Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

UNPROTECTED/NON PROTÉGÉ

ORIGINAL/ORIGINAL

CMD : 24-M5

Date signed/Signé le : 06-02-2024

Accept Regulatory Document

Accepter le document d'application de la réglementation

REGDOC-2.9.2, *Controlling Releases to the Environment*

REGDOC-2.9.2, *Contrôle des rejets dans l'environnement*

Public Meeting

Réunion publique

Scheduled for:

February 21, 2024

Prévue pour le :

21 février 2024

Submitted by:

CNSC Staff

Soumis par :

Le personnel de la CCSN

e-Doc 7143317 (WORD) - English
e-Doc 7216489 (PDF) - English
e-Doc 7215834 (WORD) - Français
e-Doc 7216492 (PDF) - Français

Summary

This Commission Member Document (CMD) pertains to a request for a decision regarding:

- draft regulatory document REGDOC-2.9.2, *Controlling Releases to the Environment*

The following action is requested of the Commission:

- accept draft REGDOC-2.9.2, *Controlling Releases to the Environment*

The following items are attached:

- disposition table of remaining areas of industry concern [Appendix A]
- draft REGDOC-2.9.2, *Controlling Releases to the Environment* [Appendix B]
- CMD 22-M27 [Appendix C]
- highlights of changes to REGDOC-2.9.2 [Appendix D]

Résumé

Ce document à l’intention des commissaires (CMD) concerne une demande de décision au sujet de :

- l’ébauche du document d’application de la réglementation REGDOC-2.9.2, *Contrôle des rejets dans l’environnement*

La Commission pourrait considérer prendre la mesure suivante :

- accepter l’ébauche du REGDOC-2.9.2, *Contrôle des rejets dans l’environnement*

Les pièces suivantes sont jointes :

- tableau de réponses aux préoccupations restantes de l’industrie [Annexe A]
- l’ébauche du REGDOC-2.9.2, *Contrôle des rejets dans l’environnement* [Annexe B]
- CMD 22-M27 (*en anglais seulement*) [Annexe C]
- faits saillants des modifications apportées au REGDOC-2.9.2 [Annexe D]

Signed/signé le

February 6, 2024 / 6 février 2024

Beaton, Dana

Digitally signed by Beaton, Dana
DN: C=CA, O=GC, OU=CNSC-CCSN, CN="
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EXECUTIVE SUMMARY

The proposed regulatory document REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment* will be part of the CNSC's environmental protection series of regulatory documents, which will also cover environmental principles, assessments, and protection measures.

This proposed regulatory document will clarify the requirements and provide guidance for controlling releases to the environment.

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

This draft document was first presented to the Commission for acceptance on September 15, 2022, at which time the Commission provided direction in its decision for further engagement with industry. Specifically, to:

- clarify terms used in the REGDOC
- clarify expectations for implementing the REGDOC
- address concerns regarding regulatory impacts and cost/benefit analysis

CNSC staff re-engaged with licensees and provincial governments from November 2022 to December 2023. There remain four areas, thoroughly discussed throughout the past year, where CNSC staff and industry understand each other's positions but are not in agreement. CNSC staff do not believe that further engagement with industry could resolve any of these items.

Referenced documents in this CMD are available to the public upon request, subject to confidentiality considerations.

1 OVERVIEW

1.1 Background

Draft REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment* (REGDOC-2.9.2) is part of the CNSC's environmental protection series of regulatory documents. It will articulate the requirements and guidance for the control of releases under the CNSC's statutory and regulatory basis which includes, but is not limited to, the *Nuclear Safety and Control Act* (NSCA), the Regulations made under the NSCA, standards, and other REGDOCs. Under the NSCA and corresponding regulations, licensees are required to take all reasonable precautions to control the release of nuclear and hazardous substances to the environment because of the licensed activity.

Under the *Canadian Environmental Protection Act* (CEPA), 1999, pollution prevention is the government's priority approach to environmental protection.

The draft REGDOC-2.9.2 will standardize and expand upon the existing practices and enhances the environmental protection framework. It will provide a consistent and formalized set of requirements and guidance for controlling releases to the environment to meet the regulatory requirements, and harmonize with national and international best practices by:

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

The information in the draft regulatory document applies to both new licence applications and existing licensees.

The concepts and technical material comprising draft REGDOC-2.9.2 underwent extensive external consultation for close to a decade (2012-2022), culminating in staff's presentation of CMD 22-M27 (Appendix C) to the Commission in September of 2022, requesting approval of draft REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment*.

The 2022 Commission decision contains important contextual considerations for this CMD:

Paragraph 43:

> The Commission acknowledges the comprehensive consultation conducted by CNSC staff on the proposed REGDOC-2.9.2. The Commission also appreciates and agrees with the rationale provided by CNSC staff on the development and need for the REGDOC. The Commission is supportive of the objectives of the REGDOC, which are to

address shortcomings with the current DRLs and to clarify requirements while providing guidance for controlling releases to the environment. The Commission is satisfied with the proposed approaches to achieve these objectives as presented in REGDOC-2.9.2 and described in Appendix B: Establishing Environment Release Targets. The Commission is also satisfied that the proposed REGDOC aligns with CSA Group standards.

Paragraph 44:

The Commission acknowledges the strongly worded consistent opposition expressed by licensees regarding REGDOC-2.9.2. With respect to the issues raised by licensees, the Commission is of the view that, while it agrees with CNSC staff's proposed approach to redefining licence limits, additional work is required to:

- clarify terms used in the REGDOC
- clarify expectations for implementing the REGDOC
- address concerns regarding regulatory impacts and cost/benefit analysis.

Therefore, the Commission directs CNSC staff to re-engage with licensees to address the aforementioned issues in a timely manner. The Commission expects licensees to clearly identify gaps and impacts, and articulate their specific concerns in order for them to be addressed. CNSC staff shall report on the resolution of these issues as soon as possible. The Commission will then reconsider whether to approve REGDOC-2.9.2 for publication and use.

If accepted, this will be the first edition of REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment.* The appended comparison document (Appendix D) highlights the technical changes that have been made from the version presented to the Commission in September 2022.

1.2 Highlights

This CMD focuses on addressing the Commission's September 15, 2022, direction to CNSC staff. CMD 22-M27 (Appendix C) provides more information and detail on the scope, objectives, content, and previous consultation / comment disposition of REGDOC-2.9.2.

CNSC Staff have made every effort to engage in a fulsome manner with industry. Engagement activities included:

- three industry workshops with regulatory affairs personnel;
- one-on-one meetings with industry's technical and regulatory affairs personnel to discuss licensee-specific concerns;
- discussions and presentations during two Chief Nuclear Officers' Forum (CNOF) meetings

- discussions with and presentations to the CANDU Owner's Group (COG)Nuclear and Environmental Affairs Peer Group in October 2022 and 2023; and
- several e-mail exchanges.

CNSC staff also provided regulatory certainty via written concurrence with specific licensee-proposed implementation approaches. In December 2023, CNSC staff sent personalized letters to Bruce Power, Ontario Power Generation (OPG), NB Power, Cameco and Canadian Nuclear Laboratories (CNL) to address their site-specific concerns and to encourage them to provide a letter outlining areas of regulatory certainty that they are seeking.

CNSC staff also engaged with provincial environmental authorities having jurisdiction over hazardous substances in New Brunswick, Ontario and Saskatchewan to ensure alignment. These discussions have been well received and are ongoing. CNSC staff anticipate the discussions will result in formalized agreements, such as a memorandum of understanding, between the CNSC and provincial authorities having jurisdiction.

2 CONSULTATION

2.1 Licensee consultation and engagement

2.1.1 Initial consultation

On November 21, 2022, CNSC staff contacted the licensees and industry stakeholders who had participated in the regulatory document development process for REGDOC-2.9.2. Based on the Commission's decision and direction, industry was requested for their input on:

- which terms or terminology needed clarification,
- the changes required to operations to meet the requirements of the draft REGDOC-2.9.2, and
- their proposed timeframe for implementing each of the changes identified.

Staff also provided guidance and potential approaches to mitigate regulatory impacts from implementation. The correspondence to industry was also posted on Let's Talk Nuclear Safety for transparency to non-industry parties. CNSC staff originally asked for input from licensees by December 31, 2022, but licensees requested an extension, and the deadline was extended to January 31, 2023.

2.1.2 Workshop #1

CNSC staff held a workshop with licensees on May 9, 2023. The workshop was to address the 42 comments received from seven commenters.

The workshop was based on five themes to address the concerns raised:

- CSA N288 alignment – the need for REGDOC-2.9.2 to be aligned with the CSA N288 series, *Environmental management of nuclear facilities*, including referencing, but not duplicating or conflicting with portions of the standards
- regulatory cooperation with environmental regulators having relevant jurisdiction to identify potential areas for alignment or cooperation
- acceptance of facility-specific alternate approaches – likelihood of acceptance not just consideration
- application of risk principals/environmental risk assessment (ERA) clarification
- expectations for BATEA assessments – clarity of expectations, requirements, and guidance

The path forward for implementation and cost benefit were discussed as a forward-looking item.

CNSC Staff Response:

Based on the concerns raised, CNSC staff made changes to the draft REGDOC-2.9.2 to provide additional clarity on terminology. CNSC staff accepted a proposed revision from industry to the definition for ‘maximum predicted design release characteristics’, and added a definition for ‘licensed release limit’ that was derived from the REGDOC text.

The new definitions can be found in glossary of the appended draft REGDOC-2.9.2 (Appendix B). There are no unresolved issues regarding the clarity of terms.

Additional text was added to provide further clarity on the proposed methodology for establishing proposed release limits.

CNSC staff also reviewed the draft REGDOC-2.9.2 to ensure consistency and alignment with the CSA N288 series of standards. CNSC identified that in some areas of the REGDOC, additional clarity was required around language associated with action levels and use of the terminology ‘upper-value of normal operation’. Additional text was added to ensure consistency with the CSA N288 series standards, including on the relationship between key terminology used in the REGDOC (for example, environmental release targets, maximum predicted design release characteristics, licenced release limits, and action levels).

At the May 2023 workshop, licensees also shared challenges with how to conduct a cost-benefit analysis, based on the draft REGDOC changes.

CNSC staff sent a detailed follow-up email, regarding the cost-benefit methodology to be used and requested licensees review their information and make changes where appropriate. CNSC staff also indicated they were available upon request, to meet one-on-one with the licensees, to provide clarity and answer any questions related to their cost assumptions, with the aim of improving the accuracy of the information provided by licensees.

2.1.3 One-on-one Meetings with Licensees

CNSC staff started to meet individually with licensees who had concerns in July 2023. These meetings were held upon request of the licensees wishing to discuss facility specific concerns, costing or seeking clarification on the REGDOC and implementation expectations.

Topics discussed included licensee-specific approaches and challenges to implementation, and proposed release limit calculation methodologies. The draft REGDOC-2.9.2 was modified to provide further clarity following these discussions.

2.1.4 Workshop #2 – Cost-Benefit Analysis Workshop

Cost benefit analysis is not an activity that the CNSC or industry have previously undertaken for a REGDOC; therefore a dedicated workshop on the subject was held in August 2023.

This workshop allowed for more discussion between CNSC staff and licensees and provided further clarity to licensees on what to include in their submissions and articulated the appropriate level of detail for the estimates.

Licensees requested an extension from the requested July 15, 2023, due to their staff availability, to September 29, 2023 to submit their revised information on costing and benefits. CNSC staff granted this extension.

2.1.5 Workshop #3 – Residual Concerns Workshop

CNSC staff met with licensees on September 8, 2023, to discuss the remaining concerns with REGDOC-2.9.2 and to provide licensees with CNSC staff’s general responses in addressing the following concerns:

- alignment with CSA Standards
- alignment with Provincial Regulators

Use of BATEA and regulatory certainty were raised and responded to by CNSC staff.

CNSC staff also addressed the subject of implementation and provided guidance on CNSC staff’s expectations for their upcoming submission of cost benefit information.

Concern Raised: Alignment with CSA Standards (1/3)

Some licensees had an expectation that Regulatory Documents should be written to be in alignment with CSA standards. Others felt that the CSA N288 series and other standards should follow the regulation that is being implemented. Licensees argued that requirements should be developed by interacting with subject matter experts in a more balanced setting.

CNSC Staff Response:

CNSC staff have made revisions to draft REGDOC-2.9.2 to ensure consistency with, but not duplication of, CSA N288 series documents.

Clarity was provided to licensees on the role of the regulator and the ability to provide further guidance or requirements necessary to adequately regulate and address opportunities for improvements. Any changes in the regulations are subject to the *Cabinet Directive on Regulations* and the Government of Canada's *Policy on Regulation Development*. This involves a large amount of engagement and consultation with Canadians, other government jurisdictions, stakeholders, and the public. It is also legally scrutinized to ensure it follows the *Charter of Rights and Freedoms*, and the legal bounds of the law.

CNSC staff also confirmed to industry that CSA standards are mechanisms produced by a third party and are used at the discretion of CNSC to complement regulatory documents guidance and requirements.

Concern Raised: Alignment with CSA Standards (2/3)

There are discrepancies between the CSA standard and REGDOC-2.9.2, specifically with regards to environmental risk assessments not including the concept of licensed release limit nor the calculation methodology.

CNSC Staff Response:

As part of establishing proposed release limit(s), Section 5.1 of draft REGDOC-2.9.2 states that, "the applicant or licensee shall 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."

The Guidance section of draft REGDOC-2.9.2 provides further guidance on how this requirement can be met. One suitable method is through the use of an ERA.

An ERA is a tool that identifies, quantifies, and characterizes the risk posed by contaminants (nuclear or hazardous substances) and physical stressors in the environment and released to the environment. In accordance with CSA N288.6, *Environmental risk assessments at class I nuclear facilities and uranium mines and mills*, the ERA is periodically updated and licensees may use a future update to demonstrate that a release at the proposed release limit will not result in an unreasonable risk.

In response to industry concerns, CNSC staff provided additional clarity on how proposed licensed release limits can be demonstrated as protective.

CNSC staff committed to participate on future revisions to CSA N288.6, with the aim to improve and promote further alignment with draft REGDOC-2.9.2.

Concern Raised: Alignment with CSA Standards (3/3)

Licensees continued to be concerned that the requirements in the REGDOC for establishing and implementing action levels, did not align with CSA N288.8 *Establishing and implementing action levels for releases to the environment from nuclear facilities*.

CNSC Staff Response:

During the workshops and in CNSC staff's disposition to industry's residual issues, CNSC staff emphasized that the requirements and guidance for establishing action levels in draft REGDOC-2.9.2 aligns and is consistent with CSA N288.8.

CNSC staff did acknowledge a mis-statement in CMD 22-M27, whereby action levels were stated to be representative of the upper value of normal operation, which is not always the case. To ensure absolute clarity, CNSC staff modified language in draft REGDOC-2.9.2 to state that, "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, the licenced release limit)".

Concern Raised: Alignment with Provincial Regulators

Licensees expressed concern that provincial regulations differ from province to province, resulting in uncertainty of how harmonization will be achieved.

CNSC Staff Response:

It is the responsibility of applicants and licensees to propose appropriate release limits for their facilities or activities. Proposed limits can be site specific or based on provincial or federal legislation.

CNSC staff encouraged harmonizing with existing provincial limits where protective and practical. In cases where provincial permit levels are used to indicate a deviation from normal operation, these values may be more suited to the purpose of an action level. CNSC staff provided additional clarity in the draft REGDOC to allow for licensees to adopt provincial limits as action levels when it can be justified. In addition, CNSC staff provided additional flexibility that licensees can choose to propose release limits based on methodology provided in draft REGDOC 2.9.2. instead of harmonizing with provincial limits.

CNSC staff addressed potential scenarios where limits existing in legislation may be deemed inadequately protective, commonly as a result of new science regarding the toxicity of a substance, or on its behaviour in the receiving ecosystem.

CNSC staff provided an overview of the outreach and engagement with provincial authorities having jurisdiction completed to date.

Supplemental Concern Raised: Use of BATEA

Industry raised concerns that BATEA could be used to stifle innovation in the nuclear industry, and that additional clarity that a BATEA assessment applies only to treatment of untreated pollutant sources was needed in the REGDOC.

CNSC Staff Response:

CNSC provided additional clarity in the REGDOC, that a BATEA assessment does not apply to nuclear facility technology (for example, reactor technology, mining and/or milling technology and/or techniques), but applies to those treatment and/or control technologies and techniques applied to untreated pollutant sources being released from a nuclear facility.

Supplemental Concern Raised: Regulatory Certainty

Industry raised concerns that some areas and words in the REGDOC were written in a manner that promotes regulatory uncertainty.

CNSC Staff Response:

CNSC staff engaged with each licensee during one-on-one sessions to understand what they meant by regulatory uncertainty. Industry clarified two instances of regulatory uncertainty in the REGDOC,

1. The 2022 draft REGDOC stated, "For nuclear substances, where there are multiple release points, facility- and/or activity-wide release limits may be applied." Some licensees wanted this language to be written as a shall. CNSC staff responded that the CNSC regulates a wide range of nuclear facilities and activities, and that some nuclear facilities have as part of other legislative requirements that license release limits be discharge-point specific. CNSC staff clarified that the REGDOC has to be flexible to apply to any nuclear facility regulated by the CNSC, and allow for harmonization with other Federal/Provincial requirements. The draft REGDOC-2.9.2 text, at the beginning of section 5.1, has been updated to increase clarity while maintaining flexibility. It specifies that licensees can choose between having proposed release limits at each controlled release point or facility-wide.
2. The draft REGDOC states that, "where other government requirements on releases that are applicable to the facility and/or activity exist, 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 licensees wanted this language to be written as a shall. However, other licensees appreciated the flexibility offered by the REGDOC.

CNSC staff reminded licensees that they are encouraged to submit letters to the CNSC outlining those areas of regulatory certainty for which they are seeking clarity (for example, to confirm in writing that specific existing provincial limits would be acceptable to CNSC staff).

2.1.6 CANDU Owner's Group (COG) – Nuclear and Environmental Affairs Peer Group (NEAPG) Presentation

On October 18, 2022, CNSC staff gave an update on draft REGDOC-2.9.2, including the purpose, proposed implementation, and safety enhancements. On October 25, 2023, CNSC staff presented to the COG Environment Workshop on regulatory issues including draft REGDOC-2.9.2. CNSC staff provided an overview of development of the draft REGDOC-2.9.2, the proposed implementation, the benefits and how we dispositioned the licensees' comments and concerns thus far. In addition, CNSC staff went through in detail, the residual concerns raised by industry during the September 2023 industry workshop and one-on-one meetings, and how those concerns have been addressed in the REGDOC.

Overall, CNSC staff affirmed and heard that licensees in attendance of the workshop were understanding of the current draft REGDOC-2.9.2.

2.1.7 Letters to licensees regarding implementation

Some licensees have expressed concerns regarding the potential for 'non-shall' statements to be interpreted in a different manner as CNSC technical staff experience turnover.

To address this concern regarding regulatory certainty for existing licensees, CNSC staff sent letters to licensees providing regulatory certainty addressing the areas of concern that had been raised (such as methodologies for establishing proposed release limits for implementation). These letters also invited further submissions if additional regulatory certainty is desired, such as for formalized implementation plans.

2.1.8 Remaining industry concerns

In the first week of December, 2023, CNSC staff received two letters from industry[1] [1][2] voicing a continuing concern with four thematic areas:

- use of a performance-based approach (instead of exposure based)
- duplication of CSA N288 series, *Environmental management of nuclear facilities* documents
- cost of implementation
- harmonizing with provincial authorities having jurisdiction over hazardous substances

All four areas have been discussed throughout the past year in detail, and addressed to the extent possible. CNSC staff and industry understand each other's positions, but have not been able to come to a consensus for each of these four areas. CNSC staff do not believe that further engagement prior to the Commission proceeding with industry could resolve these items any further.

CNSC staff have dispositioned the remaining areas of industry concern in Appendix A.

[1] The first letter was from Bruce Power, CNL, NB Power and OPG, expressing concern with all four areas. The second letter was from Cameco and Orano, and expressed concern regarding cost of implementation, alignment with CSA N288 series documents and harmonization.

2.2 Provincial government consultation and engagement

The CNSC works with other jurisdictions to ensure that, to the extent possible, authorizations are acceptable to all applicable jurisdictions. CNSC staff will continue to engage and consult with other jurisdictions to reduce any potential administrative burden, and to promote regulatory cooperation.

Section 5.1 in the draft REGDOC-2.9.2 identifies guidelines for harmonizing CNSC licensed release limits with those currently in federal / provincial / territorial regulations that are applicable to the licensed activity.

CNSC Staff have had productive meetings with provincial authorities in Ontario, New Brunswick, and Saskatchewan to discuss REGDOC-2.9.2. CNSC staff will continue to engage with provincial authorities to ensure regulatory cooperation.

Overall, the provincial authorities CNSC staff have spoken to, and corresponded with, were supportive of the approach and the proposed draft REGDOC-2.9.2.

3 REGULATORY IMPLEMENTATION AND ANALYSIS

3.1 Implementation

CNSC staff will continue to work with licensees to coordinate the implementation of the draft REGDOC-2.9.2. CNSC staff will conduct outreach and educational sessions with the public and stakeholders.

Existing licensees are considered to have incorporated appropriate controls at the time of their original design and licensing. Over time, licensees have continued to improve their treatment systems with periodic updates to their facility, including through periodic safety reviews, aging management, continuous improvement initiatives, and where necessary, adaptive management. On this basis, CNSC staff are proposing the following implementation for existing licensees is as follows:

- licensees will be required to update licensed release limits and action levels via existing cyclical updates (five-year period), such as the ERA, management system review or periodic safety review (PSR)
- for provincially regulated hazardous substances, this will involve adopting those limits already in their provincial permits or approvals, where protective.
- for nuclear substances, licensees will have to follow the methodology outlined to revise their licensed release limits. This methodology makes use of licensees existing derived release limits (DRLs), as well as their extensive operational data and experience controlling their releases.
- with respect to action levels, most licensees have already developed and implemented action levels in accordance with CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities*. Therefore, they already meet the requirements in this

REGDOC. Some action levels may need to be adjusted based on the derivation of proposed licensed release limits.

- since existing facilities met treatment technology requirements at the time of original licensing:
  - a new BATEA assessment is not required – BATEA maintained through existing regulatory framework requirements
  - PSRs to be conducted as per REGDOC-2.3.3, *Periodic Safety Reviews*
  - fitness for service – aging management to be conducted as per REGDOC-2.6.3, *Aging Management*
  - continuous improvement of objectives and target(s) in Environmental Management System

Should REGDOC-2.9.2 be accepted by the Commission for publication and use, CNSC staff will engage with impacted licensees to discuss licensee-specific implementation and associated timelines.

For new facilities on new sites, or new facilities on existing sites (provided there is a change in release characteristics that are outside of the existing licensing basis), applicants or licensees will be required to address REGDOC-2.9.2 in their licence application, which includes the following:

- conduct a BATEA assessment
- establish proposed release limits
- establish action levels
- establish a commissioning plan for the treatment system
- commission treatment system or other control measures and confirm performance
- once the facility is under normal operation
  - conduct routine monitoring and assessment
  - status quo unless Adaptive Management triggered

3.2 Regulatory Analysis

Benefits and Costs

The requirements of the draft REGDOC-2.9.2, *Controlling Releases to the Environment* would ensure that the regulatory controls are based on controls and procedures established in the licensing basis. This minimizes the likelihood of a major release to the environment outside the licensing basis.

While the monetized impacts of the draft REGDOC-2.9.2 would result in a net present value cost of $3.3 million, the non-monetized benefits associated with the reduced risk of environment incidents are expected to be far greater than the estimated costs. It is worth noting that the present value includes a significant IT cost of $1.5M from a single licensee, which staff did not feel they could justify modifying, without significant additional research and consultation, or quotes from IT vendors.

The annualized average for existing licensees would be $471,499. This is less than $1 million a year and therefore would be considered a low impact regulatory proposal.

The requirements set in regulations were not costed out in this modified cost-benefit analysis, as the cost for these requirements would have been previously calculated and thoroughly consulted on during the regulation development process as per the *Cabinet Directive on Regulation*.

Cost-benefit analysis Methodology

CNSC staff used the Government of Canada's *Policy on Cost-Benefit Analysis* as well as the Government of Canada's *Canadian Cost-Benefit Analysis Guide: Regulatory Proposal* to determine the analytical and transparency requirements.

Monetized impacts are calculated using the *Standard Cost Model* from the Organization of Economic Co-operation and Development. This is an internationally recognized methodology for determining and calculating the monetized effects of government regulation on business. The *Standard Cost Model* calculates costs by estimating the time required to complete a required task and multiplying it by the hourly wage of the employee(s) responsible for performing the task, the frequency that the task must be performed and the number of businesses affected by the requirement.

