseeable circumstances (as identified in the ERA):

- for the combination of all nuclear substances released at their MPDRCs from the licensed facility or activity under normal operations, the maximum predicted total effective annual dose to the public does not exceed 0.01 mSv/year
- for a hazardous substance, the MPDRCs is lower than the applicable and most scientifically defensible federal, provincial, territorial, or municipal environmental quality guidelines, objectives, standards, or criteria (for example, Canadian Council of Ministers of the Environment)

If a licensed release limit is not required, the licensee or applicant:

- is still required to demonstrate annually (through monitoring or modelling) that the total effective annual dose does not exceed the regulatory public dose limit of 1 mSv, and that licensed release limits continue to not be required by confirming the dose remains below 0.01 mSv and any applicable CNSC prescribed dose constraint (for example, where potential for cumulative exposure from multiple licensed activities exists)

**Note:** This assessment would be part of the facility's existing annual radiological dose assessment, using the site-specific public dose assessment model. Determination would be for the total licensed facility and/or activity.

- may be required to conduct routine effluent and/or emissions monitoring, as well as environmental monitoring (as described in REGDOC-2.9.1 [1])

### **Establish the proposed release limit(s)**

The applicant or licensee should establish the proposed release limits as follows:

Step 1: Adopt applicable governmental requirements on releases that were previously identified

- where there are other government requirements for releases that apply to the facility and/or activity, the applicant or licensee may harmonize with those requirements (in particular, with any reporting processes and procedures) and use these values as the

proposed release limit(s). Some examples include federal or provincial regulations (including those for local air quality at the point of impingement), municipal by-laws, and provincial or territorial permits, authorizations, or licences.

- proposed release limits adopted from provincial permits may be applied on a monthly, quarterly, or annual basis, as deemed appropriate based on the nature of the release, and discussions with CNSC.
- some release limits in provincial permits may be more suitable for the purpose of action levels if they are used to indicate a deviation from normal operation and identify a potential loss of control of part of the licensee's programs and/or control measures. In this case, those provincial release limits may be proposed as action levels. The licensee may still be required to propose release limits as per the guidance described in this regulatory document.
- to harmonize with requirements on releases to protect local air quality (for example, Ontario Regulation on Local Air Quality O. REG 419/05 [13]), proposed release limits for those contaminants and/or physical stressors of regulatory interest may be established by back-calculating from the point of impingement, using site-specific release characteristics (for example, flow rates, stack heights, stack temperature).
- licensed release limits harmonized with other government requirements may change from time to time, as those requirements are updated. CNSC staff should be notified of any such changes ahead of issuance, in order to review the proposed changes, and update the licence conditions handbook. The updated licensed release limits will be in effect in accordance with the date specified by the respective jurisdiction.
- where existing federal/provincial/territorial requirements do not adequately protect the environment (as supported through an ERA or other scientifically defensible assessment), the CNSC will engage with the applicable jurisdictions when determining the most appropriate licensed release limit.

Step 2: Set the proposed release limit(s) as the maximum predicted design release concentration

- set the proposed release limit as the maximum predicted design release concentration, which applies to the maximum mean concentration over a specified period of time (for example, weekly, quarterly, or bi-annual averaging period). This should be done for each contaminant requiring proposed release limits (where requirements on releases do not exist, are deemed to not be adequately protective of the environment, or where the applicant or licensee chooses not to adopt, for the purposes of harmonization, those applicable governmental requirements on releases that were previously identified). Only a proposed release limit corresponding to the maximum mean concentration over a specified period of time is required. However, to account for uncertainty in sampling results, a proposed release limit corresponding to an individual grab sample or an individual composite sample may be established. A proposed release limit that applies to an individual composite sample can be established by multiplying the maximum mean concentration by 1.5. A proposed release limit that applies to an individual grab sample can be established by multiplying the maximum mean concentration by 2. This is a common regulatory approach. It should be noted that this approach is unrelated to the factor providing a margin of operational flexibility that is incorporated in the derivation of the MPDRC.
- when historical monitoring data is used to establish the MPDRCs, it may be based on a set of grab samples or a set of composite samples. If the dataset is comprised of grab samples, then the MPDRC is set to the maximum historical grab sample value multiplied by a factor for operational flexibility. The MPDRC is then divided by 2 to determine the maximum mean concentration over a specified period of time for the



proposed release limit. If the dataset is comprised of composite samples (for example, batch pond release composite), then the MPDRC is set to the maximum historical composite sample value multiplied by a factor for operational flexibility. The MPDRC is then divided by 1.5 to determine the maximum mean concentration for the proposed release limit.

Step 3: Establish rate-based proposed release limit(s)

- where a proposed release limit is to be established on the quantity of the contaminant released in each period (that is, rate/loading), multiply the maximum predicted design release concentration by the maximum design flow rate over the specific period.
- for nuclear substances, facility-wide and/or activity-wide release limit(s) may be established for those facilities with multiple release points.
- licensed release limits based on the MPDRCs are based on the approved physical design of the facility, which should account for operational flexibility based on the anticipated operation of the facility and/or activity. Therefore, they are not expected to change over time, unless there is a major modification to the nuclear facility and/or activity that has the potential to increase or change the nature of releases to the environment and the resulting risks to receptors, which would be outside the existing licensing basis.
- during the transition from operation to decommissioning, if there is no anticipated increase in release characteristics, and existing control measures will continue to operate within the current licensed release limits, then the facility and/or activity remains within its licensing basis. However, if there is a proposed major modification of the facility and/or activity that may change the release characteristics to exceed the current licensed release limits, the result would be outside the existing licensing basis, trigger a request for a licence amendment, and require the conduct of a BATEA assessment and an update to the licensed release limits to reflect the major modification or change in activities.
- for nuclear substances, this approach incorporates limitation of exposure and optimization to achieve ALARA. Limitation is represented by the *Radiation Protection Regulations* public dose limit of 1 mSv/year. As this limit applies to the summation of exposures from all licensed releases, it is not used as the basis for establishing a licensed release limit for a single facility. A facility's licensed release limit is based on the optimization of the facility's design and treatment systems through the application of BATEA. See appendix B for further information on the role of radiation protection principles such as optimization and dose constraints relative to setting licensed release limits for nuclear substances.

**Demonstrate that the proposed release limits respect the regulatory public dose limit and do not pose an unreasonable risk to human health or the environment**

For all nuclear substances released from the facility or activity, the maximum predicted annual total effective dose (based on the proposed release limits) to a member of the public is required to be less than the regulatory public dose limit and the applicant or licensee must demonstrate that releases have been optimized (see appendix B).

To demonstrate this, the applicant or licensee should:

- identify the information from the most recent ERA, where available
- estimate the information using an appropriate environmental transport and exposure pathway model

For nuclear and hazardous substances, the applicant or licensee should assess the proposed release limits using ERA methodology to demonstrate that, at the level of the proposed release limits, there is no unreasonable risk to human health or to the environment.

A licensed release limit is recognized by the CNSC and Environment and Climate Change Canada as an authorization that the licensee can release up to the limit. Therefore, the applicant or licensee is expected to demonstrate that releases at the proposed release limit will not result in an unreasonable risk to human health and the environment. This can be demonstrated by applying the proposed release limits as a source term in a scenario, using ERA methodology. This may be assessed conservatively through a scenario whereby a continuous release at the proposed release limit(s) is assumed. This may be used for any industrial facility that has a very stable, continuous release over its operational lifetime, or for a low-risk facility whose licensee wishes to conservatively demonstrate that its releases are protective.

If, due to the nature of the facility and/or activity, the proposed release limit(s) is only expected to be reached during a specific period of normal operations or periodically for short durations, the applicant or licensee may wish to model this situation instead. In scenarios where periodic or time-limited higher releases are anticipated, the proposed release limit may incorporate temporal limits.

For an existing facility where proposed release limits are based on historical data, only the proposed release limit needs to be applied in the scenario.

In addition, the scenario corresponding to the release of nuclear substances at the proposed release limits should demonstrate that they are protective of aquatic life and/or terrestrial life, by comparing to peer-reviewed guidelines established for the protection of aquatic life and/or terrestrial life adopted by a federal or provincial body.

**Note:** The maximum predicted annual total effective dose includes direct gamma exposure.

For more information on the role and development of environmental transport and exposure pathway models, see:

- REGDOC-2.9.1, *Environmental Principles, Assessments and Protection Measures* [1]
- CSA N288.1, *Guidelines for modelling radionuclide environmental transport, fate, and exposure associated with the normal operation of nuclear facilities* [2]
- CSA N288.6, *Environmental risk assessment at Class I nuclear facilities and uranium mines and mills* [5]

## 5.2 Requirements for responding to licensed release limit exceedances

When a licensee becomes aware that a licensed release limit has been exceeded, the licensee shall:

- limit, to the extent possible, the effect and magnitude of the exceedance
- conduct an investigation to establish the cause and determine the magnitude of the exceedance
- assess the potential effects on human health and the environment
- identify and take action to restore the effectiveness of the environmental protection program and/or control measure(s) implemented, and prevent recurrence (this may include the application of adaptive management; see section 8)

- follow the reporting requirements described in the regulatory document applicable to the facility or activity:
  - REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants* [14]
  - REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills* [15]
  - REGDOC-3.1.3, *Reporting Requirements for Waste Nuclear Substance Licensees, Class II Nuclear Facilities and Users of Prescribed Equipment, Nuclear Substances and Radiation Devices* [16]

### **5.3 Requirements for revising licensed release limits**

Licensed release limits shall be revised in response to:

- a major modification of the operations of the facility, leading to a change in the licensing basis
- new or updated governmental requirements (for example, federal, provincial, territorial, and municipal requirements)

The licensee may apply for a revision to the release limits for reasons outside of those listed above, with adequate justification.

## 6. Action Levels for Environmental Protection

Within the licensing basis for a specific site, the licensee should review action levels on a periodic basis and adjust them to reflect any changes to site activities, conditions, or processes. Any revisions to action levels may be subject to CNSC review and approval.

Exceeding an action level triggers a requirement for a specific action to be taken. Exceeding an action level is not considered a lack of compliance; however, failure to respond appropriately is. To respond to an exceedance, a licensee must follow:

- the steps in subsection 6(2) of the *Radiation Protection Regulations*
- requirements in the licensee's code of practice, as set out in subsection 4(2) of the *Uranium Mines and Mills Regulations*, where applicable
- additional requirements that may be included in the licensee's licensing basis

When responding to an action level exceedance, the successful implementation of the required follow-up activities (such as notification, investigation, and corrective actions) is a clear demonstration of a well-maintained and managed environmental protection program and control measures.

Action levels are site-specific. For more information, see:

- for nuclear power plants, REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants* [14]
- for Class I nuclear facilities (excluding power reactors) and uranium mines and mills, REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills* [15]
- CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities* [7]

An action level is defined as a specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of a licensee's radiation protection program or environmental protection program, and triggers a requirement for specific action to be taken.

An action level is an indicator of a potential loss of control of part of a program and/or control measure(s). Exceeding an action level signals a potential reduction in the effectiveness of the program and/or control measure(s) and may indicate a deviation from normal operation.

### 6.1 Requirements for setting action levels

The applicant or licensee shall develop and set appropriate action levels, as control measures, on the operational parameters of the nuclear facility or activity.

#### 6.1.1 Contaminants and physical stressors

For contaminants and physical stressors released to the environment, the licensee shall establish and implement action levels in accordance with CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities* [7].

### 6.1.2 Other environmental controls

The applicant or licensee shall establish and implement action levels on other environmental controls that are necessary to ensure the effectiveness of the environmental protection program and control measures. For example, action levels may be established on:

- flow (to ensure adequate control of flow into a watershed to prevent downstream flooding or stream channel disruption)
- hydraulic head across engineered or natural barriers (to ensure adequate control of containment of contaminants and physical stressors)

**Note:** These types of action levels have typically been applied at uranium mines and mills; they may be applied at other nuclear facilities and on other environmental controls.

### 6.1.3 Documenting development of action levels

The applicant or licensee shall:

- document the development of the action levels in accordance with CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities* [7]
- submit this documentation and the proposed action levels to the CNSC

This documentation will form part of the licensing basis for the nuclear facility or activity.

The action levels are expected to change over time as they reflect actual operating conditions. The licensee shall submit any changes to the action levels and to the supporting documentation to the CNSC.

## 6.2 Requirements for responding to action level exceedances

When an action level is exceeded, the licensee shall:

- notify and report to the Commission as specified in the licence or licence conditions handbook
- conduct an investigation to identify the basis for exceeding the action level
- where necessary, take action to restore the effectiveness of the program or control measures that have been implemented

## 6.3 Guidance for action levels

Within the licensing basis for a specific site, action levels should be adjusted depending on changes to site activities or processes. The licensee should:

- review the action levels periodically in accordance with CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities* [7]
- revise them if appropriate, considering:
  - data collected from operations and performance of the nuclear facility or activity from start of operation to the current date (also called a retrospective approach)
  - current operations and performance of the nuclear facility or activity

Where appropriate, the applicant or licensee may adapt the performance-based approach described in CSA N288.8 [7] to establish action levels on other environmental controls (for example, engineered or natural barriers, or flow control).

## 7. Commissioning a Treatment System

Commissioning is essential to verify performance against the approved design and to ensure that the licensed release limits are achievable and are set at a level that is protective of the environment.

All new treatment systems must be commissioned to verify:

- whether the system has been constructed and will operate in accordance with the design basis before commencing releases to the environment
- that the system is not exceeding the maximum predicted design release(s) characteristics (MPDRCs)
- that the previously established action levels and licensed release limits are appropriate

Wherever possible, the CNSC harmonizes this process with that of any other approving jurisdiction.

**Note:** This section applies to licensed activities, and to hazardous substances or hazardous waste, other than nuclear substances, used or produced while carrying on a licensed activity that may pose a risk to the environment or the health and safety of persons. This would include a conventional sewage treatment facility that is on the licensed site.

### Requirements

For any facility or activity that has a new treatment system to be commissioned, or a major modification to an existing treatment system, the licensee shall submit a commissioning plan to the CNSC.

The licensee shall commission the treatment system and control measures in accordance with the approved commissioning plan.

After the treatment system is commissioned, the licensee shall submit a commissioning report that:

- includes an assessment of the operating performance of the treatment system against the licensed release limits and MPDRCs to ensure the operating performance is within the licensed release limits
- confirms whether the proposed action levels remain appropriate

If the licensee discovers that a specific licensed release limit on releases to the environment cannot be met, the licensee shall:

- notify the Commission
- determine the nature of the unexpected performance or behaviour
- assess if the licensed release limit can be met through further optimization, or through application of additional mitigation measures or techniques to bring releases to levels below the licensed release limit

If the licensee determines that the treatment system performance is unable to meet a specific licensed release limit, the licensee shall:

- establish a revised release limit based on achievable technology
- reassess the ERA to determine whether the predictions of the ERA remain valid

- if the reassessment of the ERA:
  - identifies an unreasonable risk to human health or the environment, then the licensee shall implement additional optimization, mitigation measures or techniques and repeat the three bullets above
  - determines there is no unreasonable risk to human health or to the environment; in this case, the licensee shall:
    - request that the CNSC amend the licensing basis
    - submit the revised ERA and proposed release limits

### Guidance

The applicant or licensee should submit the commissioning plan at the end of their construction phase. The licensee's commissioning plan should include the following information:

- commissioning schedule and process
- responsibilities
- transitioning to the next stage of commissioning ("package turnover")
- operational performance
- performance assessment
- management system (particularly quality assurance and quality control (QA/QC))
- safety (occupational health and safety, and radiation protection)
- training
- records and records maintenance
- site plan and sample locations

To confirm the performance of the treatment system, the licensee should assess the operating performance against the environmental release targets established in section 4.3.1 (as part of the BATEA assessment).

For more information on the components of a commissioning plan and on confirming the performance of the treatment system, see appendix D.

For more information on the commissioning of a wastewater treatment system, see:

- REGDOC-2.3.1, *Conduct of Licensed Activities: Construction and Commissioning Programs* [9]
- guidance from the U.S. Department of Defense, *Planning and Commissioning Wastewater Treatment Plants* [17]

## 8. Adaptive Management

Adaptive management involves, among other things, the implementation of new or modified mitigation measures over the life of a project to address unanticipated environmental effects.

Adaptive management ensures that licensees take corrective actions to mitigate an identified unreasonable risk or a potential unreasonable risk to the environment to a level accepted by the CNSC. The CNSC expects licensees to take a proactive approach if an unreasonable risk or a potential unreasonable risk to the environment has been identified.

An adaptive management plan may be considered analogous to a corrective action plan that is implemented in response to a non-conformance with the licensing basis.

### 8.1 Requirements for adaptive management

Adaptive management is required in response to:

- identification of an unreasonable risk or a potential unreasonable risk through the ERA or through monitoring; for example, because of:
  - changes to the operation or to the licensed activity
  - changes in the scientific understanding of a substance's toxicity or physical effect
- changes in the regulatory status of a substance (for example, Environment and Climate Change Canada classification of a substance as toxic under the *Canadian Environmental Protection Act, 1999*)
- new or updated regulatory requirements

When a requirement for adaptive management is identified, the licensee shall:

- notify the Commission
- develop, document, and implement an adaptive management plan to:
  - reduce releases of the identified contaminants and physical stressors to the environment
  - mitigate any potential effects on the environment
- provide periodic updates as needed to reflect the current operation

The interim period is the time from when adaptive management is triggered through to completion of commissioning of the new treatment system or other control measures. During this interim period, at a frequency specified by the CNSC, the periodic updates shall include:

- a summary of the technology and techniques being applied and their performance in reducing the contaminants and physical stressors
- for each contaminant and physical stressor:
  - an assessment of the historic and current effluent and/or emission performance data
  - an assessment of the predicted future trends in effluent and/or emission performance
- an update summarizing the potential and residual risks to the environment
- the status of implementation of the long-term adaptive management plan

The implementation of adaptive management should consider the potential impacts that mitigation measures will have on climate change, to reduce the release of greenhouse gas emissions.

Once an adaptive management plan is established, it can be integrated into the facility's routine monitoring and reporting program.



## **8.2 Guidance for adaptive management**

Early engagement with CNSC staff is encouraged for adaptive management plans. CNSC staff can provide facility- or activity-specific guidance to assist applicants and licensees.

### **8.2.1 Components of an adaptive management plan**

An adaptive management plan should include:

- an interim pollution prevention plan (IPPP)
- a BATEA assessment to identify and implement a long-term treatment solution
- the schedule of expected timelines for the implementation of the adaptive management plan

### **8.2.2 Components of an interim pollution prevention plan**

The intent of the IPPP is to focus on short-term mitigation while long-term solutions are evaluated (that is, to mitigate any potential risks in the short term, until a viable long-term treatment solution is implemented). The licensee should consider the full scope of treatment options that were identified within the BATEA assessment.