Since the Standard Cost Model is based on hourly wage, CNSC staff used data from Statistics Canada. CNSC staff reviewed the hour salary for utilities; professional, scientific and technical services; and forestry, fishing, mining, quarrying, oil and gas. CNSC staff decided to be overly conservative and use the highest hourly rate of $49.23/hr for licensees in cost benefit analysis (CBA). Present values totals are in 2022 Canadian dollars.

The revised number of hours was multiplied by the most applicable provincial rate to determine the cost per item. Each cost was then considered for the most appropriate year(s) it would be spent in for each licensee, taking into account when derived release limits (DRLs) were last revised and if the licensee provided any estimates of the year a cost would be incurred. Costs in future years were discounted using Treasury Board discount rates to determine a present value.

CNSC staff only included costs associated with implementation of REGDOC-2.9.2. CNSC staff did not include costs for facilities yet to be constructed, facilities already in compliance with the REGDOC-2.9.2 (as there is no change); or facilities yet to be licensed.

CNSC staff did not include any costs related to CNSC enforcement and compliance of these requirements as they are already accounted for in activities being completed by CNSC staff for the current DRLs.

As per the Commission's direction on September 15, 2022, CNSC staff focused only on existing licensees.

Costs

The costs are grouped according to the main themes of the proposed amendments and the expected implementation that would impose cost impacts on regulated parties. The themes are as follows:

- internal review of existing controls
- develop and propose release limits at the next cycle interval
- update environmental protection (EP) documents
- new training
- demonstrate the proposed release limit is protective (for example, by performing an ERA scenario)
- regulatory affairs
- external communications
- program maintenance
- new / modified facilities

Benefits

The non-monetary benefits of draft REGDOC-2.9.2 outlined below would apply to Canadians as well as licensees and the CNSC.

Resource Management

REGDOC-2.9.2 reduces potential duplication for compliance (provincial / CNSC for hazardous substances and CNSC / Environment and Climate Change Canada (ECCC) for releases to water bodies) and allows better utilization of government resources.

Draft REGDOC-2.9.2 documents and clarifies the means by which the CNSC regulatory framework meets the conditions necessary for the CNSC to obtain regulations under the *Fisheries Act*.

This provides regulatory certainty to both CNSC and the industry from potential enforcement action by ECCC and strengthens the regulatory function of ECCC and the CNSC. This eliminates the potential duplication of enforcement costs.

In addition, converting DRLs to LRLs is a one-time calculation for existing facilities. This calculation would only be required to recalculated if there is a major modification to the facility.

Regulatory Cooperation

REGDOC-2.9.2 allows CNSC to have a tool to engage and consult with other Canadian jurisdictions on regulatory requirements for hazardous substance releases. This will allow CNSC and the other regulators to identify potential areas for alignment or cooperation. This could potentially reduce the burden on licensees.

The proposed requirements align with the priority approach to pollution prevention established by the *Canadian Environmental Protection Act.*

Regulatory Clarity

The draft REGDOC-2.9.2 will articulate the expectations for addressing 12(1)(f) of the *General Nuclear Safety and Control Regulations*, with particular regard to hazardous substances.

Existing practices and expectations are standardized and formalized in the draft REGDOC-2.9.2. It documents CNSC expectations for applying pollution prevention in the regulatory framework, responding to potential exceedance of action levels or license limits, commissioning new treatment systems and implementing adaptive management. The regulatory control of releases will be tied directly to the licensing basis through the approved facility design under normal operating conditions.

This will provide a consistent and predictable approach. This will benefit Canadians and licensees as the information is clear on expectation and it will improve information-sharing between stakeholders as well as CNSC with stakeholders.

CNSC staff note that draft REGDOC has directly benefitted the following projects under development by reducing the quantity and duration of discussions between CNSC staff and applicant/licensee (clarity for completing a BATEA assessment):

- NexGen Rook I (uranium mine)
- Denison Wheeler River (uranium mine)
- OPG Darlington New Nuclear Project (nuclear power reactor)

The draft REGDOC’s expectations are implemented or have been used for:

- Port Hope and Port Granby Projects (BATEA assessment, commissioning, licensed release limits and action levels)
- CNL’s Near-Surface Disposal Facility (BATEA assessment)
- McClean Lake (adaptive management)
- Elliot Lake Stanleigh Operation (licensed release limit exceedance and adaptive management)

Harmonizing Internationally

The draft REGDOC-2.9.2 adopts international standards and practices on regulating the control of radioactive and non-radioactive releases to the environment. In addition, the 2019 International Atomic Energy Agency’s (IAEA's) Integrated Regulatory Review Service (IRRS) identified recommendation R2 “The CNSC should establish or approve dose constraints for all Class I type facilities” and suggestion S9 “The CNSC should consider consistently implementing the concept of dose constraints for all facilities and standardizing regulatory practice for derived release limits (DRLs).” [3]

The basis for the IRRS recommendation and suggestion come from the IAEA’s International Basic Safety Standards General Safety Requirements (GSR) Part 3 [4], Requirement 29, which states the following:

- Paragraph 3.120 “The government or the regulatory body shall establish or approve constraints on dose and constraints on risk to be used in the optimization of protection and safety for members of the public.”
- Paragraph 3.123(b) “The regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges. These operational limits and conditions: (b) Shall correspond to doses below the dose limits with account taken of the results of optimization of protection and safety;”

Canada’s response to the 2019 IRRS review noted that draft REGDOC-2.9.2 would address both the IRRS recommendation R2 and suggestion s9.

Cost-benefit statement

CNSC staff used Government of Canada standards in completing the below cost-benefit statement. The time period, present value and discount rates are provided to facilitate an understanding of how the numbers were calculated, using the model stated in the above sections.

Number of years: 10 (2024 to 2033)
Base year for costing: 2022
Present value base year: 2024
Discount rate: 7%

Overall, while the monetized impacts show a net cost for this regulatory proposal, the benefits are expected to outweigh the quantitative costs if all the benefits could reasonably be quantified.

Table 1: Monetized costs- all stakeholders

Impacted stakeholder	Description of cost	2024	2027	2033	Total (present value)
Industry	**Internal review of existing controls**	$47,110.07	$29,661.30	$0.00	**$91,681.49**
Industry	**Develop LRLs**	$0.00	$248,775.30	$0.00	**$177,648.92**
Industry	**Update EP Documents**	$0.00	$194,538.20	$0.00	**$339,833.42**
Industry	**Incorporate LRL**	$0.00	$1,526,892.00	$0.00	**$2,197,798.32**
Industry	**New Training**	$0.00	$63,922.63	$0.00	**$405,936.40**
Industry	**Perform ERA**	$0.00	$429,950.00	$0.00	**$40,147.22**
Industry	**Regulatory Affairs**	$0.00	$15,613.72	$8,508.00	**$37,520.77**
Industry	**External Communications**	$0.00	$25,710.88	$3,229.13	**$7,309.29**
Industry	**Program Maintenance**	$0.00	$112,762.00	$0.00	**$6,831.11**
Industry	**New/Modified Facilities**	$44,571.43	$44,571.43	$0.00	**$6,384.22**

All stakeholders	**Total costs**	$91,681.49	$2,692,397.44	$11,737.13	**$3,311,091.16**

Table 2: Monetary Costs- Stakeholder type

Impacted stakeholder	**Description of cost**	**2024**	**2027**	**2033**	**Total (present value)**
Nuclear Power Plants	**Implementation of REGDOC-2.9.2**	$0.00	$686,897.37	$5,495.50	**$853,524.46**
Other licensees	**Implementation of REGDOC-2.9.2**	$91,681.49	$2,005,500.08	$888.72	**$2,457,566.71**
All stakeholders	**Total costs**	$91,681.49	$2,692,397.44	$6,384.22	**$3,311,091.16**

4 OVERALL CONCLUSIONS AND RECOMMENDATIONS

4.1 Overall Conclusions

Draft REGDOC-2.9.2, *Controlling Releases to the Environment* was developed through extensive consultation with stakeholders and is important to communicating and formalizing the CNSC's requirements and guidance related to controlled environmental releases.

CNSC staff conclude REGDOC-2.9.2, *Controlling Releases to the Environment*, is ready for final acceptance by the Commission for publication and use.

4.2 Overall Recommendations

CNSC staff recommend that the Commission accept REGDOC-2.9.2, *Controlling Releases to the Environment*.

A. APPENDIX A. DISPOSITION TABLE OF REMAINING AREAS OF INDUSTRY CONCERN

#	Industry Concern	CNSC Staff Disposition
1	Use of a Performance-Based Approach Industry expressed concern that use of a limit not based on the current derived release limit (DRL) methodology would punish good performers with stricter requirements.	This area was discussed in front of the Commission in September, 2022. Paragraph 43 of the 2022 Commission decision on REGDOC-2.9.2 noted that: "The Commission is supportive of the objectives of the REGDOC, which are to address shortcomings with the current DRLs and to clarify requirements while providing guidance for controlling releases to the environment." Should draft REGDOC-2.9.2 be accepted, the licensed release limits would be based on the specific design of each facility. CNSC staff's preferred option is for licensees to use the existing design documentation of the treatment technologies and techniques to propose release limits. However, where that is not available, existing licensees can use historical releases to reflect how the facility and treatment system(s) were originally designed. The concern that good performance results in a punitively lower limit can be addressed by choosing to base proposed release limits on the design of the technologies and techniques currently in place. Operational releases are below the design numbers, as licensees have applied the principles of optimization of protection and continuous improvement,.

#	Industry Concern	CNSC Staff Disposition
2	Duplication of CSA N288 Series Documents Industry expressed continuing concern that REGDOC-2.9.2 does not align with currently published CSA standards.	CNSC staff continue to contribute to the development and revision of CSA nuclear standards. CNSC staff will contribute to the N288 series document development, during their cyclical revisions, to improve alignment with REGDOC-2.9.2 should it be accepted by the Commission. This area was discussed in front of the Commission in September, 2022. Paragraph 43 of the 2022 Commission decision on REGDOC-2.9.2 noted that: "The Commission is also satisfied that the proposed REGDOC aligns with CSA Group standards."
3	Cost of Implementation Industry expressed concern regarding the benefits and need for the document not outweighing the cost industry would bear to implement. Industry reiterated that they saw no benefit to the environment from the anticipated implementation activities.	This item was a core element of the Commission's direction on re-engaging with Industry in 2022 and is covered in detail in section 3 of this CMD. CNSC staff believe the non-monetary benefits outweigh the implementation costs. Should individual licensees have already planned projects, where implementation of REGDOC-2.9.2 may result in a diversion of funds from safety enhancements, CNSC staff are open to discussing an extended implementation timeframe on a case-by-case basis.

#	Industry Concern	CNSC Staff Disposition
4	Harmonizing with Provincial Authorities Having Jurisdiction over Hazardous Substances Industry expressed remaining concern on how harmonization with provincial authorities on the regulation of, compliance and enforcement for releases of hazardous substances would be achieved.	Harmonization was discussed during the September, 2022 Commission meeting. CNSC staff updated industry on developments in this area during the September 8, 2023 workshop. Given the overlap of mandates on the subject of hazardous substances, the issue of harmonization would exist whether or not draft REGDOC-2.9.2 is accepted by the Commission. The draft REGDOC provides a structure for provincial authorities to understand the CNSC's rationale and approach to regulating releases of hazardous substances. Discussions between CNSC staff and provincial authorities is ongoing, in a regulator-to-regulator basis. CNSC staff understand that industry is anxious for this issue to be resolved, but establishing formal agreements, such as a memorandum of understanding, takes time. Acceptance of this REGDOC by the Commission would provide a firm foundation for building formal agreements on the subject with the provincial authorities.

B. APPENDIX B. REGDOC-2.9.2, CONTROLLING RELEASES TO THE ENVIRONMENT

Please see the French CMD for the French version of REGDOC-2.9.2.

Canada's Nuclear Regulator

Environmental Protection

Controlling Releases to the Environment

REGDOC-2.9.2

February 2024

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

Canada

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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 (BATEA)
- 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

Controlling Releases to the Environment

1. Introduction

1.1 Purpose

Environmental protection for nuclear facilities and activities 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 intend to release nuclear or hazardous substances to the environment. It applies to those from direct releases to air, surface water, sewer, or through the ground, including where natural or engineered barriers for control are proposed or incorporated. This REGDOC 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 (ERA), and to develop and implement an environmental management system (EMS). 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 does 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 they meet 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 interaction 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's (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 REGDOC focuses on controlling releases to the environment under normal operations.

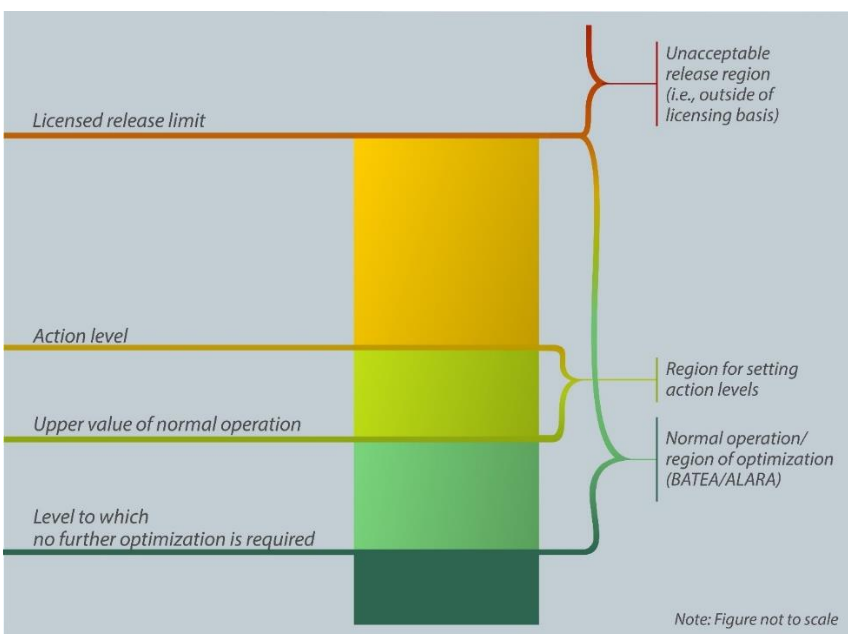
Paragraph 12(1)(f) of the *General Nuclear Safety and Control Regulations*, deals with "reasonable precautions" regarding control of releases. REGDOC-2.9.1 [1] specifies that reasonable precaution in the context of controlling releases involves the application of best available technology and techniques economically achievable (BATEA) and the application of the as low as reasonably achievable (ALARA) principle. Thus, licensees are required to control releases to limits specified within regulation and demonstrate the application of BATEA and ALARA. Hereafter, the term BATEA is considered to refer to both nuclear and hazardous substances with ALARA utilized 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).

The figures below are conceptual and are not necessarily to scale. The actual range between the values depends on the site-specific design and operation of the facility or activity, and 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 CNSCs 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.

Specific to releases to the environment, licensed release limits are part of the licensing basis and, if exceeded, represents a loss of control of part of the licensee's environmental protection program(s) or control measure(s). Exceeding a licensed release 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 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 their 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 released 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 one individual sample.

Exceeding a licensed release limit (that is, a red light) signals that the licensee is operating outside the 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 indicate an unreasonable risk to the environment or to the health and safety of persons.

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, licenced 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

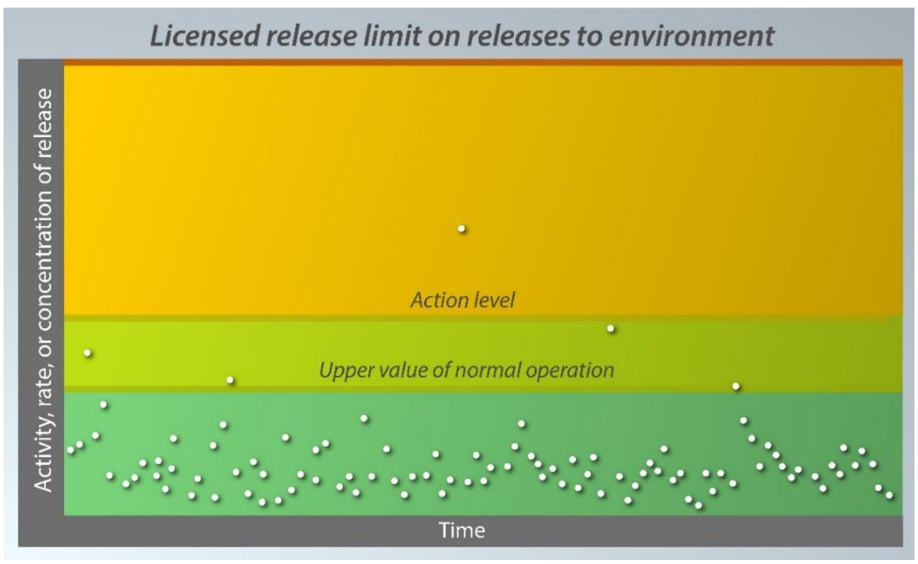
The upper value of normal operation is based on the predicted or current operating conditions, and is typically determined using either:

- 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 below 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 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)
- licence 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 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.

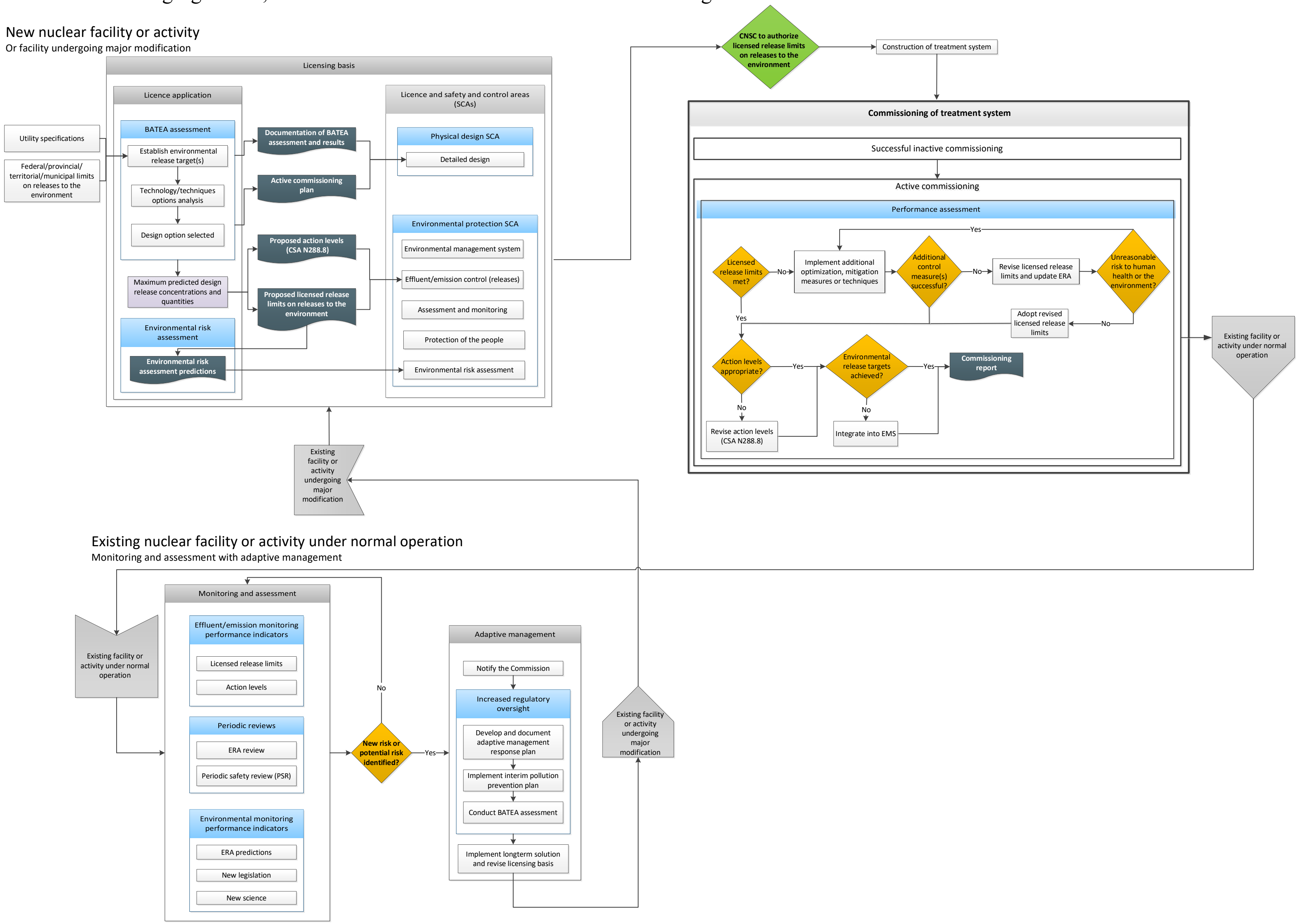


Figure 3a: Information on control measures for releases to the environment to be submitted for a new facility or activity applying for a licence to construct, or an existing facility undergoing a major modification and requiring a licence amendment

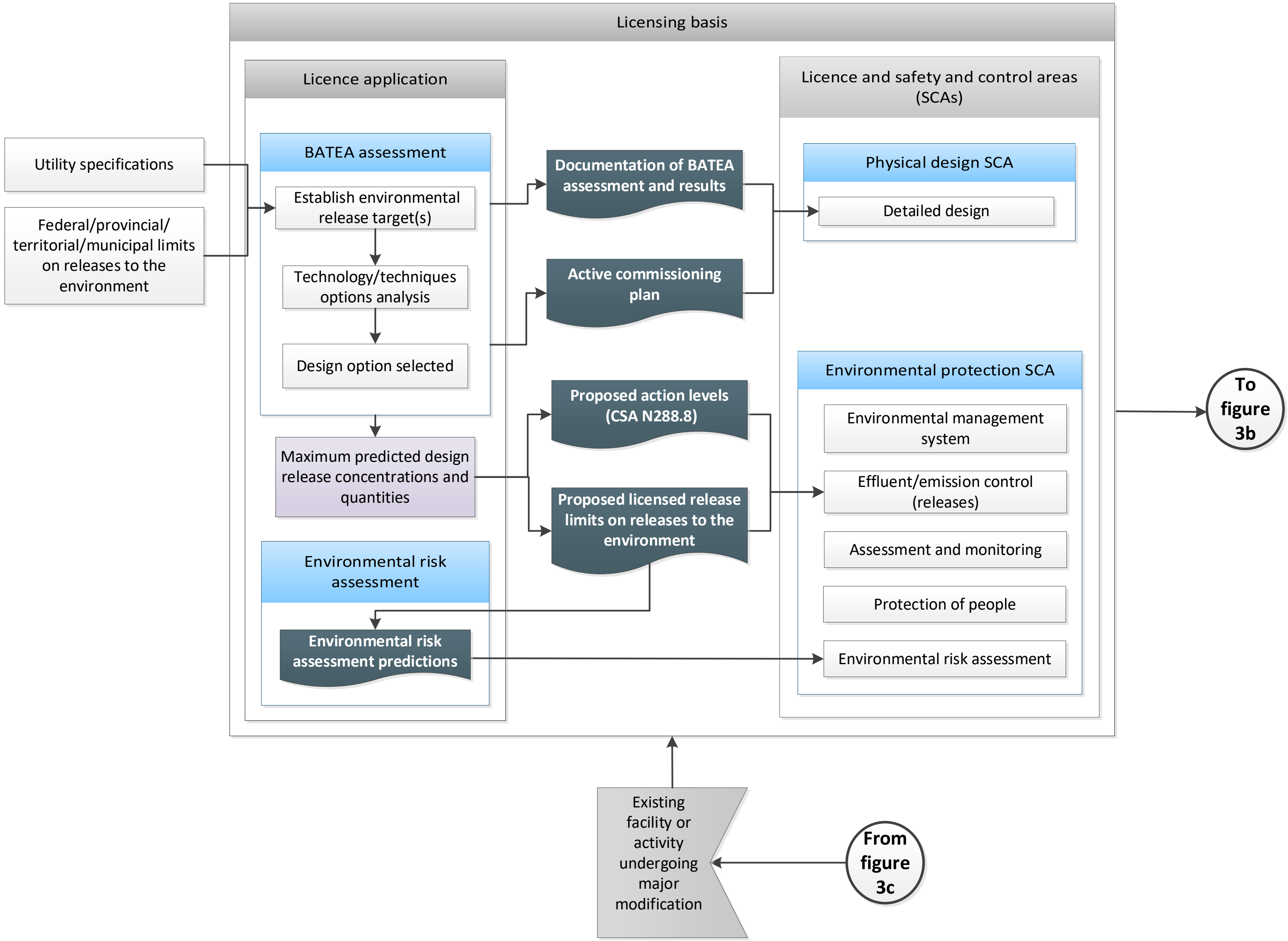


Figure 3b: Commissioning treatment system(s)