The IPPP should include:

- an assessment of any upstream processes that may affect the concentration of each contaminant entering the treatment system
- a description of the technology and techniques that have been implemented to reduce contaminant concentrations and loadings to the environment
- a description of any technology and techniques that have been assessed but not yet implemented, with a schedule outlining their expected implementation dates
- the technology and techniques that will be assessed for continuous improvement to control releases to the environment during the period of the BATEA assessment
- any changes, including any special field studies, to:
  - the effluent and/or emission monitoring programs
  - the environmental monitoring programs

Within the interim period, updates to the IPPP should identify:

- the existing continuous improvement techniques being applied
- any new continuous improvement techniques that are being assessed to reduce the levels of the contaminants and physical stressors in the environment

Updates to the IPPP may be submitted as a separate report, or as a section of a routine compliance report.

## Appendix A: Role of Clearance Levels in the Graded Approach to the Application of the Environmental Protection Framework

The information in this appendix should be consulted as referred to in the applicable sections of this regulatory document. The information in this appendix applies to Class I nuclear facilities or uranium mines and mills when assessing whether a radiological contaminant requires control as per section 4.3 and appendix B of this regulatory document. In addition, the information in this appendix applies to all other nuclear facilities.

The following terminology and acronyms are provided to assist in understanding the different types of clearance levels:

- Exemption Quantity (EQ): As specified in the *Nuclear Substances and Radiation Devices Regulations*
- Clearance Levels
  - Unconditional Clearance Levels (UCLs): As specified in the *Nuclear Substances and Radiation Devices Regulations*
  - Conditional Clearance Levels (CCLs)
    - Generic CCLs: As specified in table A.1 of this appendix
    - Practice-specific CCLs: Established by the CNSC for a specific industrial facility/activity

This appendix provides information on the application of unconditional and conditional (generic conditional and practice-specific conditional) clearance levels as they relate to the need for site-specific environmental risk assessments and authorization of operational releases to the environment. As described in section 2, licensees whose routine operational releases of radionuclides meet the radionuclide specific UCLs and/or CCLs and associated conditions identified in this appendix may not require site-specific environmental risk assessments and/or site-specific licensed release limits.

To provide further clarification and to ensure that the social benefits associated with these activities are not overly burdened with regulatory requirements out of proportion with the associated radiological risk, the CNSC has developed its environmental protection (EP) decision framework as outlined in REGDOC-2.9.1 [1].

### Environmental protection requirements for licensed activities limited to the use of sealed sources

Licensed activities limited to the use of sealed sources are characterized by the following elements regarding releases of nuclear substances to the environment:

- there are no routine interactions with, or releases to, the environment
- sealed source leak testing requirements within the *Nuclear Substance and Radiation Devices Regulations* (NSRDR) and *Class II Nuclear Facilities and Prescribed Equipment Regulations* adequately address potential breaches of sealed source encapsulation, including regulatory requirements for periodic testing, mitigation, and reporting
- the *Packaging and Transport of Nuclear Substances Regulations, 2015* adequately address similar considerations for dealing with either sealed sources or unsealed radioactive materials involved in transport incidents, which could potentially result in releases to the environment

Based on these characteristics, the following conclusions are drawn regarding EP requirements for these licences:

- as there are no routine interactions with the environment, and leaks and accidents are otherwise addressed in regulation, there is no need for a site-specific ERA
- as there are no planned releases, there is no need for authorization of releases

## Environmental Protection requirements for licences involving the use of limited quantities of unsealed nuclear substances

The following criteria apply regarding disposal or releases related to the use of unsealed sources:

- standard exemption quantity and unconditional clearance levels specified in Schedules 1 and 2, respectively, of the NSRDR
- generic CCLs (documented in table A.1), on the condition that releases occur only through the specified pathway (that is, solids to municipal landfill, gases to atmosphere, liquids to municipal sewer)
- practice-specific CCLs, which are CCLs that are only applicable to a defined practice or activity, and were developed by the CNSC for application to multiple licensees carrying out the specific practice or activity

As the activities and/or concentrations associated with the above criteria were derived from conservative public exposure risk assessment modelling (using dose criteria associated with *de minimis* risk ~ 10  $\mu\text{Sv}/\text{year}$ ), there is no need for further facility/activity-specific risk assessment(s). In other words, the dose calculations associated with their derivation serves as a generic radiological ERA applicable to the facility/activity (see subsection A.1).

The criteria pertaining to unsealed sources also serve as the basis for determining whether an authorization of disposal/discharge(s) is required, inform the nature or complexity of the authorization and support determination of associated compliance activities.

Based on these criteria, where an applicant or licensee can demonstrate (that is, at the licence application stage) that releases will not exceed:

- Criterion i): standard EQs and UCLs identified in the NSRDR, then:
  - there is no requirement to authorize a release within a licence condition or the licence
  - there is no need to monitor or record releases beyond the nuclear substance record-keeping requirements specified in the NSRDR
  - the CNSC may require notification of any change in practice or activity with the potential to result in releases greater than the specified exemption quantities or UCLs
- Criterion ii): generic CCLs (see table A.1), then:
  - a licence condition is applied using the generic CCLs as licensed release limit, conditional to the specified release pathway (that is, to atmosphere, municipal sewer, municipal solid waste stream)
    - the compliance verification methodology is determined by licensing specialists using a graded, risk informed approach as appropriate to the facility/activity. Potential mechanisms include:
      - review of release or disposal records during an inspection
      - simple confirmation, for example, via the annual compliance reports that the total quantity acquired/used over one year is less than the corresponding generic CCL
- Criterion iii): practice-specific CCLs applicable to the facility/activity
  - a licence condition is applied to limit key release parameters to the levels and under the conditions incorporated within the public dose calculations used to derive the practice-specific CCL(s)
  - a monitoring program including annual reporting of releases and any associated parameters (for example, flow rates) should be required

**Note:** Subsection A.1 provides further clarification related to the application of the CCLs where the release contains more than one radionuclide.

Where an applicant or licensee is handling or producing sufficiently high radioactivity of unsealed nuclear substances under circumstances where potential releases could exceed the above criteria (i–iii), then environmental protection measures are required in accordance with the environmental protection regulatory documents REGDOC-2.9.1 [1] and REGDOC-2.9.2. Examples of such protection measures could include, but are not limited to, a site-specific ERA, radiological release limits, and monitoring and reporting requirements.

**Note:** The levels in table A.1 are screening levels below which no site-specific authorization is required. Disposal or discharge above these levels may be acceptable but requires authorization and additional site-specific supporting information and consideration of the range of environmental protection measures documented in REGDOC-2.9.1 [1].

### **A.1 Basis for the calculation of generic conditional clearance levels**

To ensure a uniform approach to the application of EP requirements as they relate to extremely low risk disposals/releases, the CNSC has developed generic CCLs. These were developed to identify levels of releases representing such low exposures and associated risks to the public/environment that there was no need for authorization for a licensee to dispose or discharge the materials through the specified pathway.

These CCLs were developed to:

- be as simple as possible but as complex as necessary
- respect current national and international practices on disposal and discharge of radioactive material, including the requirements for disposal and discharge of radioactive material in the International Atomic Energy Agency GSR Part 3, *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards* [18]
- have regard for currently available methodologies and international experience in dealing with disposal and discharge of radioactive material by users in hospitals, universities, etc. as specified in IAEA-TECDOC-1000, *Clearance of materials resulting from the use of radionuclides in medicine, industry and research* [19]
- take account of likely exposure of people and of the environment
- be based on conservative but reasonably foreseeable exposure scenarios and modelling considered applicable to Canadian conditions
- formally document and, where necessary, refine current regulatory practices

Disposal and/or discharges above CCLs require site-specific regulatory approvals.

### **Core international radiation protection concepts associated with the derivation of CCLs**

The IAEA radiation protection framework and that of the *Nuclear Safety and Control Act* (NSCA) are built on a hierarchical structure incorporating the radiation protection concepts of Exclusion, Exemption, Clearance (either unconditional or conditional) and Authorization of Discharge (that is, “release” in parlance of regulations made under the NSCA).

The various IAEA concepts can be summarized as follows. Exclusion is for sources/exposures where it is impossible to exert control over them. As such, they are completely outside of the law and warrant no further legal considerations (for example, natural background exposures – cosmic radiation, potassium-40 in foods, terrestrial radiation), as expressed in section 10 of the *General Nuclear and Safety Control Regulations* (GNSCR). Exemption is for sources/exposures where control is potentially feasible, but it is

considered unnecessary or unwarranted, and a decision is made *a priori* to exempt it from regulatory control (for example, GNSCR s.10. NSRDR s.5(1)). Clearance can be thought of as exemption from within where it serves as permission for the materials developed or arising from a regulated activity to exit the regulatory system with no further regulatory requirements or oversight (NSRDR s.5.1).

Authorization for discharge is a separate but related concept which allows the release (that is, discharge to the environment) of the substance while continuing to maintain regulatory control and oversight of the release through the maintenance of additional regulatory requirements, such as periodic re-evaluation of the adequacy of control measures, monitoring of releases and, where necessary, monitoring of the receiving environment. Authorization for discharge is not necessary for releases meeting unconditional clearance levels. Conversely, conditional clearance levels inherently require a defined set of conditions that constrain the releases, including, but not necessarily limited to, controlling the release pathway such that the basis for the CCL remains valid. This in turn implies that some form of authorization for discharge is generally required, and necessary requirements can be incorporated using a graded approach as a condition of the licence.

The International Atomic Energy Agency (IAEA), in TECDOC-1000 [19], provides:

- "... guidance on regulatory considerations in granting clearances and on the nature and scope of radiation dose calculations which must be performed in deriving clearance levels" and
- "... conservatively derived generic clearance levels ..."

These generic CCLs are described as radioisotope-specific "values, expressed in terms of release rates of radionuclides to the environment or activity concentrations in solid materials, below which there is no need for further regulatory control." These are conditional clearance levels, as the specific releases are restricted to specified release pathways, namely solids to municipal landfill, gaseous wastes to atmosphere and water-soluble liquid wastes to sewer.

The CNSC CCLs presented here have been derived using the same basic methodology as IAEA TECDOC-1000 [19], the basics of which are provided below.

### **Dose criterion for deriving generic CCLs**

The CCLs are:

- IAEA *de minimis* dose concept of 10  $\mu\text{Sv}/\text{year}$  for a member of the public
- 10  $\mu\text{Gy}/\text{hour}$  for the non-human biota.

For a member of the public, this is the same public dose value used internationally for the development of the exemption quantities and clearance levels in IAEA GSR part III and adopted by the NSCA for the *Nuclear Substances and Radiation Devices Regulations* as EQs and Unconditional Clearance Levels, respectively.

For non-human biota, an environmental dose rate of 10  $\mu\text{Gy}/\text{hour}$  was adopted as being representative of the no-effect level below which environmental risks would be negligible (Andersson et al 2009). This is the dose rate used by the ERICA Assessment Tool (Brown et al 2008, 2016) for calculating media specific screening criteria based on the limiting organism (that is, most sensitive). This dose rate is the lowest recommended internationally (that is, less than ICRP, AIAEA, UNSCEAR and U.S. DOE) and is thus considered an appropriate proxy screening value representing *de minimis* exposure for non-human biota.

## Exposure scenarios

Following the release of radionuclides, radioactive decay during transport from the point of release to the exposure location was considered. Following release to the atmosphere, buildup and decay of deposited activity on the ground was calculated over a 30-year operating period of the facility. Deposition on food crops and forage, as well as transfer to milk and meat, was calculated as per IAEA Safety Series No. 19, *Generic Models for Use in Assessing the Impact of Discharges of Radioactive Substances to the Environment* [20]. Transfer to crops occurs only during growing seasons, which were taken to be 30 days per year for forage and 60 days per year for food crops. Decay from the time of harvest to consumption was considered, assuming hold-up times of 14 days for food crops, 90 days for stored animal feed and 0 days for forage. The decay time between collecting fresh milk and consumption is 1 day, and for meat consumption, the decay time is 20 days. These decay times are consistent with those recommended in IAEA Safety Series No. 19 [20].

Two main categories of exposure were considered:

- external exposure from radionuclides present in the air or in material incorporated in soils or sediment, for example
- internal exposure from the inhalation or ingestion of radionuclides present in air or incorporated in water or foods respectively

The relative importance of different exposure pathways was dependent on the:

- magnitude of the discharge
- route of discharge
- physical and chemical characteristics of the radionuclides discharged
- characteristics of the radioactive decay

## Disposal to municipal landfill

As recommended in IAEA TECDOC-1000 [19], the CNSC has chosen to adopt the exemption and unconditional clearance levels in the NSRDR as appropriate CCLs for release to municipal landfills. These values are based on the most restrictive exposures associated with such scenarios as public exposure from tampering with the radioactive source and from inhalation, ingestion, and skin exposure pathways.

## Release to atmosphere

The licensed release limits for the release of radionuclides to the atmosphere assume that the release is from a vent from the side of a building. The receptor is assumed to reside in a building 20 m away from the source. In addition, the receptor is assumed to consume all vegetables and other crops from a location 100 m away from the source of the atmospheric releases, and that meat and milk that are consumed are from a location 800 m from the source of the releases. The licensed release limits consider the following exposure pathways:

- inhalation of radionuclides released to air
- external dose from the cloud (immersion)
- external dose from material deposited on the ground
- ingestion of radionuclides in food

## Release to sewer

For discharges to municipal sewer systems, the licensed release limits are based on 2 main groups of pathways: those resulting from the retention of radionuclides in sewage sludge at the wastewater treatment plant (WTP), and those from the wastewater treatment plant effluent discharged to a river.

The sewage sludge pathways assume that all radionuclides are retained in sludge at the WTP. The concentration in sludge is calculated assuming that the WTP serves a population of 20,000. This is a conservative assumption, since large WTPs would allow for greater dilution with waste not affected by radionuclides. Two exposure pathways to WTP workers are included:

- external exposure to sludge
- inhalation of re-suspended activity

The pathways related to discharges to a river conservatively assume that all radionuclides received at the WTP are eventually discharged to the river, with no radionuclides retained in sludge. The following pathways are included in this group:

- ingestion of radionuclides in drinking water
- ingestion of radionuclides in fish
- external dose from radionuclides in sediment

Licensed release limits are calculated separately for both groups of pathways, namely those resulting from the retention of radionuclides in sewage sludge and those from the WTP effluent discharged to a river. The limits are calculated so that the annual effective dose to the receptor is 10  $\mu\text{Sv}$  from each of the two groups of pathways. The smaller of the 2 limits calculated in this manner was rounded to the nearest multiple of 10 and selected as the CCL for sewer release.

Table A.1 lists the resultant concentrations of radionuclides at the input of the WTP. These values were calculated for a reference WTP serving a population of 20,000, as per IAEA TECDOC-1000[19]. The influent flow rate (in  $\text{m}^3/\text{year}$ ) for this reference WTP was estimated by considering Canadian WTP influent rates for 2016–18 for 3 WTPs in Toronto and 5 WTPs in Vancouver. The “per capita” annual average inflow rate was approximately 130  $\text{m}^3/\text{year}$ , which is equivalent to 2.6 million  $\text{m}^3/\text{year}$  for a population of 20,000. The values in column 4 of table A.1 were divided by 2.6 million  $\text{m}^3/\text{year}$  to obtain the resultant concentrations.

## Releases containing more than 1 radioisotope

When more than 1 radionuclide is released via 1 mode of release (that is, releases to municipal landfills, releases to the atmosphere or releases to the municipal sewer system), for each mode of release, the following condition applies:

$$\sum_{i=1}^n \frac{Q_{i,k}}{CCL_{i,k}} \leq 1$$

In the above expression:

- $Q_{i,k}$  represents the activity or activity concentration, as applicable, of radionuclide  $i$  that is released via mode of release  $k$  in 1 calendar year
- $CCL_{i,k}$  is the corresponding conditional clearance level for radionuclide  $i$ , and release mode  $k$ , as listed in table A.1
- $n$  is the number of radionuclides released via mode of release  $k$  in 1 calendar year

**Table A.1: Generic conditional clearance levels for the release of solids, liquids and gases to the environment based on conservative dose modelling approximating a *de minimis* dose of 10  $\mu\text{Sv}/\text{year}$  (5 – 20  $\mu\text{Sv}/\text{year}$ )**

Column 1	Column 2	Column 3	Column 4
<b>Radionuclide</b>	<b>Municipal landfill (Bq/g) Note: 1</b>	<b>Annual activity released to atmosphere (MBq) Note: 2</b>	<b>Annual activity released to municipal sewer (MBq) Note: 2, 3</b>
H-3	1,000,000	100,000	1,000,000
C-11	10	100,000	-
C-14	10,000	10,000	10,000
F-18	10	10,000	0.1
Na-22	10	1	0.1
Na-24	10	1,000	100
P-32	1000	100	1
P-33	100,000	1,000	10
S-35	100,000	100	1,000
Cl-36	10,000	10	10,000
Ar-37	-	1.00E+11	-
K-42	100	10,000	1,000
Ca-45	10,000	1,000	10,000
Ca-47	10	1,000	100
Sc-46	10	-	0.1
Cr-51	1,000	1,000	100
Mn-54	10	-	1
Mn-56	10	-	0.1
Fe-55	10,000	-	10,000
Fe-59	10	100	1
Co-57	100	1,000	1,000
Co-58	10	1,000	100



<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Radionuclide</b>	<b>Municipal landfill (Bq/g) Note: 1</b>	<b>Annual activity released to atmosphere (MBq) Note: 2</b>	<b>Annual activity released to municipal sewer (MBq) Note: 2, 3</b>
Co-60	10	1	0.1
Ni-63	100,000	-	10,000
Cu-64	100	-	1
Zn-65	10	10	1
Ga-67	100	10,000	100
Ge-68+	10	-	0.1
Se-75	100	100	1
Br-82	10	-	0.1
Rb-83	100	1,000	1
Rb-86	100	-	10
Sr-82+	10	100	0.1
Sr-85	100	100	1
Sr-89	1,000	100	1,000
Sr-90+	100	1	1
Y-88	10	10	0.1
Y-90	1,000	10,000	10,000
Mo-99	100	1,000	100
Tc-99	10,000	10	10,000
Tc-99m	100	100,000	1,000
Pd-103	1,000	-	10
Ag-110m	10	-	0.1
Cd-109	10,000	100	10
In-111	100	1,000	100
Sb-124	10	-	0.1
Sb-125	100	100	1

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Radionuclide</b>	<b>Municipal landfill (Bq/g) Note: 1</b>	<b>Annual activity released to atmosphere (MBq) Note: 2</b>	<b>Annual activity released to municipal sewer (MBq) Note: 2, 3</b>
I-123	100	10,000	1,000
I-124	10	100	10
I-125	1,000	100	100
I-131	100	100	10
Xe-127	-	100,000	-
Xe-133	-	1,000,000	-
Cs-125	10	-	100,000
Cs-134	10	-	0.1
Cs-137	10	-	1
Ba-133	100	-	1
La-140	10	-	0.1
Ce-139	100	100	1
Ce-141	100	-	10
Ce-143	100	-	1
Nd-147	100	-	1
Pm-147	10,000	10,000	10,000
Sm-153	100	-	10
Eu-152	10	1	1
Eu-154	10	1	1
Gd-153	100	-	10
Er-169	10,000	10,000	10,000
Tm-170	1,000	1,000	100
Yb-169	100	100	1
Lu-177	1,000	1,000	10
Lu-177m	10	-	0.1