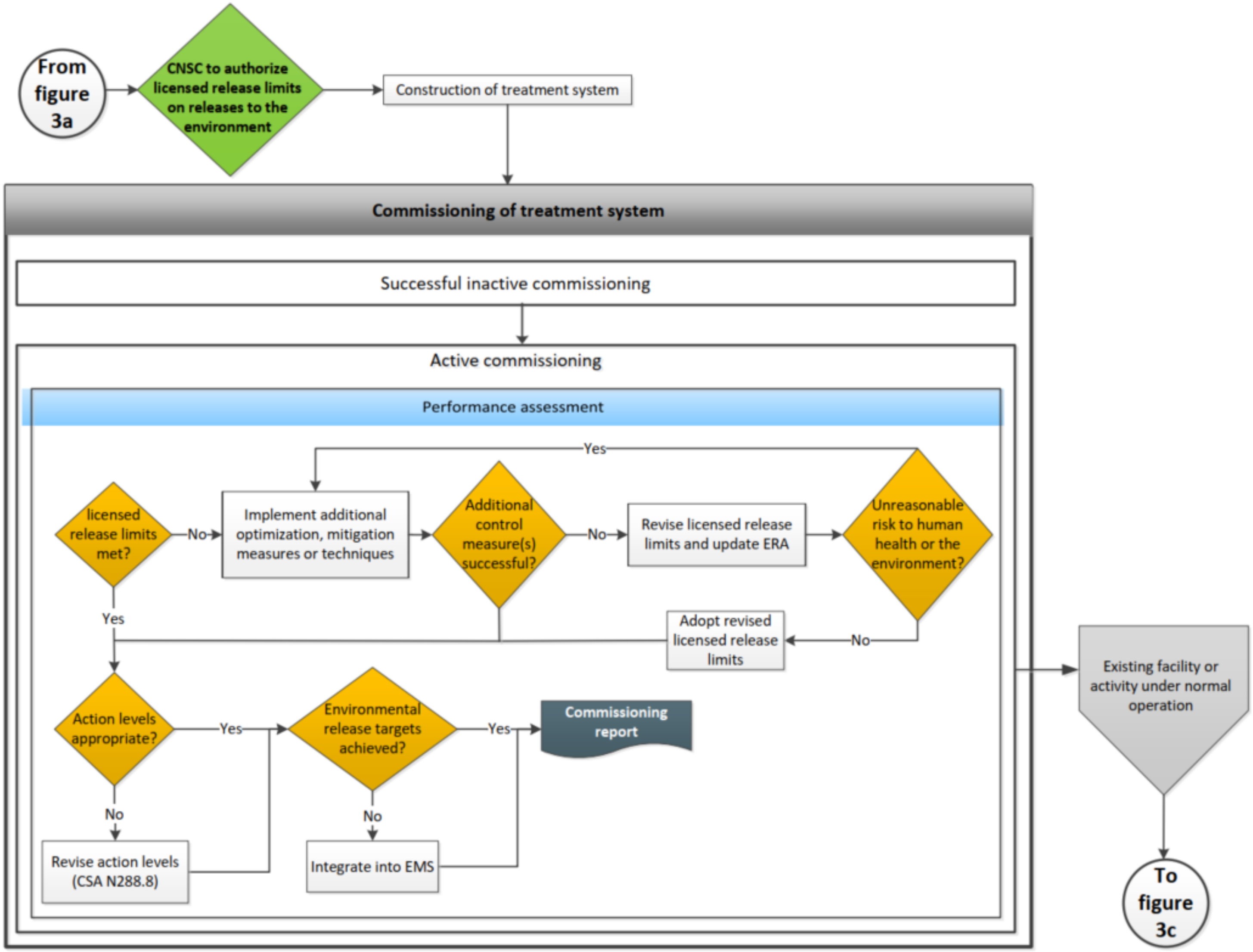
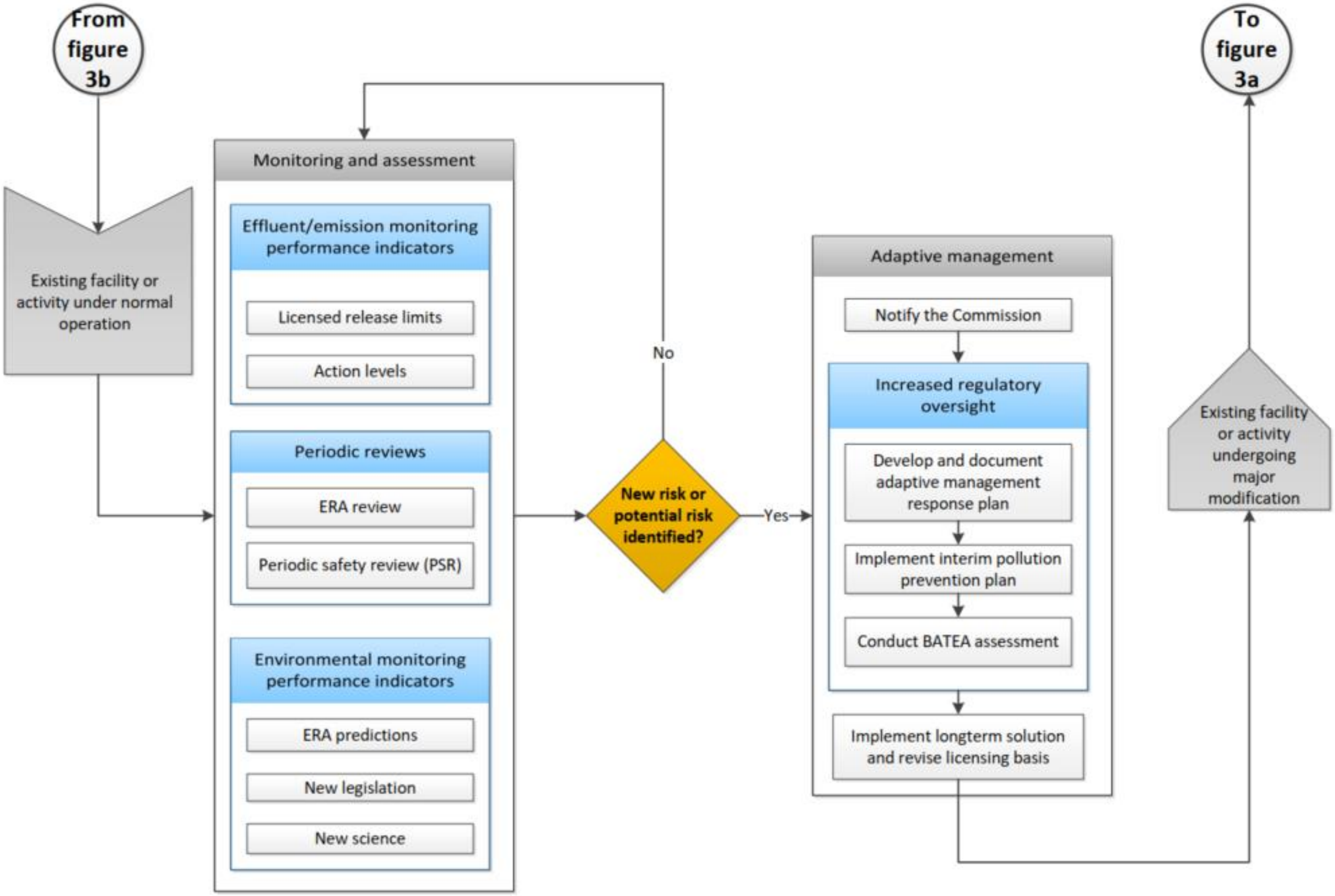


Figure 3c: The part of the overall process for establishing control measures that is specifically for a nuclear facility or activity under normal operation



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 which 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)
- if a previously unmanaged risk is identified in the ERA, and adaptive management is required to restore the effectiveness of the environmental protection program, upon completion of the ERA, notify the Commission

  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 their environmental protection program.

BATEA during operations is considered as part of a facilities commitment to pollution prevent and continuous improvement as part of their environmental policy and as managed through their EMS. Like applying the ALARA concept, 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), but applies to those 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 on 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 (ERT) 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 utilized:

- dose constraints, concentrations, or total loadings identified in federal and/or provincial regulations as being 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, CCME 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 licence 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-year 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 maximum predicted design release characteristics (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 that 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 are applicable 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 enhanced regulatory oversight is applied.

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

Note: The licensed release limit is set at a level that ensures no unreasonable risk to human health and the environment, and as a result is 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 maximum predicted design release(s) characteristics (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(s) characteristics

Identify the maximum predicted design release characteristics (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 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 those applicable governmental requirements on releases that were previously identified

- where other government requirements on releases that are applicable to the facility and/or activity exist, 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 (POI)), 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 REGDOC.
- 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 POI, 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-annually 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 (ECCC) 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 by any industrial facility that has a very stable, continuous release over their operational lifetime, or for low-risk facilities that wish to conservatively demonstrate their 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 REGDOC 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 whether the licensed release limit can be met through further optimization or application of additional mitigation measures or techniques to reduce releases below the licensed release limits

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, then 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 EP Framework

The information in this appendix should be consulted as referred to in the applicable sections of this REGDOC. 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 REGDOC. 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 (CLs)
  - 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

EP 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 conditional clearance levels 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 conditional clearance, 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 μSv/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): if 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 NSRDRs
  - 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): if 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, e.g., via the annual compliance reports that the total quantity acquired/used over one year is less than the corresponding generic CCL

- Criterion iii): the 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 conditional clearance levels (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* 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" which 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 µSv/year for a member of the public and
- 10 µGy/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 µGy/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 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 metres (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 two 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 µSv from each of the two groups of pathways. The smaller of the two 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 m^3/year) for this reference WTP was estimated by considering Canadian WTP influent rates for 2016 – 2018 for three WTPs in Toronto and 5 WTPs in Vancouver. The “per capita” annual average inflow rate was approximately 130 m^3/a, which is equivalent to 2.6 million m^3/a for a population of 20,000. The values in column 4 of table A.1 were divided by 2.6 million m^3/a to obtain the resultant concentrations.

Releases containing more than one radioisotope

When more than one radionuclide is released via one 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 one 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 one calendar year

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

Column 1	Column 2	Column 3	Column 4
Radionuclide	**Municipal landfill (Bq/g)** **Note: 1**	**Annual activity released to atmosphere (MBq)** **Note: 2**	**Annual activity released to municipal sewer (MBq)** **Note: 2, 3**
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

Column 1	Column 2	Column 3	Column 4
Radionuclide	**Municipal landfill (Bq/g)** **Note: 1**	**Annual activity released to atmosphere (MBq)** **Note: 2**	**Annual activity released to municipal sewer (MBq)** **Note: 2, 3**
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

Column 1	Column 2	Column 3	Column 4
Radionuclide	**Municipal landfill (Bq/g)** **Note: 1**	**Annual activity released to atmosphere (MBq)** **Note: 2**	**Annual activity released to municipal sewer (MBq)** **Note: 2, 3**
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

Column 1	Column 2	Column 3	Column 4
Radionuclide	**Municipal landfill (Bq/g)** **Note: 1**	**Annual activity released to atmosphere (MBq)** **Note: 2**	**Annual activity released to municipal sewer (MBq)** **Note: 2, 3**
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	

Column 1	**Column 2**	**Column 3**	**Column 4**
Radionuclide	**Municipal landfill (Bq/g)** **Note: 1**	**Annual activity released to atmosphere (MBq)** **Note: 2**	**Annual activity released to municipal sewer (MBq)** **Note: 2, 3**
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.

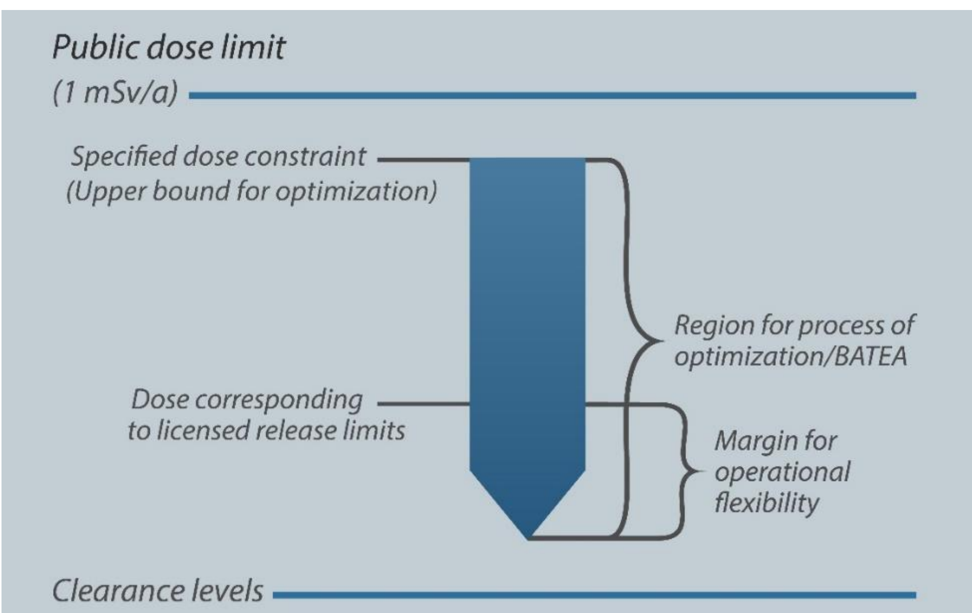
Appendix B: Additional Information

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 B1 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 (µSv) 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[1]



[1] 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 µSv/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 µSv/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 take into account a margin for operational flexibility to account for anticipated operations throughout the remaining lifecycle of the facility.

The MPDRCs are used 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 then 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 represents 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, licenced 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 CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear* *facilities* [7]). In 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 bi-annual 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(s) characteristics (MPDRCs) 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:

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 release point and contaminant or physical stressor identified as requiring control, identify the most restrictive criteria for each of the following:
   - most sensitive species or human receptors (generic or site-specific)
   - most reasonable 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 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 Environmen*t, 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, reference [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.

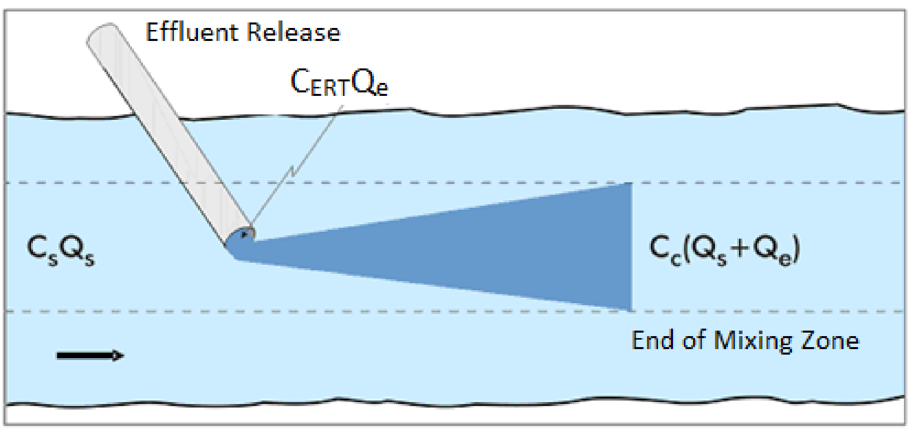
The licensee should use an exposure-based approach, where the calculation considers:
- an appropriate mixing zone in the final receiving waterbody applied only to the volume of effluent released prior to mixing with cooling water discharge
- additional dilution provided by the volume of cooling water 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 B.1.

Figure C.1: Elements of the loading mass balance



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

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

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,

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

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

A dilution factor can be defined as, $Fd = \frac{Q_e}{Q_s+Q_e}$ [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.

$$C_{ERT} = \frac{C_c-C_s}{Fd} + C_s \qquad [5]$$

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 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 MPDRCs
- 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* [27], which includes terms and definitions used in the *Nuclear Safety and Control Act* (NSCA) and the regulations made under it, and in CNSC regulatory documents and other publications. REGDOC-3.6 [27] 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* [27].

action level *(seuil d'intervention)*
An indicator of a potential loss of control of part of a licensee's program(s) or control measure(s). Exceeding an action level signals a potential reduction in effectiveness of the program and/or control measure(s) and may indicate a deviation from normal operation. Exceeding an action level is not a non-compliance, but triggers a requirement for specific action to be taken.

acutely lethal effluent *(effluents à létalité aiguë)*
Acutely lethal, in respect of an effluent, means that the effluent at 100% concentration kills more than 50% of the test organisms subjected to it for a period of 96 hours, when tested in accordance with the appropriate acute lethality test method specified below:

Where the salinity of the effluent is:
a) less than ten parts per thousand and the effluent is deposited into fresh waters, the specified test method is Reference Method EPS 1/RM/13 [1] and – if applicable – used in conjunction with the Procedure for pH Stabilization EPS 1/RM/50 [2].
b) equal to or greater than ten parts per thousand and the effluent is deposited into marine waters, the specified test method is Reference Method EPS 1/RM/10 [3].

References:
1. Biological Test Method: Reference Method for Determining Acute Lethality of Effluents to Rainbow Trout (EPS 1/RM/13 Second Edition), December 2000 (with May 2007 amendments), published by the Department of the Environment, as amended from time to time.
2. Procedure for pH Stabilization During the Testing of Acute Lethality of Wastewater Effluent to Rainbow Trout (EPS 1/RM/50), March 2008, published by the Department of the Environment, as amended from time to time.
3. Biological Test Method: Reference Method for Determining Acute Lethality Using Threespine Stickleback (EPS 1/RM10 Second Edition), December 2017, published by the Department of the Environment, as amended from time to time.

constraint *(contrainte)*
From the *IAEA Safety Glossary*
A prospective and source related value of individual dose (see dose constraint) or of individual risk (see risk constraint) that is used in planned exposure situations as a parameter for the optimization of protection and safety for the source, and that serves as a boundary in defining the range of options in optimization.

interim period *(période provisoire)*
With respect to environmental protection, the time from when adaptive management is triggered through to the completion of commissioning of the new treatment system or other control measures.

licensed limit *(limite autorisée)*
A limit that 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 limit *(limite de rejet autorisée)*
A limit that is part of the licensing basis and, if exceeded, represents a loss of control of part of the licensee's environmental protection program(s) or control measure(s). Exceeding a licensed release 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 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.

limitation *(limitation)*
With respect to environmental protection, a radiation protection principle that specifies the value of a quantity used in certain activities or circumstances that must not be exceeded, such as the public dose limit.

major modification *(modification majeure)*
A modification that requires a change to the licensing basis (that is, a licence amendment) 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)

maximum predicted design release characteristics *(caractéristiques des rejets nominaux maximaux prévus)*
In accordance with the *Class I Nuclear Facilities Regulations* and the *Uranium Mines and Mills Regulations*, 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.

mixing zone *(zone de dilution)*
An area where an effluent discharge undergoes initial dilution and is extended to cover the secondary mixing in the ambient water body. A mixing zone is an allocated impact zone where water quality criteria can be exceeded so long as acutely toxic conditions are prevented. At the end of this zone, which determines the volume of water allotted for effluent dilution, the specified water quality criteria must be respected. The allocation of a mixing zone rests on the principle that a small zone of degradation can exist without harming the sustainability of the ecosystem as a whole.

normal operation *(exploitation normale)*
The operation of a nuclear facility within specified operational limits and conditions, including (where applicable) start-up, power operation, shutting down, shutdown, maintenance, testing and refuelling. In nuclear reactors, normal operation is a plant state.
Note: Normal operations for any nuclear facility are those associated with the approved licensed activities. This includes the normal operation of any treatment system(s) during refurbishment or decommissioning, as defined by the approved licensed activities, and the specified operational limits and conditions documented within the facility's licensing basis.

optimization *(optimisation)*
With respect to environmental protection, the process of determining what level of protection and safety makes exposures and the probability and magnitude of potential exposures as low as reasonably achievable, economic and social factors being taken into account.

planned exposure *(exposition prévue)*
The situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure due to a source.

- Since provision for protection and safety can be made before embarking on the activity concerned, associated exposures and their probabilities of occurrence can be restricted from the outset.
- The primary means of controlling exposure in planned exposure situations is by good design of installations, equipment and operating procedures. In planned exposure situations, a certain level of exposure is expected to occur.

point of impingement (POI) *(point d'impact)*
The nearest point where air contamination emitted by a source impinges on a building or beyond the property line; any point on the ground or on a receptor, such as nearby buildings, at which the highest concentration of a contaminant caused by the aggregate emission of that contaminant from a facility or activity is expected to occur.

regulatory public dose limit *(limite de dose réglementaire au public)*
The prescribed limit for the general public, as specified in the *Radiation Protection Regulations*. This limit is 1 milliSievert (mSv) per calendar year, and it protects the public from radiation resulting from the normal operation of a nuclear facility or activity regulated under the *Nuclear Safety and Control Act*.

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*, https://www.ontario.ca/laws/regulation/050419/v8, 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, 2nd Edition, 2007 (translation, 2008).
26. CNSC, REGDOC-2.2.2, *Personnel Training*, Ottawa, Canada, 2016.
27. CNSC, REGDOC-3.6, *Glossary of CNSC Terminology*, Ottawa, Canada, 2018.

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.

C. APPENDIX C. CMD 22-M27

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

UNPROTECTED/NON PROTÉGÉ

ORIGINAL/ORIGINAL

CMD : 22-M27

Date signed/Signé le : 30 AUGUST-2022

Approve Regulatory Document

REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment*

Public Meeting

Scheduled for:

September 15, 2022

Submitted by:

CNSC Staff

Approuver le document d'application de la réglementation

REGDOC-2.9.2, *Protection de l'environnement* : *Contrôle des rejets dans l'environnement*

Réunion publique

Prévue pour le:

15 septembre 2022

Soumis par :

Le personnel de la CCSN

e-doc 6786175 (WORD)
e-doc 6860595 (PDF)

Summary

This CMD pertains to a request for a decision regarding:

- regulatory document REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment*

The following action is requested of the Commission:

- approve REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment*

The following items are attached:

- REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment*
- comments dispositioning table

Résumé

Ce document à l’intention descommissaires (CMD) concerne unedemande de décision au sujet du :

- document d’application de la réglementation REGDOC-2.9.2, *Protection de l’environnement : Contrôle des rejets dans l’environnement*

La Commission pourrait considérer prendre la mesure suivante :

- approuver le REGDOC-2.9.2, *Protection de l’environnement : Contrôle des rejets dans l’environnement*

Les pièces suivantes sont jointes :

- REGDOC-2.9.2, *Protection de l’environnement : Contrôle des rejets dans l’environnement*
- le tableau des réponses aux commentaires reçus

Signed/signé le

August 30, 2022/30 août 2022

DBeaton

Dana Beaton

Director General

Regulatory Policy Directorate

Directrice générale de la

Direction de la politique de réglementation

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EXECUTIVE SUMMARY

Regulatory document REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment* is part of the CNSC's environmental protection series of regulatory documents, which also covers environmental principles, assessments, and protection measures.

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

- applying the concept of best available technology and techniques, economically achievable (BATEA)
- establishing and implementing licensed release limits and action levels for releases to the environment
- commissioning of new treatment systems and confirming their 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 Protection: Environmental Principles, Assessments and Protection Measures*, previously published by the CNSC.

Environmental protection for nuclear facilities and activities is done in accordance with the *Nuclear Safety and Control Act* and the regulations made under it. The CNSC requires the environmental effects of all nuclear facilities or activities to be considered and evaluated when licensing decisions are made.

These requirements and guidance apply to licence applications for proposed new nuclear facilities or activities and amendments due to a major modification. For existing facilities and activities, this document will also be used to assess a licensee's environmental protection measures, including when a potential for unreasonable risk has been identified and adaptive management is required.

1 OVERVIEW

1.1 Background

Under the *Canadian Environmental Protection Act* (CEPA), 1999, pollution prevention is the government's priority approach to environmental protection.

Environmental protection for nuclear facilities and activities is done in accordance with the Nuclear Safety and Control Act (NSCA) and the regulations made under it. Under the NSCA and corresponding regulations, licensees are required to take all reasonable precautions to control the release of nuclear and hazardous substances to the environment because of the licensed activity.

Under section 12(1) of the General Nuclear Safety and Control Regulations, licensees of Class I nuclear facilities and uranium mines and mills are required to assess the effects on the environment and the health and safety of persons, and identify the measures that will be taken to prevent or mitigate those effects. In addition, the licence application must identify the proposed location of points of release, the proposed maximum quantities and concentrations, the anticipated volume and flow rate of releases of nuclear and hazardous substances into the environment, and the proposed measures to control releases to the environment.

For clarity of requirements and expectations related to the release of nuclear substances, the CNSC had relied on CSA N288.1, *Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities*[1], and derived release limits (DRLs) are currently applied as licensed release limits for most nuclear substances.

This reliance on Derived Release Limits or DRLs has two short-comings:

i. they only apply to releases of nuclear substances, and

ii. each DRL is based on a critical receptor achieving an effective dose equal to the Public Dose Limit of 1mSv/yr.

iii. approach not in-line with international best practices

In addition, commonly raised concerns from Commission Members and intervenors during Commission Proceedings have included:

- discussions on the lack of licensed release limits for hazardous substances (e.g., uranium, molybdenum, selenium), in the absence of which, action levels were used.
- a number of action levels and licensed release limits were set too high to be meaningful (could not be used to demonstrate pollution prevention or "loss of control"), and

[1] As of 2020, the title of the standard has changed to CSA N288.1, *Guidelines for modelling radionuclide environmental transport, fate, and exposure associated with the normal operation of nuclear facilities*.