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Radionuclide</b>	<b>Municipal landfill (Bq/g) Note: 1</b>	<b>Annual activity released to atmosphere (MBq) Note: 2</b>	<b>Annual activity released to municipal sewer (MBq) Note: 2, 3</b>
Re-186	1,000	1,000	10
Ir-192	10	-	1
Au-198	100	1,000	100
Hg-194	10	-	10
Hg-197	100	10,000	1,000
Hg-203	100	100	10
Tl-201	100	10,000	100
Tl-204	10,000	-	100
Pb-210+	10	-	1
Bi-210	1,000	-	10
Po-208	10	-	10
Po-209	10	-	10
Po-210	10	-	10
Ra-223+	100	-	1
Ra-224+	10	-	0.1
Ra-226	10	1	1
Ra-228+	10	0.1	0.1
Ac-227+	0.1	-	1
Th-230	1	-	100
Th-228	1	-	100
Th-228+	1	0.1	0.1
Th-229	1	-	1
Th-232	1	0.1	1
U-232+	1	-	0.1
U-233	10	1	-

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Radionuclide</b>	<b>Municipal landfill (Bq/g) Note: 1</b>	<b>Annual activity released to atmosphere (MBq) Note: 2</b>	<b>Annual activity released to municipal sewer (MBq) Note: 2, 3</b>
U-235	10	1	-
U-234	10	1	-
U-238	10	1	-
Np-237	1	-	10
Pu-238	1	0.01	1
Pu-239	1	-	1
Pu-240	1	-	1
Am-241	1	0.1	10
Am-243+	1	-	1
Cm-244+	10	0.1	0.1

**Notes:**

1. Standard licence condition includes a limit of 3 tonnes per building per year, and a requirement for demonstration of uniformity of distribution of the radionuclide.
2. The CCLs apply to a site that may consist of several buildings. For example, a hospital to university may be considered a site, from which there could be several points of release to a sewer or to the atmosphere.
3. The CCLs for releases to the sewer apply only to water-soluble liquids.

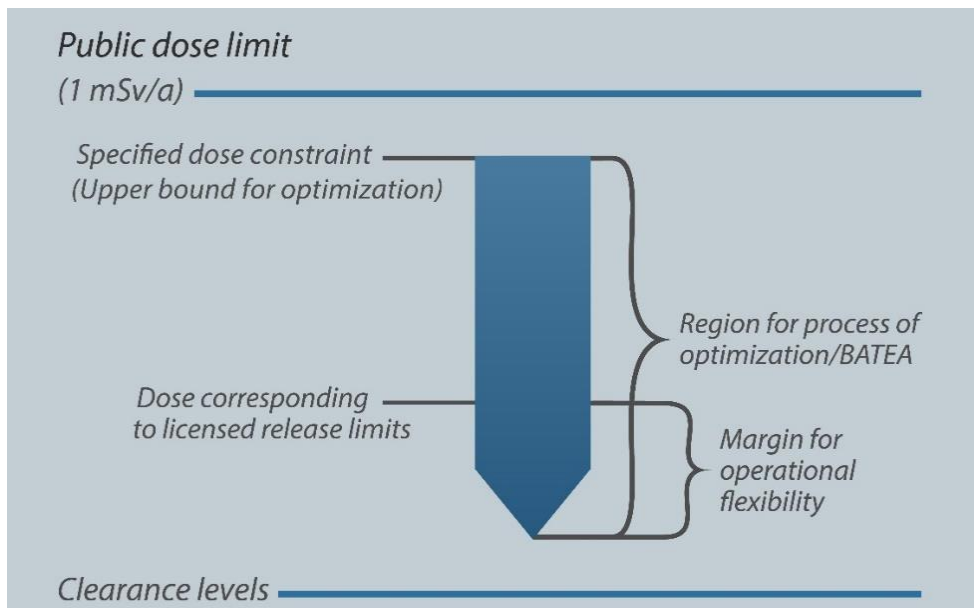
## Appendix B: Additional Information

### B.1 Optimization of Protection and Pollution Prevention

The radiation protection principle of optimization of protection can be considered as complementary to the environmental protection principle of pollution prevention. In practice, the application of BATEA is part of optimization of protection that is specific to the minimization of contaminant pollution through the control on releases to the environment, with the additional concept of ensuring that any trade-offs associated with worker and public dose are balanced out (that is, the limit of release for a small reduction in public dose is not at the expense of a large increase in worker dose). The dose associated with the final optimized release is simply an artifact of optimization; it is not the target of the optimization (dose constraints are sometimes inappropriately interpreted as being site-specific dose limits or targets for establishing site-specific licensed release limits, rather than as tools for guiding optimization).

Figure B.1 shows a general relationship between optimization and the authorization of radioactive releases to the environment (that is, licensed release limits). Through optimization, licensed release limits for both nuclear and hazardous substances can be identified. Additionally, optimization requires the application of BATEA to control releases such that they represent a site-specific public dose or doses constrained to a region less than the public dose limit (specified dose constraint) but greater than doses considered to be “de minimis.” Internationally, effective doses of approximately 10 microSieverts ( $\mu\text{Sv}$ ) per year have been used to derive clearance levels (unconditional or conditional) representing radionuclide activities (total or concentrations) that can be cleared from any further regulatory control.

**Figure B.1: Relationship between optimization and the authorization of releases to the environment<sup>1</sup>**



<sup>1</sup> Figure adapted from IAEA, General Safety Guide No. GSG 9, *Regulatory Control of Radioactive Discharges to the Environment*, Vienna, Austria, 2018 [20].

When applying the concept of optimization to establish licensed release limits, modelled doses approximating 10  $\mu\text{Sv}/\text{year}$  are recommended as the level below which further optimization and application of BATEA are no longer necessary. However, it is necessary to make a distinction between this dose criterion (that is, 10  $\mu\text{Sv}/\text{year}$ ) applied to a site-specific dose assessment associated with a licence application, versus its use in developing exemption and clearance levels. The former tends to incorporate relatively realistic (but still conservative) site-specific transport and exposure scenarios. The latter are deliberately hyper-conservative to ensure that exemption from licensing or from discharge authorization can be safely given under a wide range of scenarios encompassing a range of potential site-specific variability. Authorized releases remain under regulatory control (including periodic re-evaluation, monitoring requirements and annual public dose calculations), while exemptions from licensing or authorization result in no further regulatory controls post-release (that is, no licence requirements to receive the materials, and no environmental monitoring), hence the need for the hyper-conservatism.

Thus, licensees (other than Class I facilities and uranium mines and mills, whose routine operational releases of radionuclides meet the radionuclide-specific conditional clearance values and associated conditions identified in appendix A) may not require further regulatory authorization for their releases. For more information, see appendix A.

The approved facility or activity design will have demonstrated to the satisfaction of the CNSC that BATEA has been applied regarding the minimization of waste production and the control of releases. The maximum releases associated with the approved optimized design (which includes the addition of a margin for operational flexibility) become the authorized licensed release limits (for more information, see section 5). The dose associated with these releases can then be determined through the application of the site-specific radionuclide transport and exposure pathway model. This calculated public dose can be used for public risk communication purposes indicating that releases have been constrained to levels representing exposures lower than the regulatory public dose limit.

As the licensed release limit is based on the expected maximum release (including a margin for operational flexibility), any exceedance of this limit represents a release outside of the licensing basis and demonstrates a lack of compliance with the licence, and therefore indicates a failure in the design or operation of the facility or activity. Thus, the licensee would be non-compliant under section 12(1)(f) of the *General Nuclear Safety and Control Regulations*. However, as the licensed release limit is based on the optimized design representing a public dose less than 1 mSv/year, the exceedance would not necessarily represent an exceedance of the *Radiation Protection Regulations* public dose limit and is in no way meant to replace that public dose limit. For more information, see section 5.

Optimization is a core element of the design and planning process. Optimization of protection regarding radioactive discharges is not simply a matter of considering the balance between the radiation risks associated with the discharges during normal operation and the costs of making any reductions. The effect of waste management decisions on the exposure of workers and on the safety of the entire facility or activity should also be considered. For example, a reduction in discharges may lead to an increase in radioactive waste stored on the site, with related increases in occupational exposures; therefore, such a reduction may not be the optimal solution.

### **Optimization and dose constraints**

Public dose constraints are estimates of public dose, less than the regulatory public dose limit, that are either established or approved by the CNSC for use in the optimization process. The dose constraint for each source is intended to ensure that the sum of doses from planned operations of that source and of all the authorized sources that may contribute to the exposure of the public remains within the dose limit (see figure 1).

Dose constraints may be generic (that is, applicable to a specific subsector of the nuclear fuel cycle) or specific to a facility or activity being regulated. The CNSC may specify a generic dose constraint for a subsector or approve a facility- or activity-specific dose constraint based on an applicant's or licensee's demonstration of BATEA regarding facility design and control on releases. In situations where multiple licensees may be operating in close proximity (for example, nuclear research or energy parks), the CNSC will specify a facility- or activity-specific dose constraint as an upper bound for the optimization process (see figure 1). This factor ensures responsible apportionment of the 1 mSv/year dose limit to the public from all sources.

During the design phase, modern facility designs, which incorporate BATEA and both minimize waste production and control releases, are reviewed to establish a range of maximum predicted design quantities and concentrations of radionuclides that can be released during normal operation. For each design option, the site-specific public dose calculations, using these maximum design releases, provide the maximum equivalent doses associated with the various design options. These feed into the overall optimization process, which considers cost-benefit trade-offs between worker and public dose (see figure 1). The maximum predicted design quantities and concentrations corresponding to the best option (regarding optimization), along with a margin of error to provide operational flexibility, establishes the licensed release limits.

The public dose corresponding to the licensed release limits is determined through the application of these limits to the site-specific environmental transport and exposure model (for example, CSA N288.1, *Guidelines for modelling radionuclide environmental transport, fate, and exposure associated with the normal operation of nuclear facilities* [2]). Thus, rather than the CNSC specifically defining dose constraints, the CNSC reviews and approves the facility or activity design and the controls on releases to determine the adequacy of the application of BATEA within the optimization process and the acceptability of the associated public dose outcomes.

## **B.2 Environmental release targets, maximum predicted design release characteristics, licensed release limits, and action levels**

REGDOC-2.9.2 adopts an internationally recognized framework for controlling releases to the environment, through the application of the principle of optimization of protection, pollution prevention and BATEA.

Within this framework, for new facilities or existing facilities undergoing a major modification that require a BATEA assessment, risk-based guidelines in the receiving environment (for example, radiological dose constraints, CCME Environmental Quality Guidelines, Canadian Ambient Air Quality Standards) are used to establish environmental release targets (ERTs), taking into consideration an acceptable level of dilution within the environment (based on applicable federal/provincial guidelines) to ensure the environment remains protected. There may be instances where technology-based limits from other jurisdictions that are applicable to the facility already exist, and in those cases should be considered as potential environmental release target(s). In this scenario, the most restrictive of the exposure-based or technology-based targets should be carried through the assessment as the ERT.

The selected ERTs are used as the basis for the design of the treatment system. As part of the BATEA assessment, an options analysis is conducted to identify the most appropriate technology and techniques that have been demonstrated on an industrial scale to achieve the ERTs. Hence, since the treatment system is designed to meet the ERTs, the treatment system is designed to meet risk-informed targets.

The design option identified as BATEA may achieve significantly better effluent or emissions quality for some contaminants under their maximum design conditions (that is, maximum expected influent

concentrations and flow rates). Likewise, the design option may be unable to achieve the ERTs for other contaminants, and the applicant may be limited by the current state of technology and techniques. This residual release merits site-specific risk assessment to ensure there is no unreasonable risk to the environment and may require additional follow-up monitoring (assessed during the establishment of proposed release limits).

The proponent identifies the maximum predicted design release characteristics (MPDRCs) based on the identified BATEA design option, taking into account a margin for operational flexibility. If, for an existing facility, no design documentation is readily available, a licensee should apply historical performance data, to determine the MPDRCs. This should be informed by site-specific knowledge and professional judgement, and factor in a margin for operational flexibility to account for anticipated operations throughout the remaining lifecycle of the facility.

The MPDRCs are used to develop the proposed release limits; however, to reduce regulatory duplication, proposed release limits should first be harmonized with applicable limits in other jurisdictions. In cases where applicable federal, provincial, territorial, and/or municipal release limits already exist, these limits can be adopted in order to harmonize with other regulators, as long as they are protective. Where no limits exist, or where existing limits are deemed by the CNSC to not be protective (for example, based on an assessment within the ERA), then the MPDRCs, which now form part of the licensing basis of the facility, are established as the proposed release limits. It should be re-iterated that licensed release limits that are developed from MPDRCs are based on the design of the facility, which in itself is risk-informed. The proposed release limits are then used in a scenario using environmental risk assessment (ERA) methodology to confirm that the environment will be protected.

Since the licensed release limits represent the maximum concentrations and quantities that could be released from the facility during normal operation, exceeding a licensed release limit signals that the licensee is operating outside the licensing basis (that is, approved facility design) for normal operation, and represents a clear loss of control of the environmental protection program and/or control measure(s). A release outside of the licensing basis indicates a major failure of control systems.

Since licensed release limits that are based on the MPDRCs depend on the design of the facility, they do not change over time, unless there is a major modification to the nuclear facility and/or activity that has the potential to increase or change the nature of releases to the environment and the resulting risks to receptors that would be outside the existing licensing basis.

Action levels are operationally/performance-based, are derived using the current upper value of normal operation and lie within the maximum upper-end of normal operation (that is, licensed release limit). Licensed release limits that are based on the maximum predicted design release depend on the design of the facility and represent the maximum upper end of normal operation over the entire lifecycle of the facility.

For existing facilities, there should be sufficient margin between the action level and the licensed release limit, as described above. This is due to the fact that the facility is not likely to operate at its maximum design capacity throughout its entire lifecycle. There is a margin of operational flexibility incorporated into the licensed release limit (through the MPDRCs), and most importantly, licensees are required to apply the principles of continuous improvement, ALARA and the BATEA throughout the operating lifecycle of the facility.

For new facilities, during the initial period of operation when no historical performance data exists, action levels are based on a prospective approach to account for operational uncertainty (in accordance with CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear*



*facilities* [7]). With this approach, the action level may be set at the same magnitude as the licensed release limit; however, the sample type and averaging period that would apply to either would be different. Once sufficient operating data is available, in accordance with CSA N288.8 [7], action levels would be revised using a retrospective approach. The newly revised action levels should lie within the maximum upper end of normal operation (that is, below the licensed release limit), and there should be sufficient margin between the action level and the licensed release limit.

The environmental releases (effluent and/or emissions) monitoring program results (for example, daily or weekly grab or composite sample concentrations, daily or weekly or monthly loading rate) that correspond to a licensee's effluent and/or emission monitoring program, designed in accordance with CSA N288.5, *Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills* [4], are assessed against the action levels to determine whether an action level has been reached. Monitoring results averaged over a longer period (for example, weekly, monthly or biannual average concentrations) are assessed against the licensed release limits to ensure that the licensee is not operating outside of their licensing basis. This provides multiple early warnings, and allows time for the licensee to respond to the triggering of these action levels and restore the effectiveness of the program before a licensed release limit is potentially exceeded and complete loss of control occurs. If weeks have gone by and the licensee has triggered the action level repeatedly with little response, this may result in exceeding the licensed release limit, and is in itself a demonstration of loss of control of the environmental protection program.

## Appendix C: Establishing Environment Release Targets

This appendix provides guidance on establishing environmental release targets.

### C.1 Introduction

Environmental release targets apply during the design and commissioning phases. If these targets cannot be met, they become integrated as targets or objectives in the environmental management system (EMS). Environmental release targets are not licensed release limits but are guides in the design and development of the maximum predicted design release characteristics that become the licensed release limits.

Environmental release targets are used as criteria to inform the design of wastewater treatment systems or air pollution control systems, to constrain the quantity and concentration of contaminants and physical stressors released into the environment. Environmental release targets ensure:

- risks to human health and the environment are mitigated
- the identification of acceptable control measures (including abatement strategies) for pollution prevention (for example, to establish a minimum level of protection across a specified industrial sector)
- continuous improvement for proactive pollution prevention and control (for example, for those adopted into the EMS as continuous improvement objectives or targets)

To meet these objectives, environmental release targets are established using one of the following approaches:

- an exposure-based approach (to meet protective environmental quality guidelines at an acceptable location within the receiving environment)
- a technology-based approach (to meet technology-based licensed release limits or design criteria existing in federal, provincial/territorial, or municipal requirements or as recommended by the CNSC and in consultation with the applicant or licensee)
- a combination of exposure-based and technology-based approaches

The most restrictive environmental release targets should be used.

**Note:** Environmental release targets that are technology-based may be equivalent to licensed release limits in existing federal, provincial/territorial or municipal requirements (for example, *Metal and Diamond Mining Effluent Regulations*). Provided they are the most stringent, they are used to inform the design of the wastewater treatment systems or air pollution control systems.

### C.2 Overview of the process

The licensee should establish environmental release targets using a systematic and informed process.

A summary of a sample systematic and informed process is as follows:

1. identify the final effluent or emission release points
2. identify the contaminants and physical stressors that require environmental release targets
3. where appropriate, identify existing federal, provincial, territorial, and municipal requirements, and harmonize with those requirements

4. where step 3 does not apply:
  - a. calculate the proposed environmental release targets for each contaminant and physical stressor, using one of the following approaches:
    - i. an exposure-based approach for nuclear substances
    - ii. an exposure-based approach for hazardous substances
    - iii. a technology-based approach for nuclear and hazardous substances

**Note:** For substances that are considered both a nuclear substance and a hazardous substance (for example, uranium), calculate the proposed environmental release targets using all applicable approaches.
  - b. select the most restrictive environmental release targets identified in step a
5. document and justify selection of the proposed environmental release targets

For additional details on each step, see the following sections.

### **C.3 Identify final release points**

The licensee should identify all points of controlled releases (effluent or emission) from the facility or activity to the environment.

### **C.4 Identify contaminants and physical stressors that require control**

The licensee should conduct a screening assessment, as described in section 4.3, to identify the contaminants and physical stressors that require control, such as those that are:

- subject to existing federal, provincial, territorial, or municipal requirements
- potentially exceeding federal, provincial, or territorial environmental quality criteria prior to the consideration of treatment
- identified as exceeding standard conditional clearance levels established by the CNSC (see appendix A)
- meriting control (according to the environmental risk assessment (ERA))

### **C.5 Calculate the proposed environmental release target**

The licensee should calculate a proposed environmental release target for each contaminant and physical stressor that has been identified.

The licensee should use either an exposure-based approach for nuclear substances, an exposure-based approach for hazardous substances, a technology-based approach, or a combination of all applicable approaches.

#### **C.5.1 Exposure-based approach for nuclear substances**

For nuclear substances, the licensee should develop environmental release targets using a structured approach. The following is a sample methodology:

- identify an appropriate dose constraint to a representative person or critical group (this may be informed by the historic performance of the facility or activity, or of existing similar facilities or activities, or as specified by the CNSC)
- for each radionuclide that may be released, calculate an environmental release target from the dose constraint to the effluent or emission source (back calculation) using an appropriate environmental transport and pathway exposure model

For additional guidance on appropriate environmental transport and exposure pathway models, see:

- REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures* [1]
- CSA N288.1, *Guidelines for modelling radionuclide environmental transport, fate, and exposure associated with the normal operation of nuclear facilities* [2]
- CSA N288.6, *Environmental risk assessment at Class I nuclear facilities and uranium mines and mills* [5]
- IAEA, TECDOC 1714, *Management of Discharge of Low Level Liquid Radioactive Waste Generated in Medical, Educational, Research and Industrial Facilities* [22]

**Note:** CNSC staff may accept the use of alternate methodologies based on the nature of the nuclear facility or activity.