- inconsistencies in methodology applied for establishing licensed limits and action levels across types of nuclear facilities

In order to address this, CNSC had undertaken extensive consultation since the release of discussion paper DIS-12-02, *Process for Establishing Release Limits and Action Levels at Nuclear Facilities*, which outlined an approach for controlling releases to the environment. The outcome of this consultation process resulted in the development of CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities* and the drafting of REGDOC 2.9.2.

In addition, other drivers for the development of REGDOC 2.9.2 are,

- to provide an approach for the application of pollution prevention in line with the CEPA, 1999 priority approach to environmental protection
- to harmonize with national and international best practices for the control of release to the environment
- to address 2019 International Atomic Energy Agency (IAEA) Integrated Regulatory Review Service (IRRS) recommendation related to authorizing releases
- to provide CNSC regulatory documentation required to meet regulatory conditions necessary to authorize releases under the *Fisheries Act.*

1.2 Highlights

REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment* standardizes and expands upon existing practices, and enhances the environmental protection framework. It provides a consistent and formalized setof requirements and guidance for controlling releases to the environment to meetthe regulatory requirements, and harmonize with national and international best practices by:

- applying the concept of best available technology and techniques, economically achievable (BATEA)
- establishing and implementing licensed release limits and action levels for releases to the environment
- commissioning a treatment system and confirming 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*, previously published by the CNSC.

These requirements and guidance apply to licence applications for proposed new nuclear facilities or activities and amendments due to a major modification. For existing facilities and activities, should this document be in the licensing basis, it will also be used to assess a licensee’s environmental protection measures, including when a potential for unreasonable risk has been identified and adaptive management is required.

Following the information in this regulatory document will prepare applicants to submit appropriate information to demonstrate that they will meet the requirements under the NSCA and its regulations and will make adequate provision for the protection of the environment, and the health and safety of persons.

This document will be used:

- by applicants for new nuclear facilities to prepare their licence application
- by licensees applying for major modifications to facilities or activities
- should this document be in the licensing basis, by licensees of existing nuclear facilities, including when adaptive management is required

The information provided in REGDOC-2.9.2 does not prevent applicants or licensees from proposing alternative ways to meet a requirement. Any proposed alternative (including the use of other codes and standards) should appropriately address the complexities and hazards of the proposed activities, and the applicant must demonstrate (by providing supporting information) that the proposed alternative demonstrates that the intent of the requirement is addressed by other means and meets an equivalent level of safety.

2 CONSULTATION

On March 29, 2021, a draft version of REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment* was issued for a 90-day public consultation period. This public consultation was conducted on the CNSC's e-consultation platform Let's Talk Nuclear Safety. This platform is viewable by anyone and is open for comments from anyone. E-mails were sent to the CNSC's subscribers' list, and notices were posted on the CNSC's website and social media. In addition, CNSC invited, by email, all of its contacts from Indigenous Nations and communities to get involved in the webinar and comment on the updated REGDOC. A number of Indigenous Nations and communities participated in the public information session / webinar, however, no specific questions or comments were raised by the participants representing Indigenous Nations and communities during the webinar or public comment period. In addition, this REGDOC was raised as part of the CNSC's ongoing engagement with communities with whom the CNSC has Terms of Reference for long-term engagement, including a discussion with the Saugeen Ojibway Nation (SON) in both the spring of 2021 and summer 2022, as well as with Curve Lake First Nation in fall 2021.

Information sessions were held in both English and French on April 9 and April 12, 2021, respectively to kick-off the consultation process. 99 participants attended the English session, and 10 participants attended the French session.

On July 21, 2021, a workshop was held with industry to answer their questions and better inform their final comments on the REGDOC.

During the consultation period, the CNSC received 49 distinct comments from 9 respondents:

- Canadian Nuclear Association (CNA)
- Ontario Power Generation (OPG)
- Hydro-Quebec
- Bruce Power
- Canadian Nuclear Laboratories (CNL)
- NB Power
- Cameco
- Ecometrix
- Gilles Provost, Ralliement contre la pollution radioactive

Following the public consultation period, comments from respondents were posted on the CNSC's e-consultation platform, from July 28 to August 11, 2021, for feedback on the comments received. No additional feedback was received.

Of the comments received, 48 were from Industry and one (1) was from an environmental group. There were no comments received from Indigenous groups.

CNSC staff addressed all comments. The comments helped to improve the clarity of the REGDOC. The comments disposition table was subsequently sent to all respondents, in February 2022.

A workshop was held with the industry respondents on February 18, 2022, to discuss remaining requests for clarity on the CNSC's responses. A revised draft of the REGDOC and the draft Comments Disposition Table were provided to workshop participants in advance. The CNSC staff provided the same material and offered the same opportunity to the non-industry respondent; there was no response.

During the workshop, the comments were discussed, and clarity was provided by CNSC staff to the satisfaction of participants. Following the workshop, the additional clarifications discussed were incorporated into the REGDOC and Comments Disposition Table.

The following themes of comments raised during public consultation are of particular interest:

Comment Theme 1: Duplication of Authority

Stakeholders expressed concern that there is perceived duplication of authority with provincial regulators relating to non-radioactive hazardous substances, which increases the potential for regulatory confusion.

CNSC staff response:

Under the NSCA and its regulations, the CNSC's mandate is to regulate the release of both nuclear and hazardous substances.

The intent of this REGDOC is to reduce regulatory duplication through harmonization with other jurisdictions, by adopting licensed release limits that exist in applicable federal, provincial, territorial and municipal requirements, such as in regulations, by-laws, permits or approvals, so long as the limit values are protective of people and the environment. REGDOC-2.9.2 requires that proposed release limits be at or below applicable limits in existing legislation. CNSC staff have established Memorandum of Understanding with *Environment and Climate Change Canada*, which includes this subject.

Where existing federal/provincial/territorial requirements do not adequately protect the environment (as supported through an environmental risk assessment or other scientifically defensible assessment), CNSC will engage with the applicable jurisdictions, when determining the most appropriate licensed release limit.

Comment Theme 2: Action Levels

The term "maximum predicted design release", which is used in the REGDOC for development of licensed release limits, is similar to, and might be confused with, the term "upper value of normal operation", which is used in the development of action levels and defined in CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities*.

Stakeholders were also concerned that their current action levels are based on CSA N288.8 and will have to be revised once REGDOC-2.9.2 is implemented.

CNSC staff response:

For the first concern, CNSC staff included additional content in annex to the REGDOC which describes the relationship between environmental release targets, maximum predicted design release, licensed release limits, and action levels.

The text clarifies that licensed release limits represent the "maximum concentrations and quantities" that could be released from the facility during normal operation, and are based on the "maximum predicted design releases". As the licensed release limits are based 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 and represent the upper bound of current operational performance (e.g., most recent 5-year history), and thus are expected to change with changes in the day-to-day operation. By nature of these two threshold values, there needs to be adequate margin between the “upper value of normal operation” (the action level) and the “maximum predicted design release” (the limit) so that there is room for the action levels to work as intended.

The REGDOC allows for operational flexibility in setting the proposed release limits so that they correspond to an actual loss-of-control of normal releases.

CSA N288.8 provides requirements and guidance to update action levels when there is a change in release limits.

Comment Theme 3: Licensed Release Limits Methodology for Nuclear Substances

Stakeholders expressed concerns that the scope and methodology for proposing a licensed release limit was not fully clear. Clarifications were requested on the following topics:

- application of the REGDOC and licensed release limits to decommissioning activities
- approval process for licensed release limits
- methodology for establishing licensed release limits at existing facilities for nuclear substances
- application of licensed release limits in the environmental risk assessment (ERA)

CNSC staff response:

CNSC staff provided clarification to each of the major sub-comments as follows:

- CNSC staff revised section 1.2 to clarify that the scope of the document applies to decommissioning facilities and the normal operation of any treatment system(s) during decommissioning.

- CNSC staff revised the text to include that: for new facilities, or existing facilities undergoing major modifications requiring a licence amendment, the proposed licensed release limits are to be submitted with the licence application for approval by the Commission. Any changes to the licensed release limits for an existing facility would require approval by the Commission or its delegated authority.

- CNSC staff made minor revisions throughout Section 5.1 to provide additional information and details to improve clarity of the methodology for establishing licensed release limits for existing facilities.

- CNSC staff revised the text to clarify the requirement to demonstrate, through the ERA, that releases at the level proposed as the licensed release limit are safe, and do not pose unreasonable risk to human health or to the environment.

Comment Theme 4: Application of Environmental Release Targets

Stakeholders expressed concern that there was a lack of clarity regarding the meaning of environmental release targets and how they are to be applied.

CNSC staff response:

Environmental release targets apply during the design and commissioning phase.

Additional information was incorporated in Appendix C to clarify the relationship between environmental release target, maximum predicted design release, licensed release limit, and action levels. In addition, parts of the document were revised to reduce the confusion and add more information.

Residual Industry Concerns: Administrative Burden and Perceived Reputational Risk

Certain licensees have expressed ongoing residual concerns over the need for this document. They are concerned that the administrative burden of implementation will not result in any changes to environmental protection at the large facilities. In addition, they expressed that the publication of this document, with extensive new measures, could be perceived by stakeholders and Indigenous Groups as evidence of a need for increased regulatory surveillance. There is concern that this message is inappropriate, and unnecessarily damaging to the industry. They remain of the opinion that this document is not needed.

CNSC staff response:

This regulatory document provides tangible safety benefits and improves regulatory transparency by formally documenting existing practices.

It provides a published approach on applying a federal government priority for pollution prevention, a response to a 2019 International Atomic Energy Agency (IAEA) Integrated Regulatory Review Service recommendation related to authorizing discharges, clarity on consequences and reporting requirements when treatment systems fail under normal operations and clarity on the triggers for adaptive management.

Administrative burden on existing licensees can be minimized by updating licensee management system documents in accordance with existing cyclical review cycles (such as ERA and Periodic Safety Reviews) and providing the CNSC with a plan outlining when these updates are expected to be completed by.

In addition, REGDOC-2.9.2 is required to harmonize with international best practices, document and standardize existing practices with development of limits for hazardous substances, allow CNSC regulatory documentation to meet regulatory conditions necessary to authorize releases under the *Fisheries Act*, provide requirements and guidance on adaptive management and provide a single source of information on the control of releases for in-progress applications and potential future applicants.

Consultation Conclusion

Consultation on this project was extensive and took place over many years, starting with a discussion paper in 2012. The CNSC undertook extra efforts at the beginning of public consultation, to host information sessions in English and French which clarified the draft document for participants, in advance of submitting comments. Some members of the public, environmental groups, industry and seven Indigenous groups participated in these sessions. In addition, staff drew attention to the document in outreach with Indigenous groups with which the CNSC regularly communicates, and conversations were held with the SON. While no comments were received from Indigenous groups or the public in the final steps of the regulatory document development process, engagement and awareness of the regulatory document have been continuous. One comment was received from an environmental group. The CNSC staff are satisfied with the consultation and engagement activities conducted to date and anticipate greater interest around this REGDOC and environmental release discussions when specific projects are discussed in public Commission hearings or meetings.

Certain licensees have expressed ongoing residual concerns about the need for this document. They are concerned that the administrative burden of implementation will not result in any changes to environmental protection at the large facilities and remain of the opinion that this document is unnecessary. CNSC management and staff are of the view that the document is necessary to standardize and formalize existing industry practices, and for continued regulatory excellence to protect people and the environment as a whole. CNSC staff will consider phased implementation at existing facilities. This is further discussed in Section 3 on Implementation.

In accordance with the CNSC’s practice, the draft regulatory document along with the Comments Disposition Table is being provided to all commenters, for information, 30 days prior to the Commission meeting date. Commenters will be invited to share any follow up comments with staff in advance of the Commission meeting, in order that staff may be prepared to address any outstanding issues at the meeting.

As with all CNSC regulatory documents, this document is considered evergreen. Members of the public, Indigenous groups and stakeholders are invited to submit comments or concerns at any time.

3 IMPLEMENTATION

If approved, this regulatory document will immediately apply to all new applications for a licence to construct, operate or decommission a Class I nuclear facility or uranium mine and/or mill.

Existing facilities and activities already incorporate BATEA into their design and are considered to have maintained the intent of BATEA through their operational programs, such as:

- Periodic Safety Reviews (PSR)

- Fitness for Service and Aging Management
- Continuous improvements within the environmental management system

Most existing Class I nuclear facilities and uranium mines and mills have already implemented action levels that are in alignment with CSA N288.8 and are already in compliance with this REGDOC.

Existing licensees who have not updated their action levels, may update action levels and propose licensed release limits as part of their ongoing cyclical updates, such as an ERA and PSR, to minimize the administrative burden of implementation. Once REGDOC-2.9.2 is incorporated into the licensing basis for these facilities, action levels and licensed release limits will be updated using the methodologies outlined in this REGDOC.

For existing facilities currently practicing adaptive management, CNSC staff expect no change as this REGDOC is formalizing CNSC current practice.

CNSC staff will direct applicants and proponents of new projects to use this regulatory document in preparing an application for a licence to construct, operate or decommission a Class I nuclear facility or uranium mine and/or mill.

4 CONCLUSIONS AND RECOMMENDATIONS

4.1 Conclusions

REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment* was developed through extensive consultation with stakeholders and is essential to complement the CNSC's requirements and guidance for environmental protection of regulated facilities and activities.

CNSC staff conclude REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment*, is ready for final approval by the Commission for publication.

4.2 Recommendations

CNSC staff recommend that the Commission approve REGDOC-2.9.2, *Environmental Protection: Controlling Releases to the Environment*.

Canada's Nuclear Regulator

Environmental Protection

Controlling Releases to the Environment

REGDOC-2.9.2

September 2022

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

Canada

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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 (BATEA)
- 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 advised or permissible within the limits of this regulatory document. "Can" is used to express possibility or capability.

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

Table of Contents

Controlling Releases to the Environment

1. Introduction

1.1 Purpose

Environmental protection for nuclear facilities and activities 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 intend to release nuclear or hazardous substances to the environment. It applies to those from direct releases to air, surface water, sewer, or through the ground, including where natural or engineered barriers for control are proposed or incorporated. This REGDOC 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 (ERA), and to develop and implement an environmental management system (EMS). 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 does 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 they meet 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 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 interaction 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)

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*
- 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*
- CSA N288.6, *Environmental risk assessment at Class I nuclear facilities and uranium mines and mills* [3]
- CSA N288.7, *Groundwater protection programs at Class I nuclear facilities and uranium mines and mills* [4]
- CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities* [5]

The International Atomic Energy Agency's (IAEA) general safety guide GSG-9, *Regulatory Control of Radioactive Discharges to the Environment*, 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 REGDOC focuses on controlling releases to the environment under normal operations.

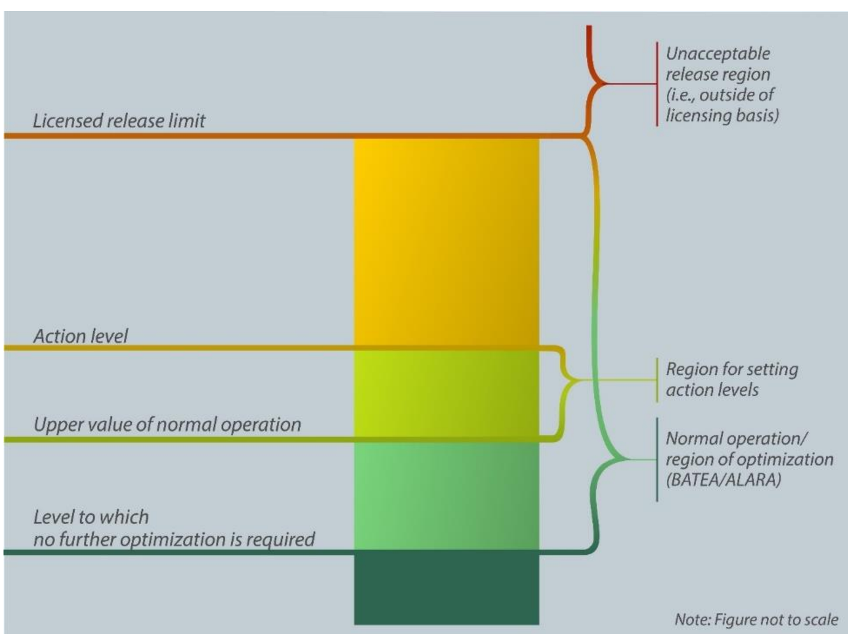
Paragraph 12(1)(f) of the *General Nuclear Safety and Control Regulations*, deals with "reasonable precautions" regarding control of releases. REGDOC-2.9.1 [1] specifies that reasonable precaution in the context of controlling releases involves the application of Best Available Technology and Techniques Economically Achievable (BATEA) and the application of the As Low As Reasonably Achievable (ALARA) principle. Thus, licensees are required to control releases to limits specified within regulation and demonstrate the application of BATEA and ALARA. Hereafter, the term BATEA is considered to refer to both nuclear and hazardous substances with ALARA utilized 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).

The figures below are conceptual and are not necessarily to scale. The actual range between the values depends on the site-specific design and operation of the facility or activity, and 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

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 their 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 released 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 one individual sample.

Exceeding a licensed release limit (i.e., red light) signals that the licensee is operating outside the 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 indicate an unreasonable risk to the environment or to the health and safety of persons.

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 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 (i.e., 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 and represent the upper bound of current operational performance, and thus are expected to periodically be reached.

Action levels are based on the most recent (e.g., 5-year) operating history of the facility, and therefore change over time. Action levels may increase or decrease, depending on the day-to-day changes of the operation that lies within the current licensing basis.

For more information on action levels, see section 6.

2.1.3 Overview of upper value of normal operation

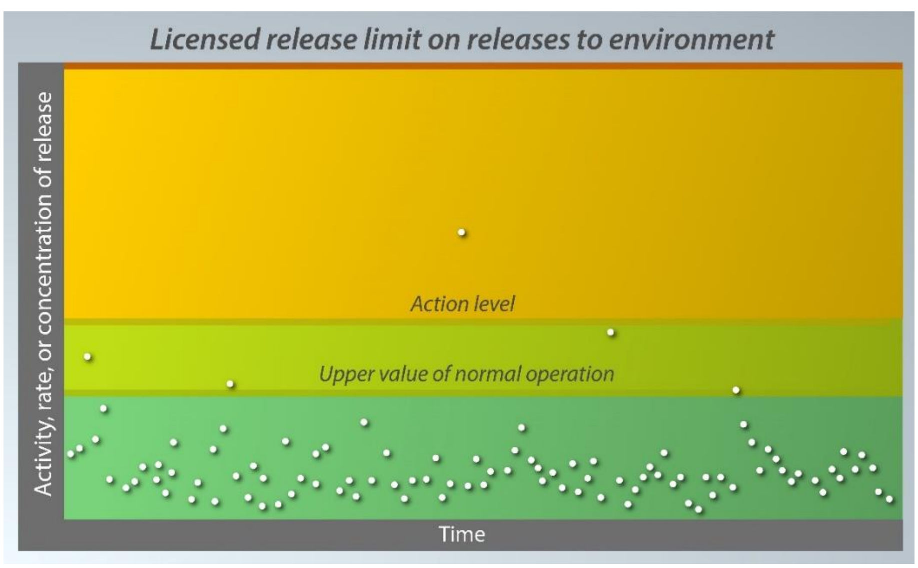
The upper value of normal operation represents the expected upper bound release, based on the predicted or current operating conditions, and is typically determined using either:

- 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.

The figure below shows operational performance data that demonstrates the relationship between the upper value of normal operation for a sample nuclear or hazardous substance, the action level for environmental releases, 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 operational monitoring program results (i.e., daily or weekly grab or composite sample concentrations) that correspond to a licensee’s effluent/emission monitoring program. Several action level exceedances may occur before triggering a licensed release limit. It also allows time for the licensee to respond to an action level exceedance and restore the effectiveness of the program before a 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.

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 (e.g., 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 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)
- licence 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 clearly outside the bounds established in the licensee's licensing basis. 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 as described in the approved ERA or similar documentation, which is submitted as part of a licence application and forms part of the licensing basis

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.

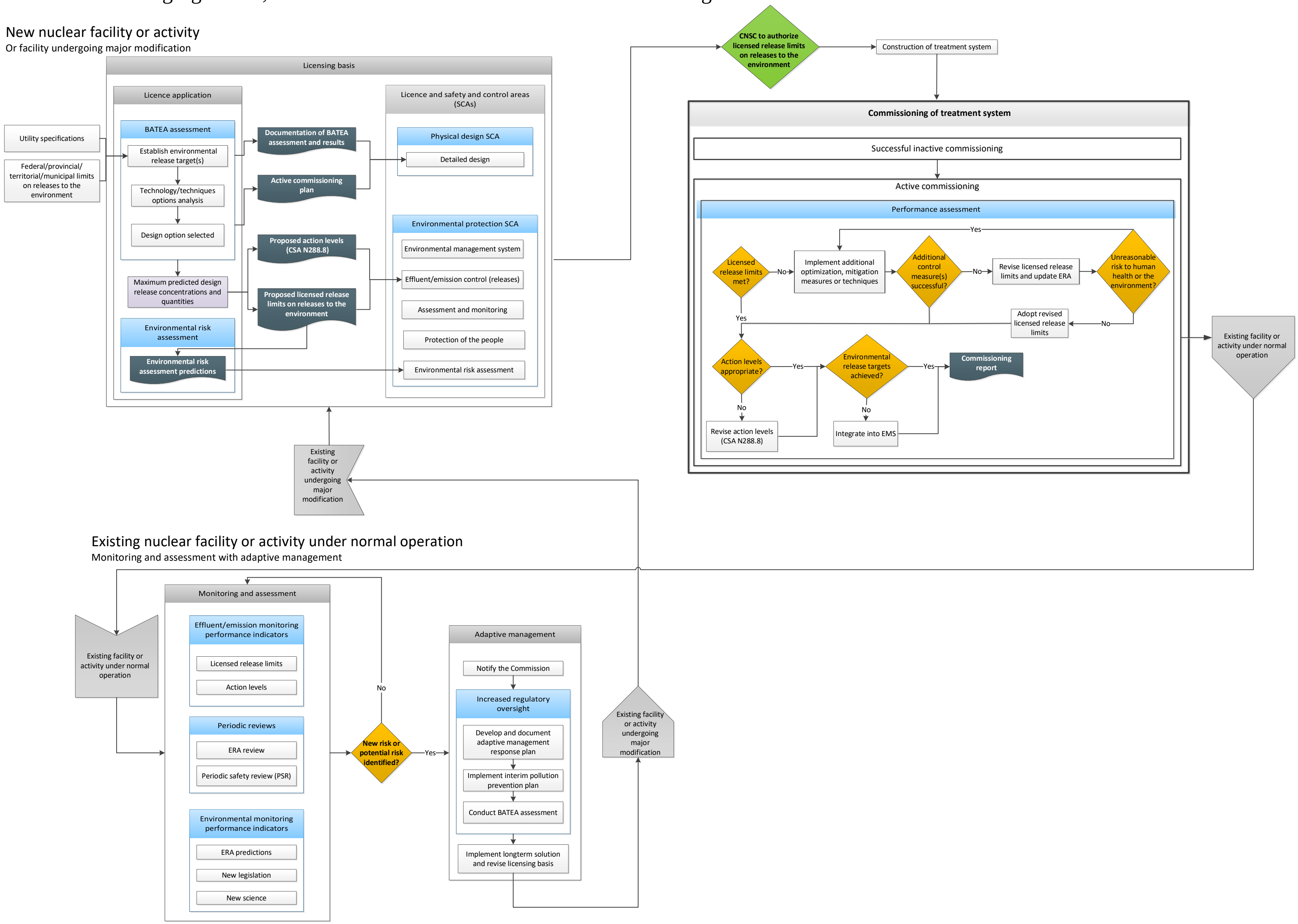


Figure 3a: Information on control measures for releases to the environment to be submitted for a new facility or activity applying for a licence to construct, or an existing facility undergoing a major modification and requiring a licence amendment