### **C.5.2 Exposure-based approach for hazardous substances**

For hazardous substances, the licensee should develop environmental release targets using a structured approach. The following is a sample methodology:

1. For each contaminant or physical stressor identified as requiring control at each release point, determine the most restrictive applicable environmental quality criteria that is protective of the most sensitive species, human receptor (generic or site-specific) or end use (for example, drinking water, recreational waters).
2. Determine the specific point within the environment at which the selected environmental quality criteria is expected to be achieved
3. Identify an appropriate environmental transport and exposure pathway model whose complexity is determined by the receptor or end use as follows:
  - for releases to surface waters for the protection of aquatic life, protection of drinking water, or protection of recreational use, a simple mixing zone approach is acceptable
  - for releases to air for the protection of human health, a point-of-impingement (POI) approach is acceptable
  - for all other releases, including those to groundwater for the protection of drinking water or other end uses, the licensee should propose an appropriate model
4. Calculate the environmental release target from the receptor or end use to the final point of release; this release target cannot be acutely lethal at the point of discharge (see section 3.1)

The most restrictive criteria may include:

- federal environmental quality guidelines, such as:
  - CCME *Guidance on the Site-Specific Application of Water Quality Guidelines in Canada* [23]
  - CCME *A Protocol for the Derivation of Water Quality Guidelines for the Protection of Aquatic Life 2007* [24]
- provincial or territorial standards, objectives, criteria, or guidelines

The most sensitive site-specific species may be identified as a valued component and is generally informed by an ERA.

For releases to air, for a POI approach, the POI should be defined to align with the applicable federal or provincial requirements.

For more information about releases to groundwater, see CSA N288.7, *Groundwater protection programs at Class I nuclear facilities and uranium mines and mills* [6].

### C.5.2.1 Dilution Factors

For calculating the environmental release targets:

- where federal, provincial, or territorial guidance exists for dilution factors, the licensee should follow that guidance
- where such guidance does not exist, the licensee should apply the general rules shown in table B.1

**Table B.1: General rules for using mixing zones for calculating environmental release targets (adapted from *Calculation and Interpretation of Effluent Discharge Objectives for Contaminants in the Aquatic Environment*, 2nd Edition [25])**

Release point	Dilution factor
Lake	1 in 10
Slow-moving stream or river	1 in 100
Fast-moving stream or river	1 in 100 (based on critical low flow)
Groundwater	Modelled based on distance to the designated end use
Air	Modelled based on distance from the stack to the POI using an acceptable dispersion model (for example, the AERMOD air dispersion model)

For more information on site-specific determination of the spatial extent of the initial mixing zone (also called a dilution zone), see provincial mixing zone guidance (for example, *Calculation and Interpretation of Effluent Discharge Objectives for Contaminants in the Aquatic Environment*, 2nd Edition [25] and *CCME Guidance on the Site-Specific Application of Water Quality Guidelines in Canada* [23]).

### C.5.2.2 Releases to sewer

Releases to sewer are considered a special case.

For releases to sewer:

- the licensee should use applicable municipal bylaw limits as the environment release targets
- for substances where no limit is specified by the municipality, the licensee should use an exposure-based approach, where the calculation considers:
  - an appropriate mixing zone in the final receiving waterbody applied only to the volume of effluent released into the sewer by the licensee
  - additional dilution from the collection of other municipal waters by the municipal wastewater treatment plant

**Note:** The calculation of the environmental release targets should not consider any treatment provided by the municipal wastewater treatment plant.

The mixing zone:

- applies only to the controlled volume regulated by the CNSC
- does not apply to the collection of other municipal waters, as they are not regulated by the CNSC

### C.5.2.3 Releases into cooling water discharge

Similarly, releases that enter or mix with cooling water discharge, are considered a special case.

The licensee should use an exposure-based approach, where the calculation considers:

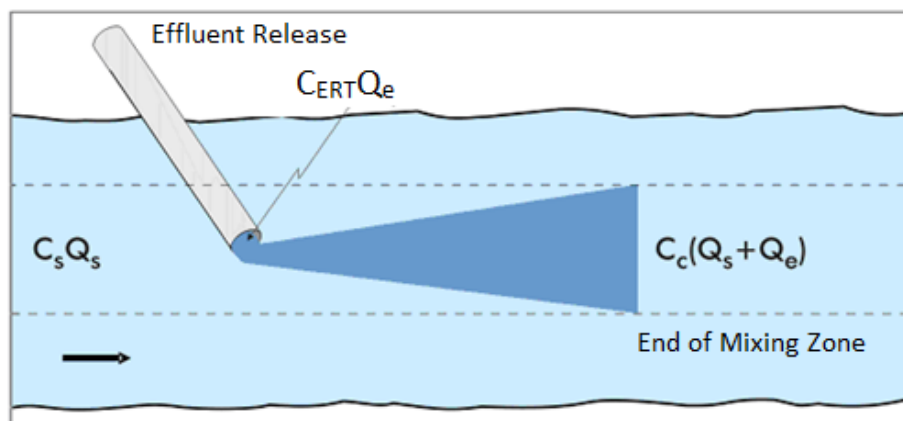
- an appropriate mixing zone in the final receiving waterbody applied only to the volume of effluent released prior to mixing with cooling water discharge
- additional dilution provided by the volume of cooling water discharge

The mixing zone applies only to the controlled volume released prior to mixing with cooling water discharge.

### C.5.2.4 Example calculations of exposure-based environmental release targets for hazardous substances released to surface water using a simple mixing zone approach

For releases to surface waters for the protection of aquatic life, protection of drinking water, or protection of recreational use, a simple mixing zone approach is acceptable. An example of a mixing zone model is provided in figure C.1.

**Figure C.1: Elements of the loading mass balance**



Based on the mixing zone approach, the following mass balance can be derived:

$$C_c(Q_s + Q_e) = C_s Q_s + C_{ERT} Q_e \quad [1]$$

where:

- $C_c$  is the concentration corresponding to the water quality criterion
- $C_s$  is the upstream or background concentration
- $C_{ERT}$  is the effluent concentration corresponding to the environmental release target
- $Q_s$  is the upstream flow rate
- $Q_e$  is the effluent flow rate

The above mass balance can then be re-arranged to isolate for  $C_{ERT}$ , to back-calculate the ERT from the appropriate water quality criteria, where:

$$C_{ERT} Q_e = C_c(Q_s + Q_e) - C_s Q_s \quad [2]$$

$$C_{ERT} = \frac{C_c(Q_s + Q_e) - C_s Q_s}{Q_e} \quad [3]$$

A dilution factor can be defined as:

$$Fd = \frac{Q_e}{Q_s + Q_e} \quad [4]$$

Through the substitution of equation [1] and equation [4] into equation [3], a simplification can be made where the resulting equation is independent of effluent and upstream flow rate and can be calculated by knowing the upstream or background receiving water concentrations, the appropriate water quality criteria for the relevant designated use, and its corresponding dilution factor.

$$C_{ERT} = \frac{C_e - C_s}{Fd} + C_s \quad [5]$$

The dilution factor should be selected based on existing federal, provincial, or territorial guidance, or when none exists, on the general mixing zone rules provided in table B.1.

### C.5.3 Technology-based approach

The licensee should develop the environmental release targets to ensure that acceptable control measures (including abatement strategies) for pollution prevention are applied by considering:

- any technology-based release limits or targets that already exist in other international, federal, provincial, territorial, or municipal requirements and guidance
- when necessary, any technology-based release targets established by the CNSC for substances of common concern within a sector
- historical performance of the facility or activity, including known or identified loss-of-control events

**Note:** Technology-based release limits are included in federal and provincial legislation. For example, the *Metal and Diamond Mining Effluent Regulations* (SOR/2002-222) use technology-based release limits to establish a baseline level of protection across a specified industrial sector.

### C.6 Select the most restrictive environmental release targets

To ensure that all intended objectives are met, the licensee should review the environmental release targets that have been identified and select the most restrictive ones.

### C.7 Document and justify the selection

The licensee should document:

- the environmental release targets that have been selected
- the methodology used to establish them
- justification for selection of the final values

## **Appendix D: Guidance on Developing a Commissioning Plan and on Confirming Performance of a Treatment System**

Some examples of treatment systems are wastewater control treatment systems and air pollution control treatment systems.

### **D.1 Additional guidance for developing a commissioning plan for a treatment system**

As described in section 7, the applicant or licensee submits a commissioning plan to the CNSC. The commissioning plan should consider the following information.

#### **Commissioning schedule and process**

The applicant or licensee should establish a schedule (an expected timeframe) for completion of commissioning. The schedule should:

- consider seasonal variations and their effects on operations and process (for example, effects of levels of contaminants and physical stressors, volume of effluent)
- indicate the commissioning dates of different subsystems (for example, water treatment subsystems, residual solids management) and identify where limitations may be encountered (for example, delays in testing or delivery of specialty parts or equipment)

The applicant or licensee should describe the overall commissioning process. For example:

- factory acceptance testing
- installation acceptance inspection (also referred to as site acceptance testing (SAT))
- start-up testing
- non-active functional testing
- non-active operational training
- transition from non-active to active
- active operational training
- active performance testing

#### **Description of responsibilities**

The applicant or licensee should provide a list of position titles, a list of any external personnel involved in commissioning activities, and descriptions of their responsibilities.