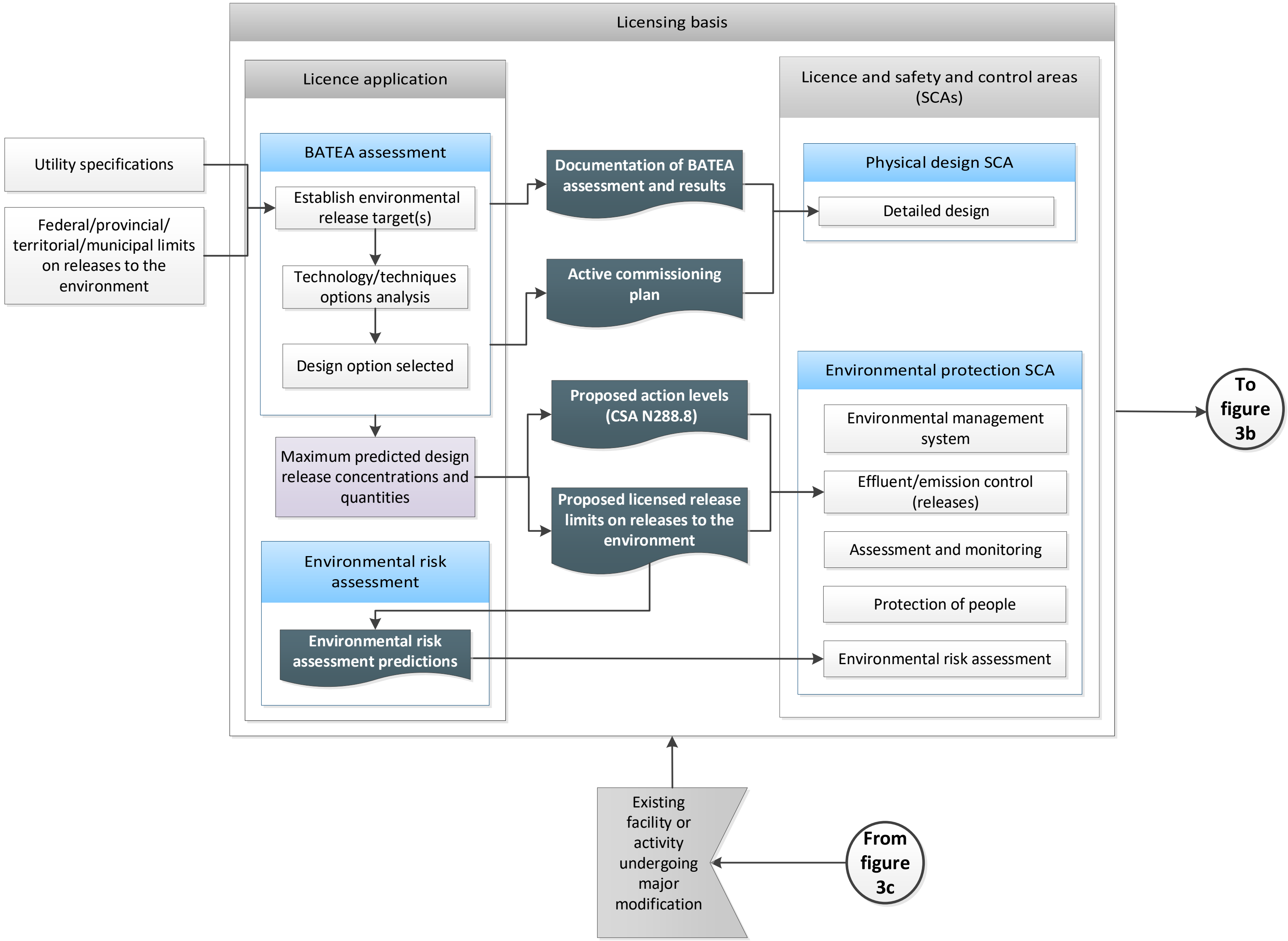


Figure 3b: Commissioning treatment system(s)

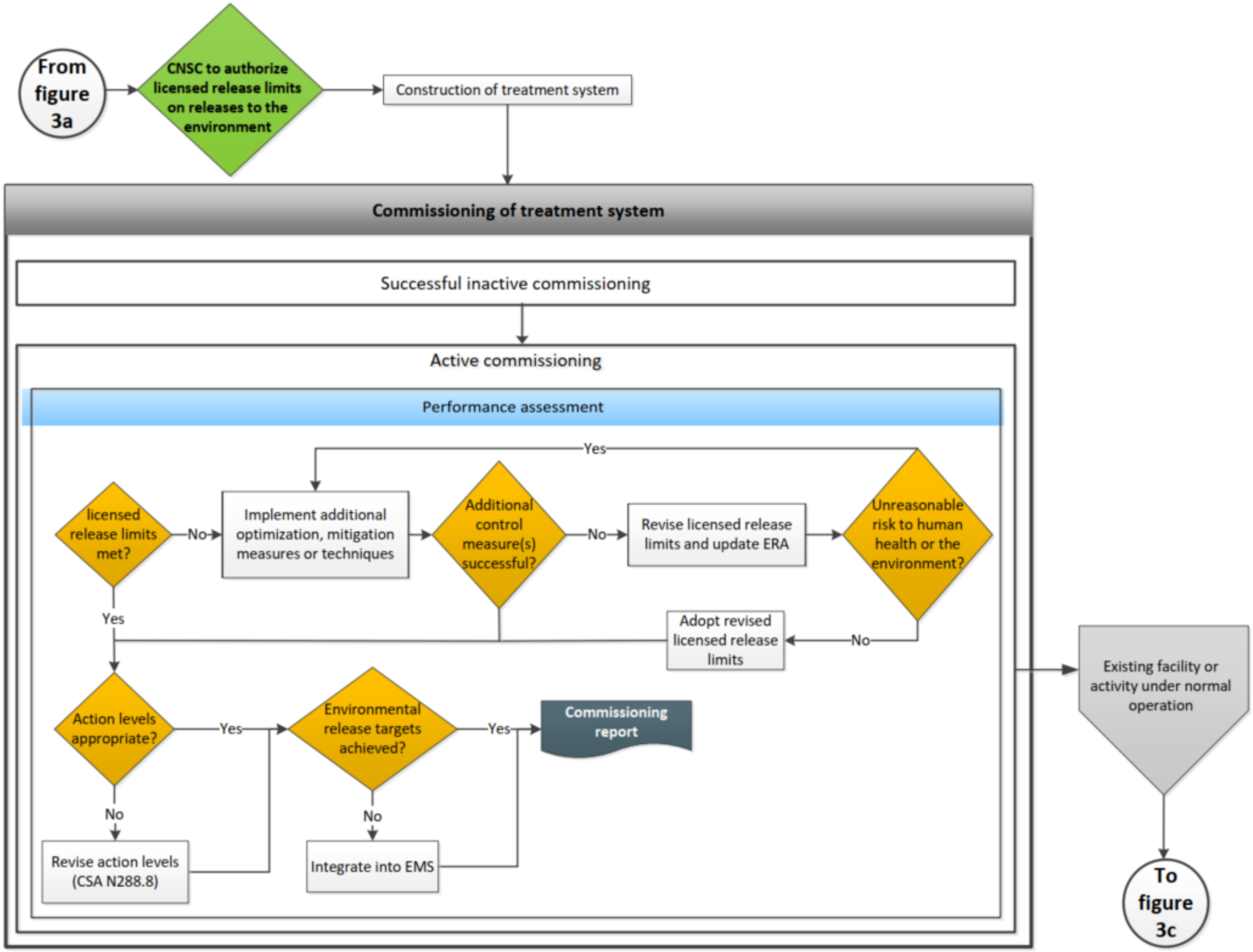
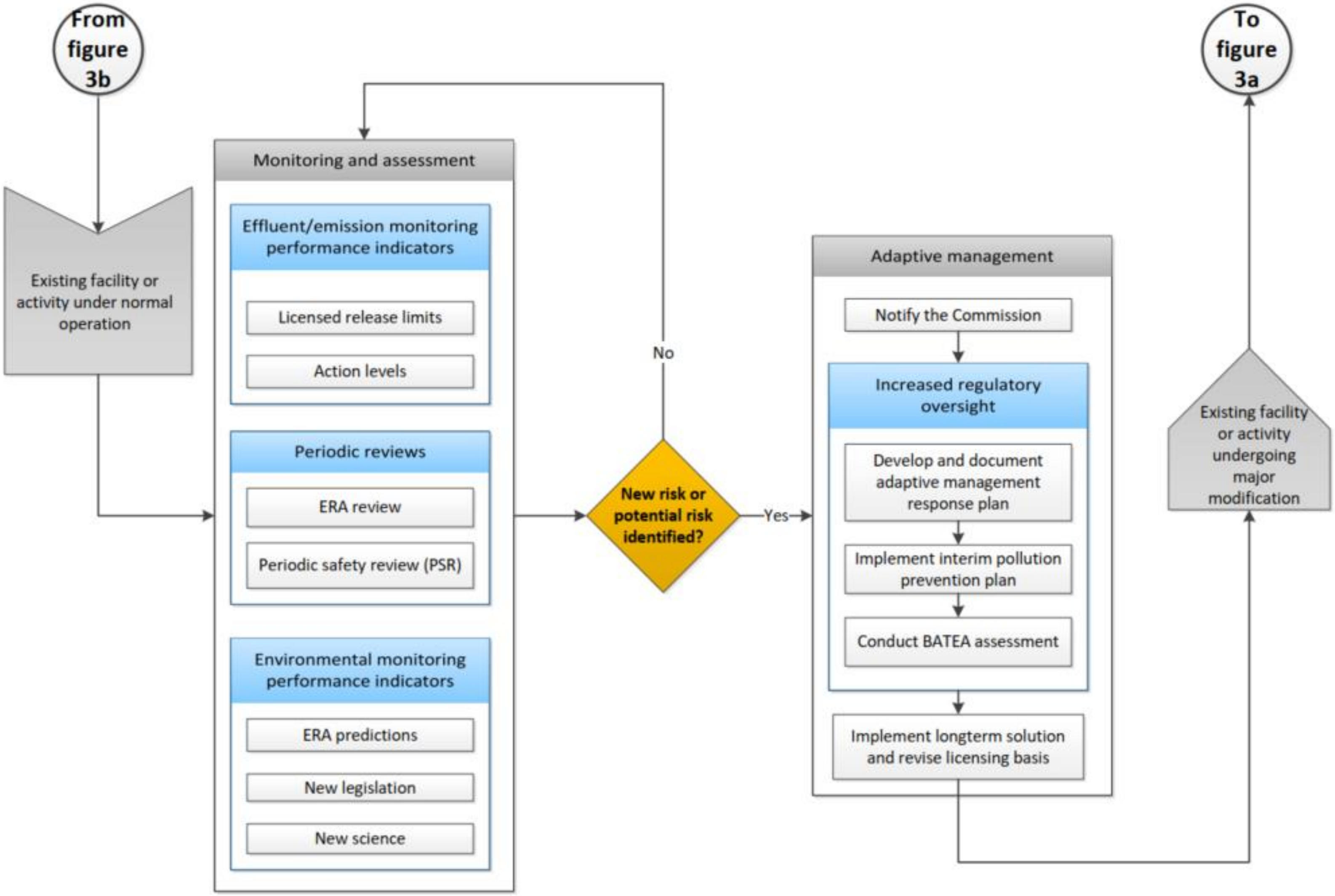


Figure 3c: The part of the overall process for establishing control measures that is specifically for a nuclear facility or activity under normal operation



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 the ERA are used to identify any contaminants or physical stressors which may require mitigation including implementation of additional controls on releases to the environment. The 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, in accordance with federal, provincial and territorial requirements

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* [10])

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 effluent 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)
- if a previously unmanaged risk is identified in the ERA, and adaptive management is required to restore the effectiveness of the environmental protection program, upon completion of the ERA, notify the Commission

  Note: Some examples of unmanaged risks are those arising 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 the environment or on human 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 characteristics 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 their environmental protection program.

Like applying the ALARA concept, 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* [7]
- REGDOC-2.6.3, *Aging Management* [11]

4. Best Available Technology and Techniques Economically Achievable (BATEA)

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 characteristics to:
  - set licensed release limits
  - develop action levels (for new facilities)

The maximum predicted design release characteristics include the location of the points of release, the maximum quantities and concentrations, and the anticipated volume and flow rate of nuclear and hazardous substances expected to be released to the environment. The maximum predicted design release characteristics correspond to the residual release: that is, the remaining release of a nuclear or hazardous substance, after accounting for all treatment and mitigation.

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 on 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 (ERT) 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 utilized:

- dose constraints, concentrations, or total loadings identified in federal and/or provincial regulations as being applicable to the substance and type of release (emission/effluent) being evaluated
- risk based ERTs based on receiving environment quality criteria (e.g., dose constraints, CCME 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 licence 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 (e.g., 1 in 100-year 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* 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 maximum predicted design release characteristics includes the concentration and quantities expected to be released from the facility or activity.

When determining the maximum predicted design release characteristics, 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, maximum predicted design release characteristics, 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*.

5. Licensed Release Limits

Licensed release limits apply to releases to the environment from that facility or activity and are applied to the final point of control.

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, and includes a margin providing operational flexibility (i.e., the maximum predicted design release) as described in the licensee's design basis documentation. 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 for that facility or activity.

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 licenced release limits represent the upper bound on acceptable releases, 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 is demonstrated through the 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

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 enhanced regulatory oversight is applied. 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 licenced release limits with those currently in federal/provincial/territorial regulations that are applicable to the licenced activity.

The licenced release limits are based on the predicted maximum design release with a margin incorporated to allow for operational flexibility. The approach establishes licensed release limits at levels well below anticipated harm, but if exceeded clearly indicate a failure in the environmental protection program for control of releases.

For nuclear substances, this 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 licenced 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.

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

Note: The licensed release limit is set at a level that ensures no unreasonable risk to human health and the environment, and as a result is protective of human health and the environment. This is supported by its application as a source term in the ERA. 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
- 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)

The proposed site-specific 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; i.e. licensed release limits)

For contaminants and physical stressors that do not have established limits on releases, the applicant or licensee shall use the maximum predicted design release concentrations or quantities 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 release points where release limit(s) will apply
- identify the maximum predicted design release(s) (MPDRs)
- 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 release points where release limits will apply

The list of points of release 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 release limits may be applied.

Identify the maximum predicted design release(s)

Identify the maximum predicted design release concentrations and quantities for each 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 maximum predicted design release should be established by using historical performance data for each controlled release point
    - for nuclear substances specifically, facility-wide and/or activity-wide maximum predicted design release(s) 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, and
            - their fraction contribution to the total dose
        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 maximum predicted design release 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, back calculate from the dose corresponding to the maximum predicted design release and multiply by its fraction contribution to the total dose identified in step i, to obtain a facility-wide and/or activity-wide maximum predicted design release

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* [5], for a retrospective approach, using a percentile that represents a clear loss of control, and as informed by site-specific knowledge and professional judgement.

For those licensed nuclear facilities where, due to the nature of the operation (e.g., 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 maximum predicted design release to account for anticipated operations throughout the lifetime of the facility.

Identify each contaminant and physical stressor that requires a release limit

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

i. that are subject to existing federal, provincial, territorial, or municipal requirements on releases; or
ii. where the MPDR 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. that are identified within the ERA as requiring control.

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 that this review is already required for a licensee's environmental management system).

A 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 maximum predicted design release 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 maximum predicted design release 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 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 release limits continue to not be required by confirming the dose remains below 0.01 mSv and any applicable CNSC prescribed dose constraint (e.g., 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

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

- adopt those applicable governmental requirements on releases that were previously identified

  Note: Where other government requirements on releases that are applicable to the facility and/or activity exist, 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 (POI)), municipal by-laws, and provincial or territorial permits, authorizations, or licences.

  Note: To harmonize with requirements on releases to protect local air quality (e.g., O. REG 419/05), proposed release limits for those contaminants and/or physical stressors of regulatory interest may be established by back calculating from the POI, using site-specific release characteristics (e.g., flow rates, stack heights, stack temperature).

  Note: 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 in a timely manner to update the licence conditions handbook. The updated licensed release limits will be in effect in accordance with the date specified by the respectable jurisdiction.

  Note: 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.

- for each contaminant, where existing requirements on releases do not exist, or are deemed to not be adequately protective of the environment, set the proposed release limit as the maximum predicted design release concentration that applies to the maximum monthly mean concentration

  Note: To allow for operational flexibility, a proposed release limit for waterborne releases may be applied for a composite sample at 1.5 times the maximum monthly mean concentration, or to a "grab sample" at 2 times the maximum monthly mean concentration. The application of these factors is a common regulatory approach.

- 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

  Note: For nuclear substances, facility-wide and/or activity-wide release limit(s) may be established for those facilities with multiple release points.

Note: Licensed release limits based on the maximum predicted design release 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.

Note: 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.

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 use the proposed release limits in the ERA to demonstrate that, at the level of the proposed release limits, there is no unreasonable risk to human health or to the environment.

Note: A licensed release limit is 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 may be assessed conservatively in the ERA through a scenario whereby a continuous release at the proposed release limit(s) is assumed. If, due to the nature of the facility and/or activity, the maximum predicted design release 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 in the ERA. Exceeding the approved ERA release values means operating outside of the licensing basis, which results in the facility or activity entering adaptive phased management. In scenarios where periodic or time-limited higher releases are anticipated, the proposed release limit may incorporate temporal limits.

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* [3]

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 REGDOC applicable to the facility or activity:
  - REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants* [8]
  - REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills* [9]
  - 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* [13]

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)

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 and operationally based. For more information, see:

- for nuclear power plants, REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants* [8]
- 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* [9]
- CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities* [5]

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 [14].

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 action levels appropriate to the operational parameters of the type of 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* [5].

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* [5]
- 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* [5]
- 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 [5] 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 characteristics
- 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 (for example, with the Ontario Ministry of the Environment, Conservation and Parks).

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 maximum predicted design release characteristics 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 whether the licensed release limit can be met through further optimization or application of additional mitigation measures or techniques to reduce releases below the licensed release limits

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, then 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 targets established in section 4.2.1 (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* [15]
- guidance from the U.S. Department of Defense, *Planning and Commissioning Wastewater Treatment Plants* [16]

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 [14].

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 EP Framework

The information in this appendix should be consulted as referred to in the applicable sections of this REGDOC. 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 REGDOC. 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 (CLs)
  - 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.

Environmental protection (EP) 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

EP 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 conditional clearance levels documented in table A.1), on the condition that releases occur only through the specified pathway (i.e., solids to municipal landfill, gases to atmosphere, liquids to municipal sewer)
- practice-specific conditional clearance, 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 µSv/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 (i.e., at the licence application stage) that releases will not exceed:

- Criterion i): if 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 NSRDRs
  - 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): if 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 (i.e., 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, e.g., via the annual compliance reports that the total quantity acquired/used over one year is less than the corresponding generic CCL

- Criterion iii): the 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 (e.g., 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 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.

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 conditional clearance levels (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* [17]
- 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* [18]
- 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* are built on a hierarchical structure incorporating the radiation protection concepts of Exclusion, Exemption, Clearance (either unconditional or conditional) and Authorization of Discharge (i.e., "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 (e.g., 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 (e.g., 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 (i.e., 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" which 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, 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, the basics of which are provided below.

Dose criterion for deriving generic CCLs

The CCLS are:

- IAEA *de minimis* dose concept of 10 µSv/year for a member of the public and
- 10 µGy/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 µGy/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 (i.e., most sensitive). This dose rate is the lowest recommended internationally (i.e., < 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* [19]. 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 19 [19].

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 TECDOC-1000, 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 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 metres (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 two 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 μSv from each of the two groups of pathways. The smaller of the two 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. The influent flow rate (in m^3/year) for this reference WTP was estimated by considering Canadian WTP influent rates for 2016 – 2018 for three WTPs in Toronto and 5 WTPs in Vancouver. The “per capita” annual average inflow rate was approximately 130 m^3/a, which is equivalent to 2.6 million m^3/a for a population of 20,000. The values in column 4 of table A.1 were divided by 2.6 million m^3/a to obtain the resultant concentrations.

Releases containing more than one radioisotope

When more than one radionuclide is released via one mode of release (i.e., 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 one 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 one calendar year

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

Column 1	Column 2	Column 3	Column 4
Radionuclide	**Municipal landfill (Bq/g) Note: 1**	**Annual activity released to atmosphere (MBq) Note: 2**	**Annual activity released to municipal sewer (MBq) Note: 2, 3**
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

Column 1	Column 2	Column 3	Column 4
Radionuclide	**Municipal landfill (Bq/g) Note: 1**	**Annual activity released to atmosphere (MBq) Note: 2**	**Annual activity released to municipal sewer (MBq) Note: 2, 3**
Co-58	10	1,000	100
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

Column 1	Column 2	Column 3	Column 4
Radionuclide	**Municipal landfill (Bq/g) Note: 1**	**Annual activity released to atmosphere (MBq) Note: 2**	**Annual activity released to municipal sewer (MBq) Note: 2, 3**
Sb-124	10	-	0.1
Sb-125	100	100	1
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

Column 1	Column 2	Column 3	Column 4
Radionuclide	**Municipal landfill (Bq/g) Note: 1**	**Annual activity released to atmosphere (MBq) Note: 2**	**Annual activity released to municipal sewer (MBq) Note: 2, 3**
Yb-169	100	100	1
Lu-177	1,000	1,000	10
Lu-177m	10	-	0.1
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

Column 1	Column 2	Column 3	Column 4
Radionuclide	**Municipal landfill (Bq/g) Note: 1**	**Annual activity released to atmosphere (MBq) Note: 2**	**Annual activity released to municipal sewer (MBq) Note: 2, 3**
Th-229	1	-	1
Th-232	1	0.1	1
U-232+	1	-	0.1
U-233	10	1	
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

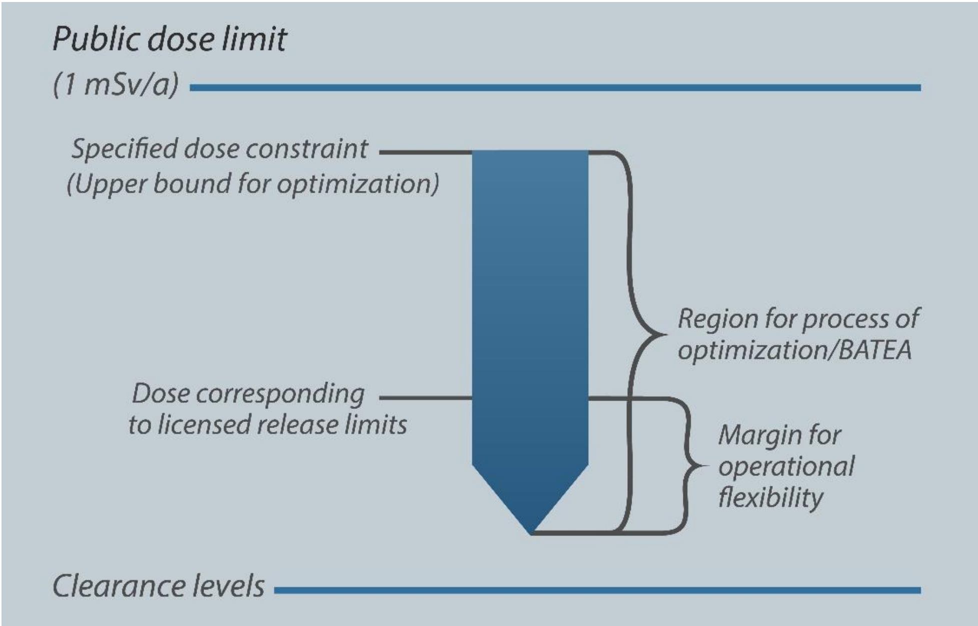
B.1 Radiation Protection Principles and BATEA

Optimization and authorized releases to the environment (licensed release limits)

In practice, optimization is BATEA regarding minimization of contaminant pollution and controls on the 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). Optimization of protection can be considered as complementary to the concept of pollution prevention (a core principle of the environmental protection measures described in REGDOC-2.9.1 [1]).

Figure B1 shows a general relationship between optimization and the authorization of radioactive releases to the environment (that is, licensed release limits). Through optimization (demonstrated by the application of BATEA), 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 (μSv) 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[1]



When applying the concept of optimization to establish licensed release limits, modelled doses approximating 10 µSv/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 µSv/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

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

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 (e.g., 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 (e.g., N288.1). 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, 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 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 (e.g., 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 (i.e., 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 quantities and concentrations based on the identified BATEA design option, taking into account a margin for operational flexibility. In cases where applicable federal, provincial, territorial, and/or municipal release limits already exist, these limits will 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 (e.g., based on an assessment within the ERA), then the maximum predicted design releases, which now form part of the licensing basis of the facility, are then established as the proposed release limits. The proposed release limits are then used in the environmental risk assessment (ERA) 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 (i.e., 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 maximum predicted design release 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.

It should be noted that there is a clear distinction between action levels and licensed release limits as described below.

Action levels are operationally/performance-based and represent the upper bound of current (most recent historical) operational performance, and thus are expected to periodically be reached. Licensed release limits that are based on the maximum predicted design release depend on the design of the facility, which in itself is risk-informed.

Action levels are based on the most recent (e.g., 5-year) operating history of the facility, and therefore change over time, either increasing or decreasing, depending on the day-to-day changes of the operation that lies **within** the current licensing basis. Licensed release limits do not change over time as stated above.

Exceeding an action level signals a potential loss of control (i.e., 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 (i.e., red light), and that the facility is operating outside of its approved facility design, and hence its licensing basis.