For example, the applicant or licensee may include a description of the commissioning team, operations staff, licensing representatives, facility manager, management system personnel (in particular, those responsible for quality assurance and quality control (QA/QC)), and external organizations.

#### **Transitioning to the next stage of commissioning (“package turnover”)**

The applicant or licensee should describe the turnover process from inactive commissioning to active commissioning, and from active commissioning to operations. The description should include the contents of the turnover package.

Typical contents of a turnover package may include:

- operations and maintenance manuals and data
- standard operating procedures (SOPs)
- as-built drawings and specifications



- installation checklists, product information and data, and performance verification records
- spare parts, special tools, and maintenance materials
- materials samples and finishes, and related information
- training manuals and resources
- results of SAT and factory acceptance testing (FAT)
- inspection and manufacturer's certificates
- a final site survey

### **Operational performance**

The applicant or licensee should describe the operational performance for commissioning activities, including:

- checking process systems and unit operations to ensure they are operating correctly
- an ongoing assessment of influent/effluent and/or emission quality, removal efficiencies, flow rates and total loadings
- any revisions to the operation and maintenance manual that reflect actual operating experiences
- operator training
- engineering consultation
- reviewing laboratory procedures
- other activities as appropriate to the facility or activity

### **Performance assessment**

The applicant or licensee should describe the performance assessment, including an assessment of operational performance against the performance criteria developed during the design of the facility or activity (including all performance criteria, not specific to effluent or emissions quality).

Regarding effluent or emissions quality and regulatory requirements, the licensed release limits and environmental release targets should be used as the criteria to assess the performance.

### **Management system (particularly quality assurance / quality control)**

The applicant or licensee should provide a description of how the management system (particularly quality assurance and quality control) will be applied to commissioning.

**Note:** Not all facilities or activities require a full management system.

### **Safety**

The applicant or licensee should reference any occupational health and safety (OHS) and radiation protection requirements relevant during commissioning. In particular, any new safety aspects arising from the commissioning and eventual operation of the new system should be identified and addressed.

### **Training**

The applicant or licensee should describe a training plan for the commissioning and operation of the treatment system that ensures the staff are trained appropriately. For more information, see REGDOC-2.2.2, *Personnel Training* [26].

### **Records and records maintenance**

The applicant or licensee should provide references for records and records maintenance, such as:

- the SOPs that will be developed
- the process for revising, finalizing, and maintaining the SOPs for each process or system as part of the systems operations and maintenance manuals, to reflect actual operating experience
- the results of SAT and FAT
- site drawings
- verification reports
- product information

### **Site plan and sample locations**

The applicant or licensee should provide a site plan that includes:

- a process diagram of the treatment system
- the location of the influent and effluent and/or emissions sampling points (to assess the performance of pertinent unit operations)

## **D.2 Additional guidance for confirming performance of the treatment system**

As described in section 7, the licensee confirms the performance of the treatment system.

### **Confirm whether the action levels remain appropriate**

The licensee should review the commissioning performance results to confirm that the action levels remain indicative of a potential loss of control of the environmental protection program or control measures.

If the action levels do not remain appropriate, the licensee should revise them in accordance with CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities* [7].

The licensee may use the prospective approach and should update the action level documentation accordingly.

### **Assess the operating performance against the environmental targets**

The licensee should assess the operating performance against the environmental targets. If any environmental targets cannot be met, the licensee should integrate them as objectives for continuous improvement within the licensee's environmental management system.

### **Develop a commissioning report**

The commissioning report should include the following information:

- influent and effluent and/or emissions performance data
- calculated treatment efficiencies
- a comparison of actual performance data to the maximum predicted design release characteristics
- trending of data over time
- a comparison of performance data to the environmental release targets

- confirmation that the action levels are appropriate
- confirmation that the licensed release limits are being met

**Note:** CNSC staff may conduct a commissioning inspection that includes taking independent influent and effluent samples to confirm the performance results.

## 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.

The following terms are either new terms being defined, or include revisions to the current definition for that term. Following public consultation, the final terms and definitions will be submitted for inclusion in the next revision of REGDOC-3.6, *Glossary of CNSC Terminology*.

## 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 webpage “[How to gain free access to all nuclear-related CSA standards](#)”.

1. Canadian Nuclear Safety Commission (CNSC), REGDOC-2.9.1, [Environmental Principles, Assessments and Protection Measures 1.1](#), Ottawa, Canada, 2017.
2. CSA Group, CSA N288.1, [Guidelines for modelling radionuclide environmental transport, fate, and exposure associated with the normal operation of nuclear facilities](#).
3. CSA Group, CSA N288.3.4, [Performance testing of nuclear air-cleaning systems at nuclear facilities](#), reaffirmed in 2018.
4. CSA Group, CSA N288.5, [Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills](#).
5. CSA Group, CSA N288.6, [Environmental risk assessment at Class I nuclear facilities and uranium mines and mills](#).
6. CSA Group, CSA N288.7, [Groundwater protection programs at Class I nuclear facilities and uranium mines and mills](#).
7. CSA Group, CSA N288.8, [Establishing and implementing action levels for releases to the environment from nuclear facilities](#).
8. CNSC, REGDOC-3.2.1, [Public Information and Disclosure](#), Ottawa, Canada, 2018.
9. CNSC, REGDOC-2.3.1, [Conduct of Licensed Activities: Construction and Commissioning Programs](#), Ottawa, Canada, 2016.
10. CNSC, REGDOC-2.3.3, [Periodic Safety Reviews](#), Ottawa, Canada, 2015.
11. CNSC, REGDOC-2.6.3, [Aging Management](#), Ottawa, Canada, 2014.
12. CNSC, REGDOC-3.5.3, [Regulatory Fundamentals](#), Ottawa, Canada, 2023.
13. Ontario Regulation, [O. Reg. 419/05: AIR POLLUTION – LOCAL AIR QUALITY](#), 2022.
14. CNSC, REGDOC-3.1.1, [Reporting Requirements for Nuclear Power Plants](#), Ottawa, Canada, 2016.
15. CNSC, REGDOC-3.1.2, [Reporting Requirements, Volume 1: Non-Power Reactor Class I Facilities and Uranium Mines and Mills](#), Ottawa, Canada, 2022.
16. CNSC, REGDOC-3.1.3, [Reporting Requirements for Waste Nuclear Substance Licensees, Class II Nuclear Facilities and Users of Prescribed Equipment, Nuclear Substances and Radiation Devices](#), Ottawa, Canada, 2020.
17. U.S. Department of Defense, Military Handbook: [Planning and Commissioning Wastewater Treatment Plants](#), MIL-HDBK-353, United States of America, 1996.
18. IAEA, [GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards](#), Vienna, Austria, 2014.
19. IAEA, [TECDOC-1000, Clearance of Materials Resulting from the Use of Radionuclides in Medicine, Industry and Research](#), Vienna, Austria, 1998.
20. IAEA, Safety Series No. 19, [Generic Models for Use in Assessing the Impact of Discharges of Radioactive Substances to the Environment](#), Vienna, Austria, 2001.

21. IAEA, IAEA GSG-9: [Regulatory control of discharges to the environment: General Safety Guide](#), Vienna, Austria, 2018.
22. IAEA, IAEA TECDOC 1714, [Management of Discharge of Low Level Liquid Radioactive Waste Generated in Medical, Educational, Research and Industrial Facilities](#), Vienna, Austria, 2013
23. Canadian Council of Ministers of the Environment (CCME), Canadian Water Quality Guidelines for the Protection of Aquatic Life, [Guidance on the Site-Specific Application of Water Quality Guidelines in Canada](#), 2003.
24. CCME, Canadian Water Quality Guidelines for the Protection of Aquatic Life, [A Protocol for the Derivation of Water Quality Guidelines for the Protection of Aquatic Life](#), 2007.
25. Ministère du Développement durable, Environnement et Parcs Québec, [Calculation and Interpretation of Effluent Discharge Objectives for Contaminants in the Aquatic Environment](#), 2<sup>nd</sup> Edition, 2007 (translation, 2008).
26. CNSC, REGDOC-2.2.2, [Personnel Training](#), Ottawa, Canada, 2016.

## Additional Information

The CNSC may recommend additional 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 webpage “[How to gain free access to all nuclear-related CSA standards](#)”.

The following documents provide additional information that may be relevant and useful for understanding the requirements and guidance provided in this regulatory document:

- IAEA, [Application of the Concepts of Exclusion, Exemption and Clearance](#), IAEA Safety Guide No. RS-G-1.7., 2004.
- Canadian Environmental Assessment Agency, [Practitioners Glossary for the Environmental Assessment of Designated Projects Under the Canadian Environmental Assessment Act, 2012](#), Ottawa, Canada
- CSA Group, CAN/CSA ISO 14001, [Environmental Management Systems – Requirements with Guidance for Use](#), 2004 (1st edition).  
or  
CSA Group, CAN/CSA ISO 14001, [Environmental Management Systems – Requirements with Guidance for Use](#) (successor editions).
- CSA Group, CSA N288.0, [Environmental management of nuclear facilities: Common requirements of the CSA N288 series of Standards](#), 2022 (1st edition).
- CSA Group, CSA N288.4, [Environmental monitoring programs at Class I nuclear facilities and uranium mines and mills](#).
- Government of Canada, [A Framework for the Application of Precaution in Science-based Decision Making about Risk](#), Ottawa Canada, 2003.
- United States Environmental Protection Agency (USEP), [Guidance on the Development, Evaluation, and Application of Environmental Models](#), Washington, DC, USA, 2009.

## 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     |

**Note:** The regulatory document series may be adjusted periodically by the CNSC. Each regulatory document series listed above may contain multiple regulatory documents. Visit the CNSC's website for the latest [list of regulatory documents](#).