In this approach, there is sufficient margin between triggering an action level and triggering a licensed release limit. Action levels are compared to the operational monitoring program results (i.e., daily or weekly grab or composite sample concentrations) that correspond to a licensee's effluent/emission monitoring program. Licensed release limits are compared to periodic average monitoring results (i.e., monthly average concentrations). This allows for several action level exceedances to occur before triggering a licensed release limit. It also allows time for the licensee to respond to an action level exceedance and restore the effectiveness of the program before a 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 concentrations or the quantities 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 environmental management system (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 (e.g., 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:

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. 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 based on the historic performance of the facility or activity, or of existing similar facilities or activities

- 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 [3]
- IAEA, TECDOC 1714, Management of Discharge of Low Level Liquid Radioactive Waste Generated in Medical, Educational, Research and Industrial Facilities [12]

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 release point and contaminant or physical stressor identified as requiring control, identify the most restrictive criteria for each of the following:
   - most sensitive species or human receptors (generic or site-specific)
   - most reasonable 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 ambient air for the protection of human health, a 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* [20]
  - CCME *A Protocol for the Derivation of Water Quality Guidelines for the Protection of Aquatic Life 2007* [21]
- 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 a POI approach, the POI should be defined to align with the applicable federal or provincial requirements (e.g., Ontario Ministry of Environment and Climate Change).

For more information about releases to groundwater, see CSA N288.7, *Groundwater protection programs at Class I nuclear facilities and uranium mines and mills* [4].

C.5.2.1 Mixing zones

For calculating the environmental release targets:

- where federal, provincial, or territorial guidance exists for mixing zones, the licensee should follow that guidance
- where such guidance does not exist for mixing zones, the licensee should apply the general mixing zone 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 [22])

Release point	Maximum mixing zone 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
Ambient 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 aerial extent of the initial mixing zone (also called a dilution zone), see provincial mixing zone guidance (for example, reference [22] and CCME *Guidance on the Site-Specific Application of Water Quality Guidelines in Canada)* [20]).

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.

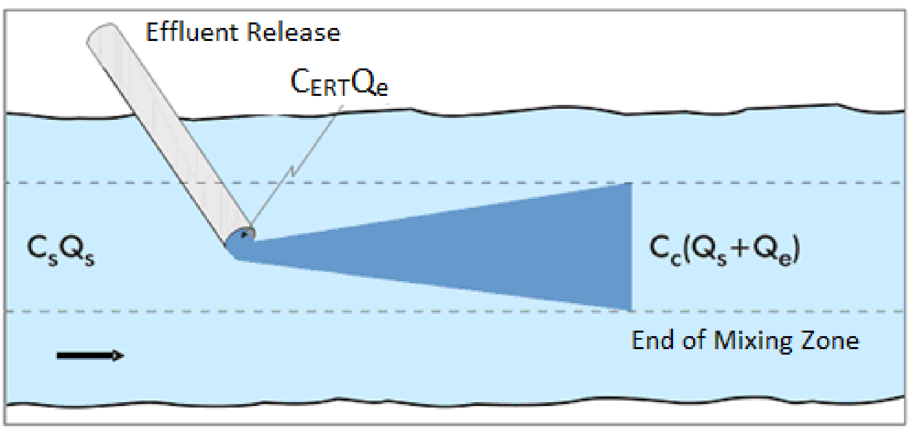
The mixing zone:

- 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 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 B.1.

Figure C.1: Elements of the loading mass balance



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

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

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,

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

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

A dilution factor can be defined as, $Fd = \frac{Q_e}{Q_s + Q_e}$ [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.

$$C_{ERT} = \frac{C_c - C_s}{Fd} + C_s \qquad [5]$$

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 1: 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 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* [23].

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* [5].

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 releases
- 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* (NSCA) 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.

action level *(French)*
An indicator of a potential loss of control of part of a licensee's program(s) or control measure(s). Exceeding an action level signals a potential reduction in effectiveness of the program and/or control measure(s) and may indicate a deviation from normal operation. Exceeding an action level is not a non-compliance, but triggers a requirement for specific action to be taken.

acutely lethal effluent *(French)*
Acutely lethal, in respect of an effluent, means that the effluent at 100% concentration kills more than 50% of the test organisms subjected to it for a period of 96 hours, when tested in accordance with the appropriate acute lethality test method specified below:

Where the salinity of the effluent is:
a) less than ten parts per thousand and the effluent is deposited into fresh waters, the specified test method is Reference Method EPS 1/RM/13 [1] and – if applicable – used in conjunction with the Procedure for pH Stabilization EPS 1/RM/50 [2].
b) equal to or greater than ten parts per thousand and the effluent is deposited into marine waters, the specified test method is Reference Method EPS 1/RM/10 [3].

References:
1. Biological Test Method: Reference Method for Determining Acute Lethality of Effluents to Rainbow Trout (EPS 1/RM/13 Second Edition), December 2000 (with May 2007 amendments), published by the Department of the Environment, as amended from time to time.
2. Procedure for pH Stabilization During the Testing of Acute Lethality of Wastewater Effluent to Rainbow Trout (EPS 1/RM/50), March 2008, published by the Department of the Environment, as amended from time to time.
3. Biological Test Method: Reference Method for Determining Acute Lethality Using Threespine Stickleback (EPS 1/RM10 Second Edition), December 2017, published by the Department of the Environment, as amended from time to time.

constraint *(French)*
From the *IAEA Safety Glossary*
A prospective and source related value of individual dose (see dose constraint) or of individual risk (see risk constraint) that is used in planned exposure situations as a parameter for the optimization of protection and safety for the source, and that serves as a boundary in defining the range of options in optimization.

interim period *(French)*
With respect to environmental protection, the time from when adaptive management is triggered through to the completion of commissioning of the new treatment system or other control measures.

licensed limit *(French)*
A limit that 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 release 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 release limit is a non-compliance and triggers a requirement for the licensee to take specific action. **Note:** The licensed release limits may include any limits specified in the licensing basis.

limitation *(French)*
With respect to environmental protection, a radiation protection principle that specifies the value of a quantity used in certain activities or circumstances that must not be exceeded, such as the public dose limit.

major modification *(French)*
A modification that requires a change to the licensing basis (i.e., a licence amendment) 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 (e.g. commissioning a treatment system)
- a response to adaptive management
- a result of a periodic safety review (PSR)

maximum predicted design release *(French)*
The maximum release characteristics (that is, quantities, concentrations and volumes plus operational margin) that are anticipated, following treatment and mitigation through the application of BATEA.

mixing zone *(French)*
An area where an effluent discharge undergoes initial dilution and is extended to cover the secondary mixing in the ambient water body. A mixing zone is an allocated impact zone where water quality criteria can be exceeded so long as acutely toxic conditions are prevented. At the end of this zone, which determines the volume of water allotted for effluent dilution, the specified water quality criteria must be respected. The allocation of a mixing zone rests on the principle that a small zone of degradation can exist without harming the sustainability of the ecosystem as a whole.

normal operation *(exploitation normale)*
The operation of a nuclear facility within specified operational limits and conditions, including (where applicable) start-up, power operation, shutting down, shutdown, maintenance, testing and refuelling. In nuclear reactors, normal operation is a plant state.

Note: Normal operations for any nuclear facility are those associated with the approved licensed activities. This includes the normal operation of any treatment system(s) during refurbishment or decommissioning, as defined by the approved licensed activities, and the specified operational limits and conditions documented within the facility's licensing basis.

optimization *(French)*
With respect to environmental protection, the process of determining what level of protection and safety makes exposures and the probability and magnitude of potential exposures as low as reasonably achievable, economic and social factors being taken into account.

planned exposure *(French)*
The situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure due to a source.

- Since provision for protection and safety can be made before embarking on the activity concerned, associated exposures and their probabilities of occurrence can be restricted from the outset.
- The primary means of controlling exposure in planned exposure situations is by good design of installations, equipment and operating procedures. In planned exposure situations, a certain level of exposure is expected to occur.

point of impingement (POI) *(French)*
The nearest point where air contamination emitted by a source impinges on a building or beyond the property line; any point on the ground or on a receptor, such as nearby buildings, at which the highest concentration of a contaminant caused by the aggregate emission of that contaminant from a facility or activity is expected to occur. **Note:** For a facility, the point of impingement occurs outside the facility's property boundaries.

regulatory public dose limit *(French)*
The prescribed limit for the general public, as specified in the *Radiation Protection Regulations*. This limit is 1 milliSievert (mSv) per calendar year, and it protects the public from radiation resulting from the normal operation of a nuclear facility or activity regulated under the *Nuclear Safety and Control Act*.

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 N288.6, *Environmental risk assessment at Class I nuclear facilities and uranium mines and mills.*
4. CSA Group, CSA N288.7, *Groundwater protection programs at Class I nuclear facilities and uranium mines and mills.*
5. CSA Group, CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities.*
6. IAEA, IAEA GSG-9: *Regulatory control of discharges to the environment: General Safety Guide*, Vienna, Austria, 2018.
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14. CNSC, REGDOC-3.6, *Glossary of CNSC Terminology*, Ottawa, Canada, 2018.
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16. U.S. Department of Defense, Military Handbook: *Planning and Commissioning Wastewater Treatment Plants*, MIL-HDBK-353, United States of America, 1996.
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18. IAEA, TECDOC-1000, *Clearance of Materials Resulting from the Use of Radionuclides in Medicine, Industry and Research*, Vienna, Austria, 1998.
19. IAEA, Safety Series No. 19, *Generic Models for Use in Assessing the Impact of Discharges of Radioactive Substances to the Environment*, Vienna, Austria, 2001.

20. 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.

21. 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.

22. Ministère du Développement durable, Environnement et Parcs Québec, Calculation and Interpretation of Effluent Discharge Objectives for Contaminants in the Aquatic Environment, 2nd Edition, 2007 (translation, 2008).

23. 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:

- International Atomic Energy Agency (IAEA), *Clearance of Materials Resulting from the Use of Radionuclides in Medicine, Industry and Research*, IAEA-TECDOC-1000, 1998.
- IAEA, *Application of the Concepts of Exclusion, Exemption and Clearance*, IAEA Safety Guide No. RS-G-1.7., 2004.
- IAEA, *Generic Models for use in Assessing the Impact of Discharges of Radioactive Substances to the Environment*, Safety Series No. 19, 2001.
- Canadian Environmental Assessment Agency, *Practitioners Glossary for the Environmental Assessment of Designated Projects Under the Canadian Environmental Assessment Act, 2012*, Ottawa, Canada
- CNSC, process map (a detailed process flowchart for new facilities or activities, for existing facilities or activities that are undergoing major modifications, and for existing facilities or activities under normal operations).
- CSA Group, CAN/CSA ISO 14001, *Environmental Management Systems – Requirements with Guidance for Use*, 2004 (1st edition).
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- CSA Group, CSA N288.0, *Environmental management of nuclear facilities: Common requirements of the CSA N288 series of Standards*, 2022 (1st edition).
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- CSA Group, CSA N288.4, *Environmental monitoring programs at Class I nuclear facilities and uranium mines and mills.*
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- Government of Canada, A Framework for the Application of Precaution in Science-based Decision Making about Risk, Ottawa Canada, 2003.
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- IAEA, General Safety Requirements No. GSR Part 3, *Radiation Protection and Safety of Radiation Sources: International Basis Safety Standards*, Vienna, Austria, 2014.
- 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.

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1.6 Nuclear substances and radiation devices

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2.3 Operating performance
2.4 Safety analysis
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2.6 Fitness for service
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2.9 Environmental protection
2.10 Emergency management and fire protection
2.11 Waste management
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3.4 Commission proceedings
3.5 CNSC processes and practices
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L'organisme de réglementation nucléaire du Canada

Protection de l'environnement

Contrôle des rejets dans l'environnement

REGDOC-2.9.2

Septembre 2022

Commission canadienne de sûreté nucléaire

Canadian Nuclear Safety Commission

Canada

Protection de l'environnement : Contrôle des rejets dans l'environnement
Document d'application de la réglementation REGDOC-2.9.2

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Les personnes intéressées peuvent consulter le document sur le site Web de la CCSN ou l'obtenir, en français ou en anglais, en communiquant avec la :

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Historique de publication

Préface

Le présent document d'application de la réglementation (REGDOC) fait partie de la série de REGDOC de la CCSN portant sur la protection de l'environnement, qui couvrent également les principes, les évaluations environnementales et les mesures de protection de l'environnement. La liste complète des séries de REGDOC figure à la fin de ce document et elle est disponible sur le site Web de la CCSN.

Le REGDOC-2.9.2, *Contrôle des rejets dans l'environnement*, clarifie les exigences de la CCSN en matière de contrôle des rejets dans l'environnement et donne des orientations à cet égard, par les mesures suivantes :

- application du concept des meilleures techniques existantes d'application rentable (MTEAR)
- établissement et mise en œuvre de limites de rejet autorisées et de seuils d'intervention pour les rejets dans l'environnement
- mise en service d'un système de traitement et confirmation du rendement du système
- mise en place de la gestion adaptative, lorsqu'exigée

Il s'agit de la première version publiée de ce document d'application de la réglementation (REGDOC). Ce document est destiné à être utilisé conjointement avec le document REGDOC-2.9.1, *Principes, évaluations environnementales et mesures de protection de l'environnement*.

Ces exigences et ces orientations s'appliquent aux demandes de permis pour de nouvelles installations ou activités nucléaires proposées et aux demandes de renouvellement et de modification de permis. Ce document sera également utilisé pour évaluer les mesures de protection de l'environnement d'un titulaire de permis lorsqu'un risque déraisonnable est constaté et que la gestion adaptative s'impose.

Les demandeurs et les titulaires de permis sont invités à contacter le plus tôt possible le personnel de la CCSN lorsque des installations ou des activités peuvent interagir avec l'environnement ou lorsqu'il existe une incertitude quant au potentiel d'interaction avec l'environnement. Le personnel de la CCSN peut fournir des conseils propres à l'installation ou à l'activité en cause afin d'aider les demandeurs et les titulaires de permis.

Pour en savoir plus sur la mise en œuvre des documents d'application de la réglementation et sur l'approche graduelle, veuillez consulter le REGDOC-3.5.3, *Principes fondamentaux de réglementation*.

> Le terme « doit » est employé pour exprimer une exigence à laquelle le titulaire ou le demandeur de permis doit se conformer; le terme « devrait » dénote une orientation ou une mesure conseillée; le terme « pourrait » exprime une option ou une mesure conseillée ou acceptable dans les limites de ce document d'application de la réglementation; et le terme « peut » exprime une possibilité ou une capacité.
>
> Aucune information contenue dans le présent document ne doit être interprétée comme libérant le titulaire de permis de toute autre exigence pertinente. Le titulaire de permis a la responsabilité de prendre connaissance de tous les règlements et de toutes les conditions de permis applicables et d'y adhérer.

Table des matières

Contrôle des rejets dans l’environnement

1. Introduction

1.1 Objet

La protection de l’environnement aux installations et activités nucléaires est faite conformément à la *Loi sur la sûreté et la réglementation nucléaires* (LSRN) et aux règlements pris en vertu de celle-ci. La législation contient des dispositions pour veiller à ce que les titulaires de permis respectent le mandat de la Commission canadienne de sûreté nucléaire (CCSN) visant à préserver la santé, la sûreté et la sécurité et à protéger l’environnement. En vertu de la LSRN et de ses règlements, les titulaires de permis sont tenus de prendre toutes les précautions raisonnables pour contrôler les rejets dans l’environnement de substances nucléaires et de substances dangereuses qui proviennent des installations ou des activités autorisées.

Dans le cadre d’une demande de permis de construction, d’exploitation ou de déclassement d’une installation nucléaire, les demandeurs et les titulaires de permis sont tenus d’évaluer les effets sur l’environnement ainsi que sur la santé et la sécurité des personnes, et de définir les mesures qui seront prises pour éviter ou atténuer ces effets. En outre, la demande doit déterminer les éléments suivants :

- emplacement des points de rejet proposé
- quantités et concentrations maximales proposées
- volume et débit d’écoulement prévus des rejets de substances nucléaires et de substances dangereuses dans l’environnement
- mesures proposées pour contrôler les rejets de substances nucléaires et de substances dangereuses dans l’environnement.

Le présent document définit les exigences et l’orientation en matière de contrôle des rejets dans l’environnement, par les mesures suivantes :

- application du concept des meilleures techniques existantes d’application rentable (MTEAR)
- mise en œuvre de limites de rejet autorisées et de seuils d’intervention pour les rejets dans l’environnement
- mise en service d’un système de traitement et confirmation du rendement
- mise en place de la gestion adaptative, lorsqu’exigée

1.2 Portée

Le présent document s’applique aux installations ou activités nucléaires qui, dans des conditions d’exploitation normale, rejettent ou comptent rejeter des substances nucléaires ou dangereuses dans l’environnement. Il s’applique aux rejets directs dans l’atmosphère, dans les eaux de surface ou les égouts, soit par des rejets dans le sol, y compris lorsque des barrières naturelles ou artificielles sont proposées ou incorporées. Le présent REGDOC s’applique également aux installations de réfection et de déclassement, ainsi qu’au fonctionnement normal de tout système de traitement pendant la réfection et le déclassement.

Ce document est destiné à être utilisé conjointement avec le document REGDOC-2.9.1, *Principes, évaluations environnementales et mesures de protection de l’environnement* [1] qui contient des exigences et de l’orientation concernant l’élaboration et la mise en œuvre de mesures de protection de l’environnement visant à surveiller et à contrôler les rejets dans l’environnement, à réaliser une évaluation des risques environnementaux (ERE) et à élaborer et mettre en œuvre un système de gestion de l’environnement (SGE). Le présent document contient des exigences et de l’orientation aux mesures supplémentaires de protection de l’environnement (comme les seuils d’intervention et les limites de rejet autorisées) qui sont liées aux mesures de protection de l’environnement décrites dans le REGDOC-2.9.1 [1], et qui ont une influence sur ces mesures ou qui sont touchées par celles-ci.

Les demandeurs et les titulaires de permis sont tenus d’utiliser ces documents pour élaborer ou réviser leurs mesures de protection de l’environnement, ou pour élaborer des mesures de protection de l’environnement supplémentaires lorsqu’une gestion adaptative s’impose.

Les normes du groupe CSA auxquelles il est fait référence dans le présent REGDOC s’appliquent aux installations nucléaires de catégorie I et aux mines et usines de concentration d’uranium. En ce qui concerne les installations ou activités autres que les installations nucléaires de catégorie I et les mines et usines de concentration d’uranium, la CCSN examine chaque demande de permis pour vérifier qu’il n’y a pas d’interactions importantes avec l’environnement. Si, après avoir examiné la demande, la CCSN détermine que l’installation ou l’activité n’interagit pas avec l’environnement, alors seuls les principes directeurs de la CCSN pour la protection de l’environnement (voir le REGDOC-2.9.1 [1]) sont applicables à ces installations ou activités.

Pour les demandes de permis pour une installation autre qu’une installation nucléaire de catégorie I et qu’une mine ou usine de concentration d’uranium, si la CCSN détermine que l’installation ou l’activité peut avoir des interactions avec l’environnement et que, par conséquent, des mesures de protection sont justifiées, les informations contenues dans le présent document peuvent être appliquées de manière graduelle. Le demandeur ou le titulaire de permis peut démontrer qu’il respecte l’esprit du présent document comme suit :

- Pour le contrôle des substances nucléaires – en comparant les quantités et les concentrations maximales proposées pour les rejets dans l’environnement, associées à la conception de l’installation ou de l’activité en mode d’exploitation normale :
  - aux critères d’exemption ou aux niveaux de libération inconditionnelle stipulés par le *Règlement sur les substances nucléaires et les appareils à rayonnement*, ou
  - aux niveaux de libération conditionnelle (NLC) génériques indiqués à l’annexe A
    - pour tout radionucléide qui dépasse les NLC génériques, la CCSN peut établir des NLC propres à la pratique, c.-à-d. qui sont applicables au type d’installation ou d’activité
    - pour tout radionucléide dont le rejet maximal proposé est inférieur aux NLC applicables (génériques ou propres à la pratique), les NLC sont appliqués en tant que limites de rejet autorisées
    - pour tout radionucléide dont le rejet maximal proposé dépasse les NLC (génériques ou propres à la pratique), il faut appliquer un juste équilibre de l’information contenue dans le présent document

- Pour le contrôle des substances dangereuses – en comparant les quantités et les concentrations maximales proposées pour les rejets dans l’environnement associés à la conception de l’installation ou de l’activité en mode d’exploitation normale :
  - aux recommandations fédérales, provinciales, territoriales ou municipales en matière de qualité de l’environnement
  - lorsqu’un rejet maximal proposé dépasse les lignes directrices concernant la qualité de l’environnement, il faut appliquer un juste équilibre de l’information contenue dans le présent document

Les demandeurs et les titulaires de permis sont invités à contacter le plus tôt possible le personnel de la CCSN lorsque des installations ou des activités peuvent interagir avec l’environnement ou lorsqu’il existe une incertitude quant au potentiel d’interaction avec l’environnement. Le personnel de la CCSN peut fournir des conseils propres à l’installation ou à l’activité en cause afin d’aider les demandeurs et les titulaires de permis.

Le présent document d’application de la réglementation ne porte pas sur la gestion des déversements, des émissions fugitives ou des rejets non contrôlés.

Ce document ne vise pas à remplacer ni à reproduire les exigences d’autres lois fédérales, provinciales, territoriales ou municipales. Le respect de ces autres exigences législatives peut être suffisant pour satisfaire aux exigences du présent REGDOC. Dans de nombreux cas, ce REGDOC fournit des exigences et de l’orientation visant à réduire le chevauchement des règlements, dans la mesure du possible, tout en continuant à appliquer le mandat de la CCSN en vertu de la LSRN, qui consiste à assurer le contrôle des rejets de substances nucléaires et dangereuses.

1.3 Dispositions législatives pertinentes

Les dispositions suivantes de la LSRN et des règlements connexes qui s’appliquent au présent document sont les suivantes :

- LSRN :
  - paragraphe 24(4)
  - paragraphe 24(5)

- *Règlement général sur la sûreté et la réglementation nucléaires :*
  - alinéa 3(1)f)
  - alinéas 12(1)c) et f)

- *Règlement sur les installations nucléaires de catégorie I :*
  - alinéas 3e), g), h) et j)
  - alinéas 4b), c) et e)
  - alinéas 5b), i), j) et k)
  - alinéas 6h), i), j) et k)
  - alinéas 7e), f), g), h), i) et k)
  - alinéa 8b)

- *Règlement sur les installations nucléaires et l’équipement réglementé de catégorie II :*
  - alinéa 3p)
  - alinéas 5e), f), h) et i)

- *Règlement sur la radioprotection :*
  - alinéas 4a) et b)
  - paragraphes 6(1) et (2)
  - paragraphe 13(1)

- *Règlement sur les substances nucléaires et les appareils à rayonnement :*
  - alinéas 3(1)b), g) et i)
  - alinéa 12(1)k)

- *Règlement sur les mines et les usines de concentration d'uranium :*
  - sous-alinéa 3a)(v)
  - sous-alinéas 3c)(ii), (iii), (v), (vi), (vii), (viii), (ix) et (x)
  - sous-alinéas 3d)(i) et (vi)

La CCSN tient également compte de la législation pertinente d'autres ministères, notamment :

- *Loi sur l'évaluation d'impact*
- *Loi canadienne sur l'évaluation environnementale (2012)*
- *Loi canadienne sur la protection de l'environnement (1999)*
- *Loi sur les pêches*
- *Loi sur les espèces en péril*
- *Loi sur la convention concernant les oiseaux migrateurs (1994)*

1.4 Normes nationales et internationales

Les principes et éléments clés utilisés dans l'élaboration du présent document sont conformes aux normes nationales et internationales.

Les normes du Groupe CSA qui s'appliquent à ce document d'application de la réglementation sont les suivantes :

- CAN/CSA ISO 14001, *Systèmes de management environnemental – Exigences et lignes directrices pour son utilisation* (édition de 2004 ou éditions suivantes)
- CSA N288.1, *Lignes directrices pour la modélisation du transport, du devenir et de l'exposition environnementale des radionucléides associés à l'exploitation normale des installations nucléaires* [2]
- CSA N288.3.4, *Essais de performance des systèmes d'épuration d'air radioactif des installations nucléaires*
- CSA N288.4, *Programmes de surveillance de l'environnement aux installations nucléaires de catégorie I et aux mines et usines de concentration d'uranium*
- CSA N288.5, *Programmes de surveillance des effluents aux installations nucléaires de catégorie I et usines de concentration d'uranium*
- CSA N288.6, *Évaluation des risques environnementaux aux installations nucléaires de catégorie I et aux mines et usines de concentration d'uranium* [3]
- CSA N288.7, *Programmes de protection des eaux souterraines aux installations nucléaires de catégorie I et aux mines et usines de concentration d'uranium* [4]
- CSA N288.8, *Établissement et mise en œuvre de seuils d'intervention pour les rejets dans l'environnement par les installations nucléaires* [5]

- Le Guide de sûreté GSG-9 de l’Agence internationale de l’énergie atomique (AIEA), *Contrôle réglementaire des rejets radioactifs dans l’environnement*, est également utile pour le présent REGDOC.

Le Guide de sûreté GSG-9 de l’Agence internationale de l’énergie atomique, *Contrôle réglementaire des rejets radioactifs dans l’environnement*, est également utile pour le présent REGDOC.

1.5 Coordonnées des personnes-ressources de la CCSN

Le demandeur ou le titulaire de permis devrait consulter le personnel de la CCSN dès les premières phases du processus de planification (avant la présentation d’une demande de permis) pour déterminer les REGDOC applicables et confirmer la compréhension du processus d’autorisation de la CCSN. Pour contacter la CCSN, veuillez consulter le site Web de la CCSN.

2. Contexte

La CCSN exige que les effets environnementaux de toutes les installations ou activités nucléaires soient pris en compte et évalués lorsque des décisions d'autorisation sont rendues. Le REGDOC-2.9.1, *Principes, évaluations environnementales et mesures de protection de l'environnement* [1] indique les exigences en matière de protection de l'environnement et donne de l'orientation supplémentaire concernant le programme global de protection de l'environnement d'un titulaire de permis. Ce REGDOC porte sur le contrôle des rejets dans l'environnement dans le cadre d'activités normales.

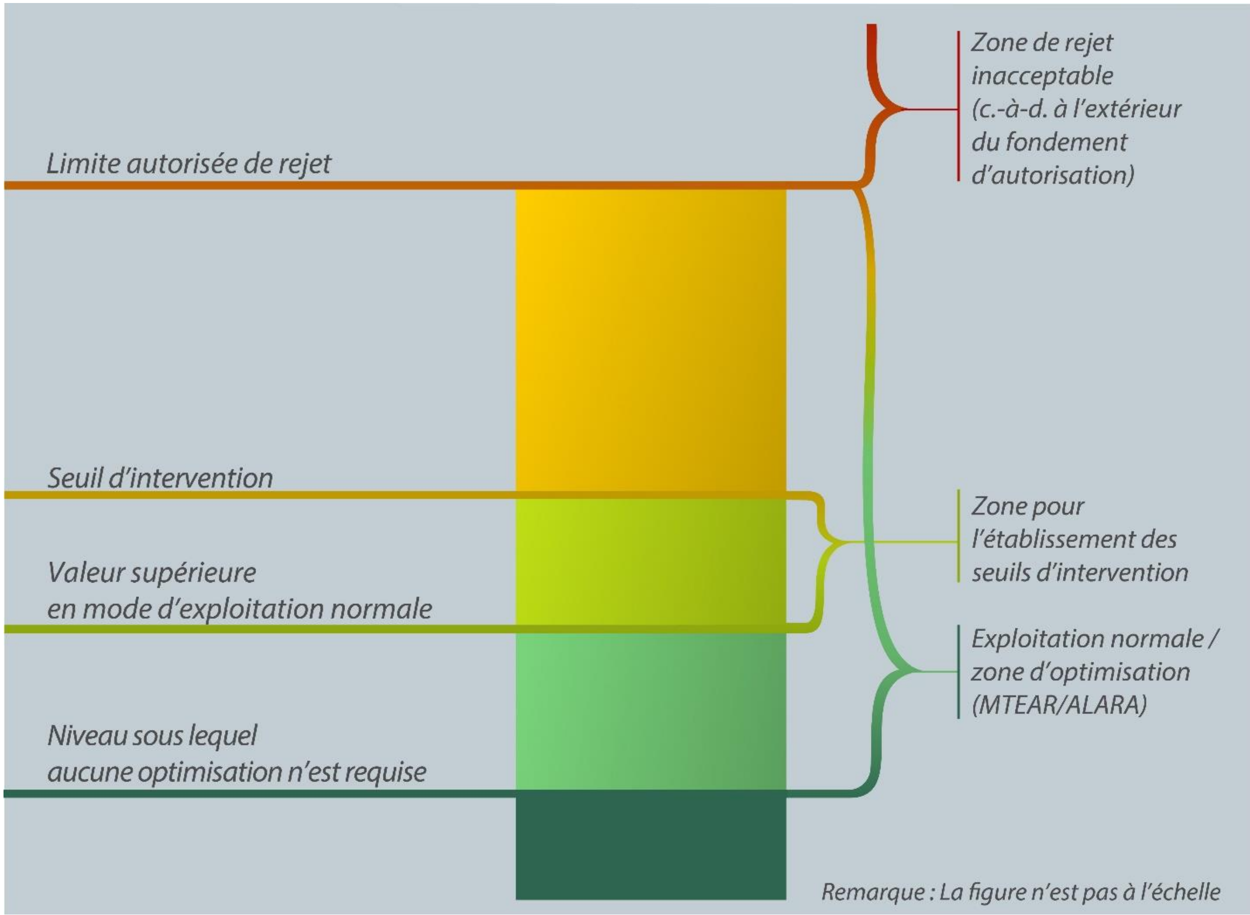
Selon l'alinéa 12(1)f) du *Règlement général sur la sûreté et la réglementation nucléaires* (RGRSN), le titulaire de permis doit prendre « toutes les précautions raisonnables » pour contrôler les rejets. Le REGDOC-2.9.1 [1] précise que la précaution raisonnable dans le contexte du contrôle des rejets implique l'application du principe des « meilleures techniques existantes d'application rentable » (MTEAR) pour les substances dangereuses, et le maintien de tous les rejets dans l'environnement au niveau le plus bas qu'il soit raisonnablement possible d'atteindre (principe ALARA). Ainsi, les titulaires de permis sont tenus de contrôler les rejets aux limites spécifiées dans la réglementation et de démontrer l'application des principes des MTEAR et ALARA. Dans la suite de ce document, l'acronyme MTEAR est considéré comme faisant référence à la fois aux substances nucléaires et aux substances dangereuses, et l'acronyme ALARA est utilisé lorsqu'il s'agit uniquement des substances nucléaires. Pour les exigences et l'orientation concernant l'application du principe des MTEAR, voir la section 4.

2.1 Approche à plusieurs niveaux pour la réglementation des rejets

Une approche à plusieurs niveaux a été mise en place pour assurer la protection de la santé humaine et de l'environnement et démontrer la prévention de la pollution par l'application du principe des MTEAR. Les niveaux sont spécifiques à chaque substance et comprennent les limites de rejet autorisées, les seuils d'intervention, les valeurs supérieures des conditions d'exploitation normale et le niveau de libération (où aucune autre optimisation n'est requise).

Les figures ci-dessous sont conceptuelles et ne sont pas nécessairement à l'échelle. L'écart réel entre les valeurs dépend de la conception et de l'exploitation propres au site de l'installation ou de l'activité, et de la variabilité prévue de la qualité des effluents et/ou des émissions dans des conditions d'exploitation normale.

Figure 1 : Relation conceptuelle entre une valeur supérieure en mode d’exploitation normale pour une substance nucléaire ou dangereuse, un seuil d’intervention et une limite de rejet autorisée



La CCSN utilise des instruments de réglementation, comme les limites de rejet autorisées et les seuils d’intervention, pour vérifier si le titulaire de permis mène ses activités conformément à son fondement d’autorisation.

2.1.1 Aperçu des limites de rejet autorisées

La mise en œuvre des limites de rejet autorisées permet de s’assurer que :

- le titulaire de permis assure la protection de la santé humaine et de l’environnement
- le titulaire de permis applique des mesures de contrôle appropriées (y compris des stratégies de réduction) pour la prévention de la pollution en démontrant une optimisation par l’application des MTEAR et du principe ALARA
- le titulaire de permis fonctionne dans les limites du fondement d’autorisation pour une exploitation normale

Le demandeur ou le titulaire de permis propose des limites de rejet dans le cadre de sa demande de permis. Une fois approuvées par la CCSN, celles-ci deviennent des limites de rejet autorisées et font partie du fondement d’autorisation de l’installation ou de l’activité. Comme les limites de rejet autorisées sont basées sur la conception acceptée de l’installation ou sur les limites indiquées dans la réglementation fédérale/provinciale/territoriale, elles changent rarement avec le temps. Si une modification majeure est apportée à l’installation et/ou à l’activité nucléaire ou à la réglementation, le fondement d’autorisation et les limites de rejet autorisées seront mises à jour pour refléter la modification.

Les limites de rejet autorisées sont souvent propres à un site ou à un sous-secteur, car les caractéristiques de conception varient dans l’industrie nucléaire et chaque installation ou activité dispose d’un programme de protection de l’environnement ou de mesures de contrôle qui lui sont propres.

Le dépassement d’une limite de rejet autorisée (c’est-à-dire un feu rouge) indique que les activités du titulaire de permis sont à l’extérieur de son fondement d’autorisation pour l’exploitation normale et qu’il y a une perte de contrôle évidente du programme de protection de l’environnement et/ou de la ou des mesures de contrôle. Un rejet excédant les limites du fondement d’autorisation indique une défaillance majeure des systèmes de contrôle et est assujetti à des mesures d’application de la loi. Cela n’indique pas nécessairement un risque déraisonnable pour l’environnement ou pour la santé et la sécurité des personnes.

Pour de plus amples renseignements sur les limites de rejet autorisées, voir la section 5.

2.1.2 Aperçu des seuils d’intervention

Les seuils d’intervention pour la protection de l’environnement fournissent au titulaire de permis un outil lui permettant de démontrer qu’il maîtrise correctement son programme de protection de l’environnement. Les seuils d’intervention sont fixés en dessous des limites de rejet autorisées et au-dessus de la valeur supérieure en mode d’exploitation normale. Ils servent d’indicateur d’alerte précoce.

Le dépassement d’un seuil d’intervention (c’est-à-dire un feu jaune) :

- indique une perte potentielle de contrôle du programme de protection de l’environnement du titulaire de permis
- signale une réduction potentielle de l’efficacité du programme de protection de l’environnement ou des mesures de contrôle
- peut indiquer un écart par rapport au mode d’exploitation normale
- déclenche l’obligation pour le titulaire de permis de prendre des mesures spécifiques

Les seuils d’intervention sont proposés par le titulaire de permis et soumis à l’examen et à l’approbation de la CCSN.

Les seuils d’intervention sont basés sur les opérations et le rendement et ils représentent la limite supérieure du rendement opérationnel en cours; ils sont donc censés être atteints périodiquement.

Les seuils d’intervention sont basés sur l’historique d’exploitation le plus récent de l’installation (par exemple, 5 ans) et changent donc au fil du temps. Les seuils d’intervention peuvent augmenter ou diminuer, en fonction des changements quotidiens des activités faisant partie du fondement d’autorisation existant.

Pour obtenir plus de renseignements à ce sujet, consultez la section 6.

2.1.3 Aperçu de la valeur supérieure en mode d’exploitation normale

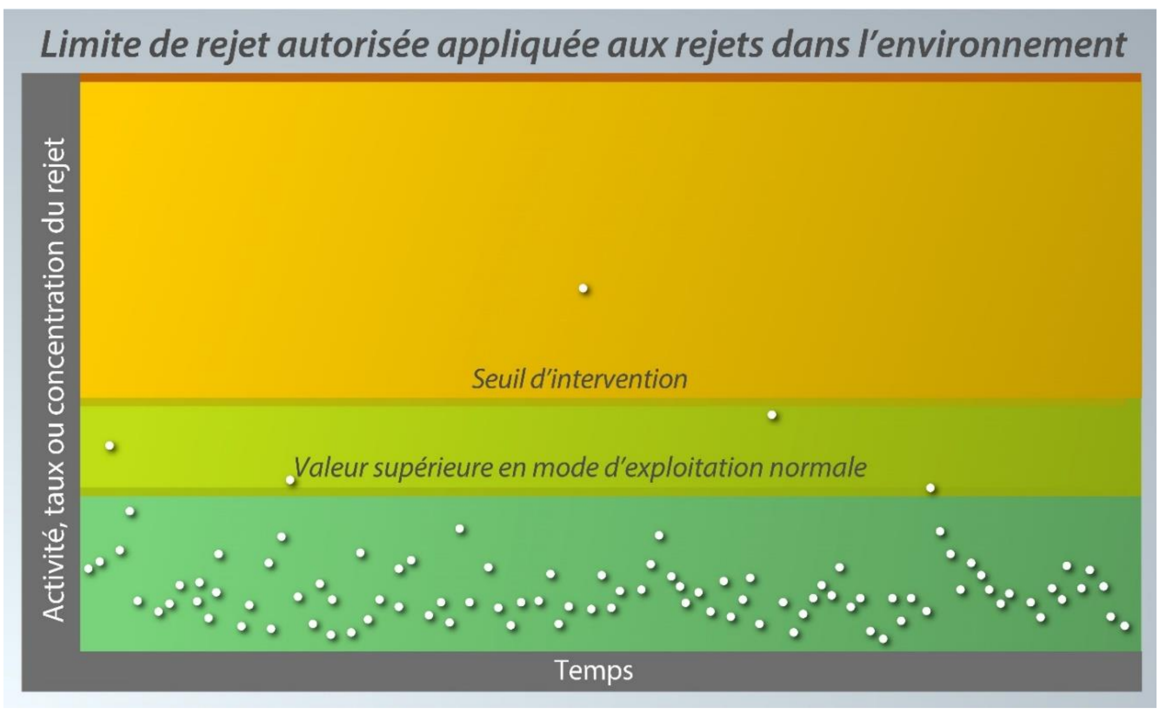
La valeur supérieure en mode d’exploitation normale représente la limite supérieure prévue de rejets, d’après les conditions d’exploitation prévues ou actuelles (p. ex., 95e percentile), que l’on détermine généralement en utilisant l’une ou l’autre des méthodes suivantes :

- une approche prospective pour une installation ou activité nouvelle, basée sur la conception approuvée et d’autres renseignements pertinents
- une approche rétrospective pour une installation ou une activité existante, basée sur toutes les données de rendement disponibles (y compris les données historiques)

Le demandeur ou le titulaire de permis peut également utiliser la valeur supérieure en mode d’exploitation normale comme niveau de contrôle interne, ou pour éclairer les niveaux de contrôle interne (également appelé niveau d’enquête interne ou seuil administratif). Le dépassement de la valeur supérieure en mode d’exploitation normale déclenche généralement une action interne de la part du titulaire de permis. Toutefois, l’utilisation de niveaux de contrôle interne n’est pas une exigence réglementaire. Leur utilisation est laissée à la discrétion du titulaire de permis.

La figure ci-dessous présente des données de rendement opérationnel qui démontrent la relation entre la valeur supérieure en mode d’exploitation normale pour un échantillon de substance nucléaire ou dangereuse, le seuil d’intervention pour les rejets dans l’environnement et la limite de rejet autorisée.

Figure 2 : Données sur le rendement des rejets pour une quantité ou une concentration d’un échantillon de substance nucléaire ou dangereuse au fil du temps



Les seuils d’intervention sont comparés aux résultats du programme de surveillance opérationnelle (c.-à-d. les concentrations dans les échantillons composites collectés quotidiennement ou hebdomadairement) qui correspondent au programme de surveillance des effluents et/ou des émissions du titulaire de permis. Les limites de rejet autorisées sont comparées aux résultats moyens périodiques du programme de surveillance (c.-à-d. les concentrations moyennes mensuelles). Cela permet le dépassement de plusieurs seuils d’intervention avant le déclenchement d’une limite de rejet autorisée. Cela donne également au titulaire de permis le temps de réagir au dépassement du seuil d’intervention et de rétablir l’efficacité du programme, avant qu’une perte totale de contrôle ne se produise. Si des semaines se sont écoulées et que le titulaire de permis a déclenché le seuil d’intervention à plusieurs reprises sans réagir adéquatement, cela peut entraîner le dépassement de la limite de rejet autorisée et représente en soi une perte de contrôle du programme de protection de l’environnement.

3. Mesures de contrôle des rejets dans l’environnement

La Figure 3 sur la page suivante montre le processus de cycle de vie pour établir des mesures de contrôle des rejets dans l’environnement pour :

- une installation ou une activité nouvelle
- une installation ou une activité existante en mode d’exploitation normale
- une installation ou activité existante qui fait l’objet d’une modification majeure

Une modification majeure est une modification qui nécessite un changement au fondement d’autorisation de l’installation ou de l’activité. Voici quelques exemples de modifications majeures :

- les changements apportés à l’installation physique autorisée, ou aux procédés de l’installation ou de l’activité, qui sont susceptibles de modifier la nature des effluents et/ou des émissions et les risques qui en résultent pour les récepteurs (p. ex. la mise en service d’un système de traitement).
- des mesures prises en réponse à la gestion adaptative
- un résultat découlant d’un bilan périodique de sûreté (BPS)

Système de gestion de l’environnement

La politique environnementale d’une organisation (documentée dans le SGE) comprend l’engagement de l’organisation en matière d’amélioration continue, de prévention de la pollution et d’autres domaines spécifiques, qui peuvent inclure le développement durable et la gestion adaptative. Ces principes sont les composantes essentielles du contrôle des rejets dans l’environnement pour garantir le respect du principe ALARA et l’application des MTEAR.

Le SGE comprend des cibles et des objectifs clairement définis en matière de rejets. La portée de ces cibles et objectifs peut comprendre les éléments suivants, qui sont décrits dans le présent REGDOC :

- les éléments liés à la conception, dont les objectifs de rejet dans l’environnement (voir la section 4)
- les limites de rejet autorisées (voir la section 5) et les seuils d’intervention (voir la section 6)
- d’autres indicateurs de rendement environnementaux (p. ex., les initiatives d’amélioration continue) [voir la section 8]
- les initiatives de prévention de la pollution (voir la section 8)

Une perte de contrôle du programme de protection de l’environnement se produit si les rejets sont manifestement en dehors des limites établies dans le fondement d’autorisation du titulaire de permis. Dans le cadre d’une exploitation normale, le fondement d’autorisation fixe des limites de rejets en établissant :

- les quantités et concentrations maximales indiquées dans la documentation du fondement d’autorisation du titulaire de permis
- les prévisions des effets environnementaux figurant dans l’ERE approuvée ou dans un document similaire, qui est soumis dans le cadre d’une demande de permis et fait partie du fondement d’autorisation.

Figure 3 : Aperçu simplifié du processus intégré d’établissement et de mise en œuvre des mesures de contrôle des rejets dans l’environnement

Remarque : Les figures suivantes (3a, 3b et 3c) présentent plus en détail chaque section de la figure 3.

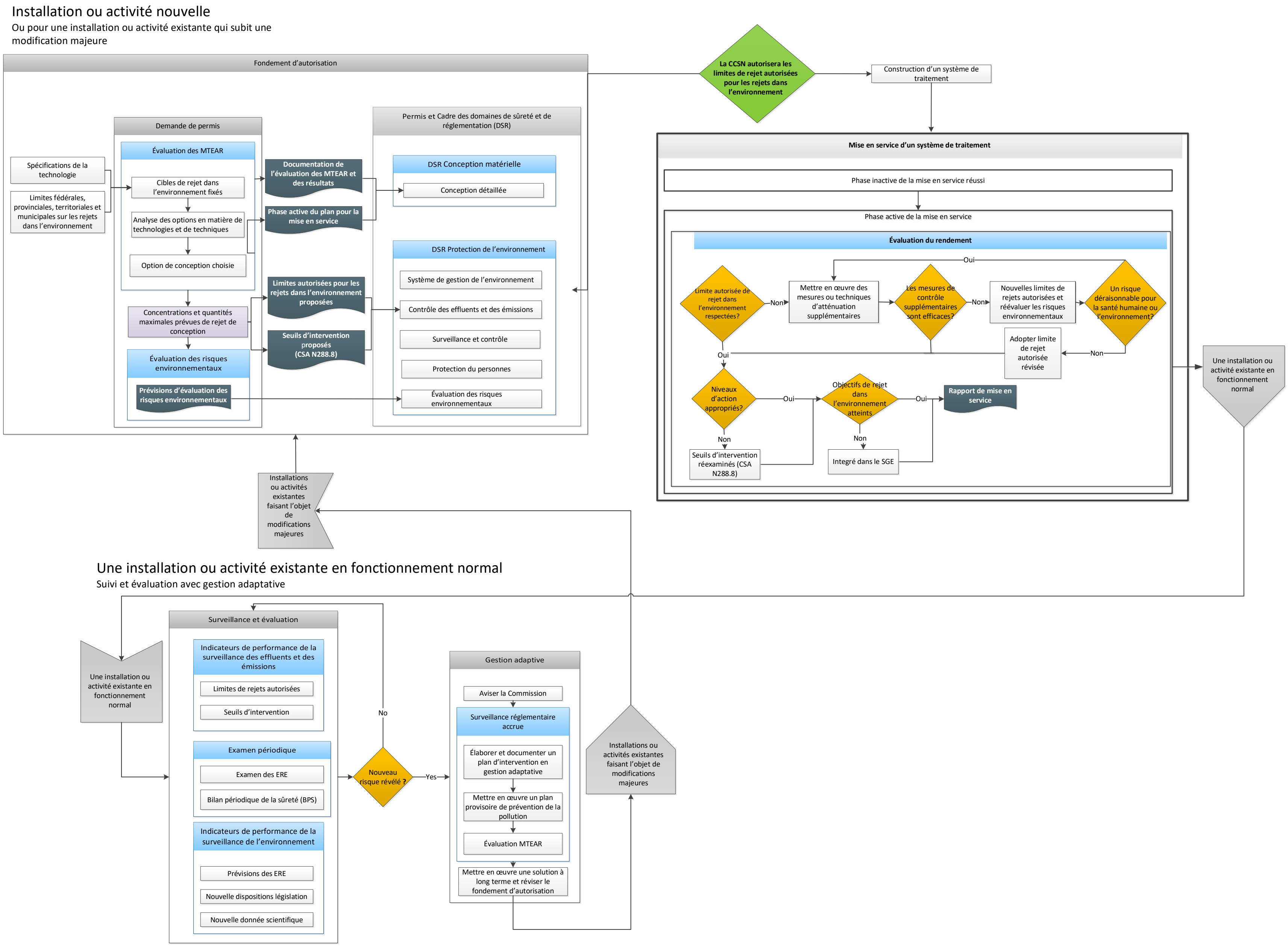


Figure 3a : Informations sur les mesures de contrôle des rejets dans l'environnement à soumettre pour une nouvelle installation ou activité demandant un permis de construire, ou pour une installation existante soumise à une modification majeure et nécessitant une modification de permis

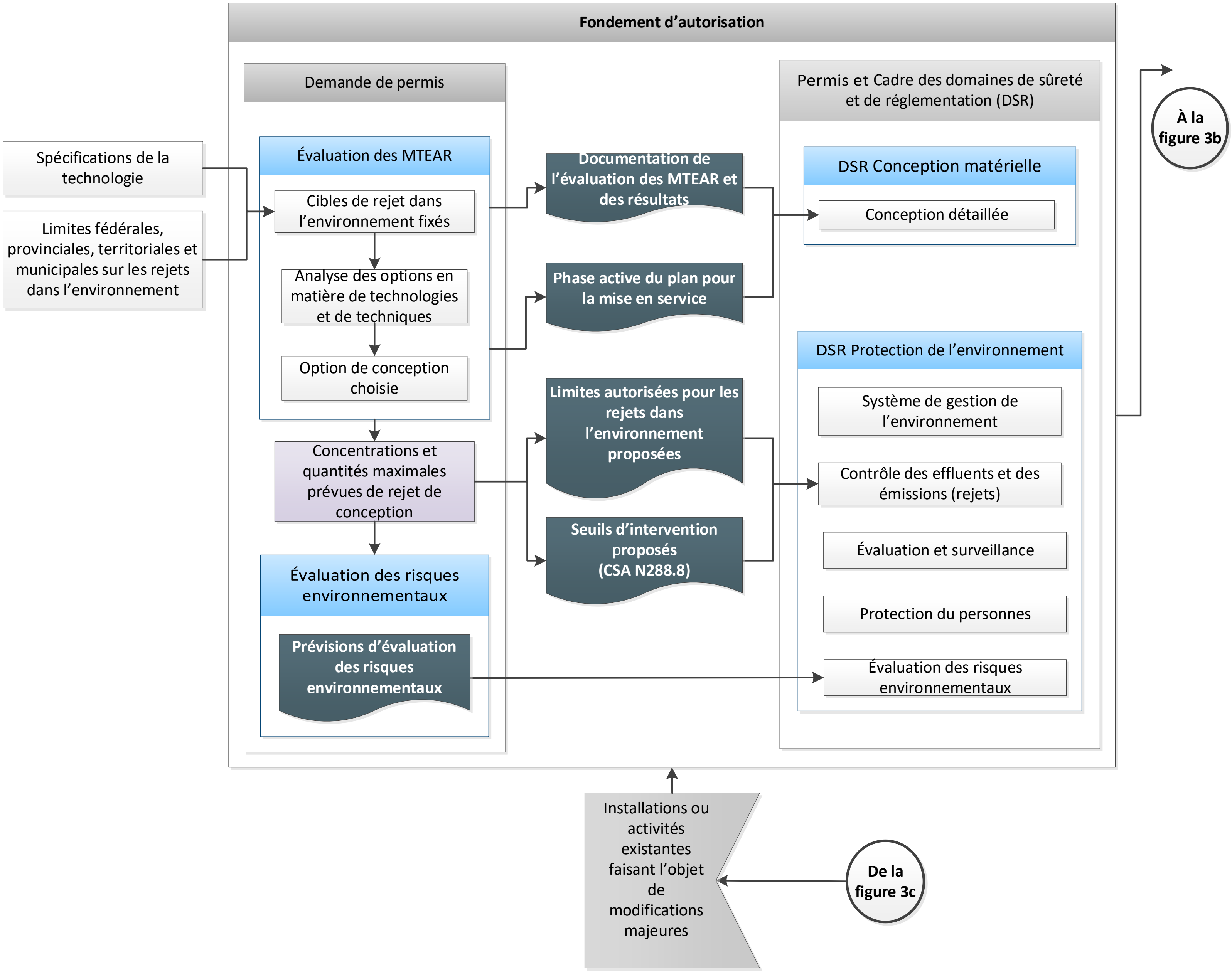


Figure 3b : Mise en service d'un système de traitement

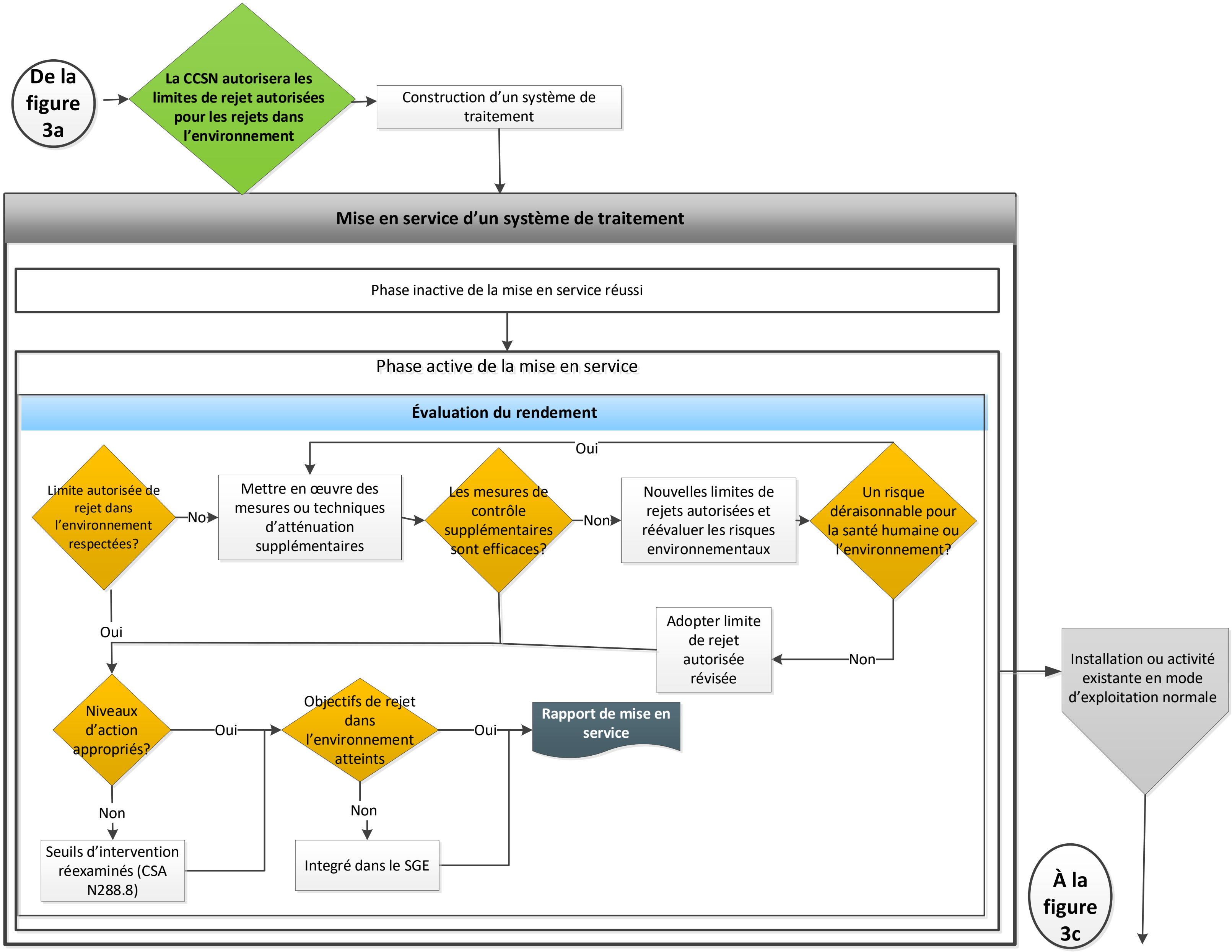
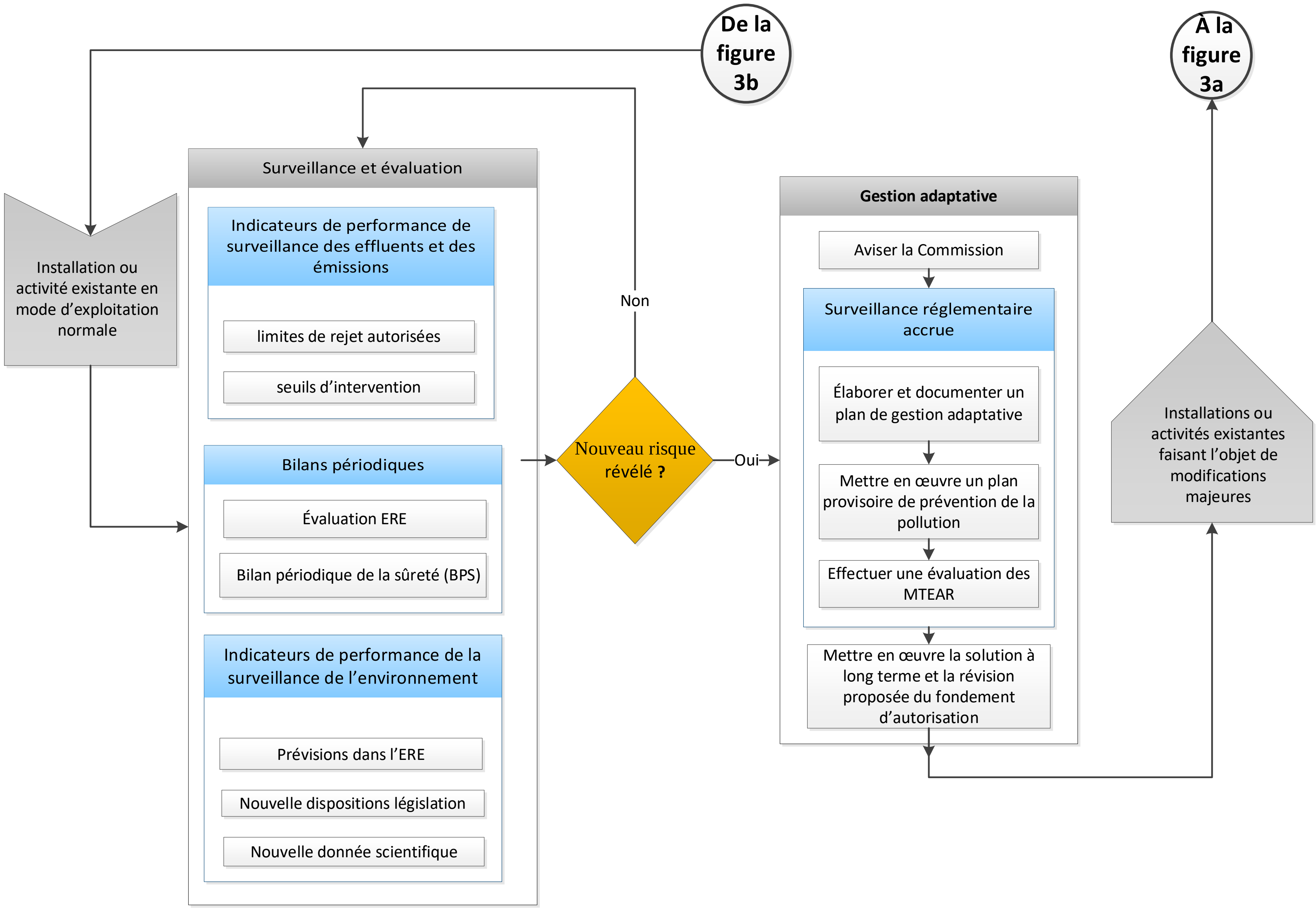


Figure 3c : Partie du processus global d'établissement des mesures de contrôle qui concerne spécifiquement une installation ou une activité nucléaire en mode d'exploitation normale



Surveillance et contrôle des effluents et des émissions

Les mesures de surveillance des effluents et des émissions servent à :

- éclairer l’élaboration des seuils d’intervention et des limites de rejet autorisées
- démontrer le respect de ces seuils d’intervention et limites de rejet autorisées

Évaluation des risques environnementaux

Les résultats de l’ERE sont utilisés pour identifier les contaminants ou les facteurs de stress physique qui pourraient nécessiter des mesures d’atténuation, notamment la mise en œuvre de contrôles supplémentaires des rejets dans l’environnement. L’ERE peut également servir aux fins suivantes :

- déterminer les substances nucléaires et dangereuses qui justifient des seuils d’intervention ou des limites de rejet autorisées
- déterminer les renseignements justificatifs sur les modèles des zones de dilution, ou trouver des modèles détaillés de voie d’exposition et de transport dans l’environnement, pour :
- calculer les objectifs de rejet dans l’environnement en fonction de l’exposition pour les installations nouvelles ou existantes qui subissent des modifications majeures
- démontrer que les objectifs de rejet dans l’environnement basés sur la technologie sont acceptables
- cerner les récepteurs et les scénarios d’exposition connexes utilisés pour déterminer les critères de référence appropriés (c.-à-d. pour déterminer les valeurs de référence des rejets et de l’exposition qui définissent le scénario de rejet « limitatif »)
- démontrer que les rejets nominaux maximaux prévus permettent de protéger les personnes et l’environnement

L’ERE fournit également des renseignements qui seront utilisés dans toute décision concernant la gestion adaptative.

3.1 Contrôle des rejets dans l’environnement (pour toutes les installations et activités)

Les exigences et orientations suivantes s’appliquent à toutes les installations et activités. Afin d’obtenir des exigences et des orientations supplémentaires concernant le contrôle des rejets dans l’environnement :

- pour une installation ou activité nouvelle, ou pour une installation ou activité existante qui fait l’objet d’une modification majeure (voir la section 3.2)
- pour une installation ou activité existante en mode d’exploitation normale (voir la section 3.3)

Exigences

Le demandeur ou le titulaire de permis doit :

- décrire les mesures de contrôle qui seront prises pour la protection de l’environnement, y compris les technologies et techniques de contrôle et de réduction de la pollution
- démontrer que les précautions raisonnables ont été prises :
    - pour prévenir ou atténuer les perturbations physiques et les rejets de substances nucléaires ou dangereuses

    - pour prévenir ou réduire tout effet associé à ces perturbations et rejets
- démontrer que le principe ALARA et les MTEAR ont été intégrés (sur la base de la conception approuvée; voir la section 4) pour :
    - réduire au minimum les rejets contrôlés et prévenir les rejets non contrôlés de substances nucléaires et dangereuses dans l’environnement
    - atténuer les effets physiques comme l’impaction et l’entraînement du biote
    - réduire l’exposition aux rayonnements
- veiller à ce que les rejets ne causent pas une létalité aiguë, conformément aux exigences fédérales, provinciales et territoriales

Pour de plus amples renseignements, consulter le REGDOC-2.9.1, *Principes, évaluations environnementales et mesures de protection de l’environnement* [1].

Orientation

La description des mesures de contrôle devrait comprendre :

- une liste de tous les systèmes, structures et composants qui constituent des mesures de contrôle importantes (p. ex., les barrières techniques, les systèmes de traitement des eaux usées, les systèmes technologiques de contrôle de la pollution de l’air, les équipements de surveillance des déchets liquides et les équipements de surveillance des cheminées)
- le programme d’entretien établi pour assurer le rendement opérationnel continu des mesures de prévention et de contrôle
- tout système d’alarme qui sera installé pour répondre à une défaillance des mesures de contrôle
- les méthodes qui seront utilisées pour :
    - préparer, stocker et conserver les données sur les rejets qui seront effectués régulièrement à partir du site
    - comparer ces données aux indicateurs de rendement disponibles (p. ex., les niveaux d’enquête interne, les seuils administratifs et autres objectifs et cibles de surveillance de l’environnement)
- la détermination des mesures qui seront prises pour mettre les renseignements appropriés à la disposition des autorités et du public (pour de plus amples renseignements, voir le REGDOC-3.2.1, *L’information et la divulgation publiques* [10])

3.2 Installation ou activité nouvelle, ou installation ou activité existante faisant l’objet d’une modification majeure

Exigences

Dans le cadre de la demande de permis pour une installation ou activité nouvelle, ou pour une installation ou activité existante qui subit une modification majeure, le demandeur ou le titulaire de permis doit :

- effectuer une évaluation des MTEAR pour déterminer les caractéristiques des rejets nominaux maximaux prévus (voir la section 4)
- établir les limites de rejet autorisées proposées (voir la section 5)

- établir les seuils d’intervention (voir la section 6)
- effectuer une ERE conformément au REGDOC-2.9.1
- établir un plan de mise en service du système de traitement et des mesures de contrôle, et procéder à leur mise en service (voir la section 7)

3.3 Installation ou activité existante en mode d’exploitation normale

Pour ce qui est d’une installation ou d’une activité existante en mode d’exploitation normale, une évaluation des MTEAR n’est pas nécessaire, à moins que l’ERE n’ait révélé un nouveau risque et que la gestion adaptative s’impose.

Exigences

Pour une installation ou une activité existante en mode d’exploitation normale, et conformément à son programme de protection de l’environnement, le titulaire de permis doit :

- effectuer une surveillance régulière des effluents/émissions et de l’environnement, conformément au programme de protection de l’environnement approuvé du titulaire de permis
- évaluer les résultats de la surveillance des effluents ou des émissions par rapport aux limites de rejet autorisées et aux seuils d’intervention
- évaluer les résultats de la surveillance de l’environnement par rapport :
  - aux prévisions de l’ERE
  - à toute nouvelle législation ou modification de la législation
- mettre à jour l’ERE propre au site et caractériser les risques environnementaux (conformément aux exigences de mise à jour périodique de l’ERE)
  si un risque qui n’était pas géré auparavant est relevé dans l’ERE et qu’une gestion adaptative s’impose pour rétablir l’efficacité du programme de protection de l’environnement, en informer la Commission lors de l’achèvement de l’ERE
  Remarque : Les risques non gérés sont notamment ceux qui découlent de nouvelles données scientifiques ou d’une nouvelle législation, ou encore de l’augmentation démontrée et importante de l’ampleur ou de la portée spatiale d’un risque connu précédemment dans une mesure susceptible d’avoir des effets mesurables sur l’environnement ou la santé humaine, comme cela est défini dans l’ERE.

Lorsqu’il faut recourir à la gestion adaptative, le titulaire de permis doit :

- élaborer et documenter un plan d’intervention et de gestion adaptative (voir la section 8)
- mettre en œuvre un plan provisoire de prévention de la pollution, le cas échéant (voir la section 8)
- effectuer une évaluation des MTEAR pour déterminer les caractéristiques des rejets nominaux maximaux prévus et mettre à jour les limites de rejets proposées qui seront utilisés dans l’ERE nouvelle ou révisée (voir la section 4)
- soumettre à la CCSN les informations concernant la révision proposée du fondement d’autorisation
  - le cas échéant, mettre en œuvre la solution à long terme découlant de l’évaluation des MTEAR (voir la section 8)

  Remarque : Une fois qu’un plan de gestion adaptative est établi, il peut être intégré au programme de surveillance et d’établissement de rapports de l’installation.

Orientation

De nouvelles données scientifiques ou l’application de la gestion adaptative pourraient fournir des preuves à l’appui du retrait d’une limite de rejet autorisée. Un titulaire de permis peut présenter à la CCSN une demande de retrait d’une limite de rejet autorisée dans le cadre de l’examen périodique de son programme de protection de l’environnement.

Tout comme pour l’application du principe ALARA, le titulaire de permis devrait appliquer le concept des MTEAR tout au long du cycle de vie de l’installation ou de l’activité. La meilleure pratique pour les titulaires de permis consiste à réévaluer périodiquement la pertinence de leurs technologies et techniques, par exemple, lorsqu’ils gèrent le vieillissement des structures, systèmes et composants, ou lorsqu’ils apportent des améliorations à une installation ou une activité existante qui pourraient affecter les rejets dans l’environnement. Pour de plus amples renseignements, voir la section 4.

L’évaluation de la pertinence des technologies du titulaire de permis consiste à tenir compte de l’amélioration du cycle de vie des composants et autres améliorations rentables de l’installation ou de l’activité existante. Ces aspects sont souvent déjà considérés comme des améliorations continues et documentés dans le cadre du SGE ou du système de gestion intégrée. Dans le cas des centrales nucléaires, l’évaluation périodique des principaux systèmes et mesures de traitement, de contrôle et de prévention de la pollution devrait être effectuée dans le cadre du BPS. Pour en savoir plus, consulter les documents suivants :

- REGDOC-2.3, *Bilans périodiques de la sûreté* [7]
- REGDOC-2.6.3, *Gestion du vieillissement* [11]

4. Meilleures techniques existantes d’application rentable (MTEAR)

Pour une évaluation des MTEAR, le demandeur ou le titulaire de permis examine les technologies et techniques nouvelles et existantes pour :

- Déterminer une conception adéquate des technologies et techniques de contrôle de la pollution afin de réduire les rejets dans l’environnement, de sorte que :
  i. des mesures de contrôle appropriées de prévention de la pollution sont appliquées (y compris les stratégies de réduction)
  ii. les risques sont atténués afin de protéger la santé humaine et l’environnement
  iii. déterminer les caractéristiques des rejets nominaux maximaux prévus pour : établir les limites de rejet autoriséesétablir des seuils d’intervention (pour les nouvelles installations)

Les caractéristiques des rejets nominaux maximaux prévus comprennent l’emplacement des points de rejet, les quantités et les concentrations maximales, ainsi que le volume et le débit prévus des substances nucléaires et dangereuses qui pourraient être rejetées dans l’environnement. Les caractéristiques des rejets nominaux maximaux prévus correspondent aux rejets résiduels, c’est-à-dire les rejets d’une substance nucléaire ou dangereuse qu’il reste, après avoir tenu compte de tous les traitements et mesures d’atténuation.

4.1 Exigences concernant la réalisation d’une évaluation des MTEAR

Pour les installations et les activités nouvelles ou faisant l’objet de modifications majeures susceptibles d’augmenter ou de modifier la nature des rejets dans l’environnement et les risques qui en résultent pour les récepteurs, le demandeur ou le titulaire de permis doit procéder à une évaluation afin de trouver les meilleures technologies ou techniques de contrôle disponibles, dont il a été démontré à l’échelle industrielle qu’elles permettent de réduire les rejets de contaminants ou les facteurs de stress physique dans l’environnement.

Remarque : La démonstration d’une technologie ou d’une technique comme pratique exemplaire dans une industrie ou pour une activité similaire pourrait indiquer que la technologie ou la technique est économiquement réalisable. Le demandeur ou le titulaire de permis peut décider d’évaluer l’utilisation des technologies émergentes, en justifiant qu’elles offrent un résultat similaire ou meilleur.

Le demandeur ou le titulaire de permis doit documenter l’évaluation des MTEAR et les résultats, et les soumettre à la CCSN (voir la figure 3a). Ce document peut faire partie du fondement d’autorisation de l’installation ou de l’activité.

4.2 Éléments requis d’une évaluation des MTEAR

Une évaluation des MTEAR doit comprendre les éléments suivants :

- la caractérisation des sources de polluants
- l’identification des contaminants et des facteurs de stress physique qui devront être contrôlés
- l’établissement de cibles de rejet dans l’environnement
- l’analyse des options en matière de technologies et de techniques
- la détermination des caractéristiques des rejets nominaux maximaux prévus
- l’analyse des avantages
- le choix de la meilleure MTEAR

4.3 Orientation concernant l’évaluation des MTEAR

Le demandeur ou le titulaire de permis devrait utiliser une approche systématique pour effectuer une évaluation des MTEAR.

L’évaluation des MTEAR comprend le processus d’optimisation qui a été utilisé pour déterminer la conception adéquate des technologies et techniques de contrôle de la pollution. L’annexe B fournit des informations supplémentaires sur le rôle des principes de radioprotection tels que l’optimisation et les contraintes de dose par rapport aux évaluations des MTEAR et à la fixation des limites de rejet des substances nucléaires.

Caractérisation des sources de polluants

La caractérisation des sources de polluants consiste à déterminer la nature, la qualité et la quantité de matières à traiter avant leur rejet dans l’environnement.

Les eaux de traitement, les eaux de collecte non traitées, les rejets gazeux et autres flux de déchets sont des exemples de sources de polluants.

On devrait calculer les quantités en utilisant les concentrations moyennes et maximales prévues des influents pendant le cycle de vie de l’installation ou de l’activité.

Détermination des contaminants et des facteurs de stress physique

Une évaluation préliminaire permet de déterminer les contaminants et les facteurs de stress physique qui devront être contrôlés (c.-à-d. traités ou gérés).

Les contaminants et les facteurs de stress physique qui doivent être contrôlés comprennent les sources de polluants qui :

- sont des substances nucléaires identifiées comme dépassant les niveaux de libération conditionnelle établis par la CCSN (voir l’annexe A)
- sont assujetties à des exigences fédérales, provinciales, territoriales ou municipales existantes sur les rejets
- pourraient dépasser les recommandations, objectifs, normes ou critères fédéraux, provinciaux, territoriaux ou municipaux qui sont applicables et valables sur le plan scientifique en matière de qualité de l’environnement, avant même d’envisager leur traitement
- sont indiqués dans l’évaluation des risques environnementaux comme nécessitant un contrôle, lorsqu’un risque déraisonnable ou un risque potentiellement déraisonnable pour la santé humaine et l’environnement a été relevé

Établissement des cibles de rejet dans l’environnement

Les cibles de rejets dans l’environnement ne sont pas des limites de rejet autorisées, mais plutôt des critères d’évaluation utilisés comme base de la conception des technologies et techniques de traitement évaluées dans le cadre de l’évaluation des MTEAR. Deux types fondamentaux de cibles de rejets dans l’environnement peuvent être utilisés :

- les contraintes de dose, les concentrations ou les charges totales identifiées dans les règlements fédéraux et/ou provinciaux comme étant applicables à la substance et au type de rejet (émission/effluent) évalué

- des cibles de rejets dans l’environnement fondées sur le risque et sur des critères de qualité de l’environnement récepteur (p. ex. contraintes de dose, lignes directrices sur la qualité de l’environnement du CCME, lignes directrices fédérales sur la qualité de l’environnement, normes canadiennes de qualité de l’air ambiant)

En raison des complexités et des compromis associés à l’optimisation de la conception du traitement pour des rejets complexes (caractéristiques et compositions multiples des flux de déchets) et des limites de la technologie, toutes les cibles de rejets dans l’environnement ne sont pas forcément réalisables. L’évaluation des MTEAR indique la composition optimale de la conception (technologies et techniques) qui permettent de :

- atteindre toutes les cibles considérées comme des limites dans les règlements fédéraux ou provinciaux
- obtenir la série la plus complète de cibles de rejets dans l’environnement de l’environnement récepteur

Remarque : En raison du vaste éventail de cibles de rejets dans l’environnement potentielles et des nombreuses différences pour leur calcul et leur application particulière au site, l’annexe C fournit une analyse détaillée et des exemples pour l’établissement des cibles de rejets dans l’environnement, leur rôle dans l’évaluation des MTEAR et l’élaboration finale des limites de rejet autorisées.

Analyse des options technologiques et techniques

L’analyse des options technologiques consiste à déterminer :

- les technologies disponibles
- leur rendement en matière de réduction des contaminants à la source et des facteurs de stress physique (en d’autres mots, l’efficacité des traitements et les concentrations attendues)
- leurs avantages et inconvénients

Une analyse des techniques consiste à trouver les domaines d’optimisation qui peuvent avoir un effet direct sur la réduction des rejets dans l’environnement. L’analyse des techniques devrait couvrir les points suivants :

- l’aspect ingénierie de l’application de divers types de techniques de contrôle
- les différentes configurations d’une technologie
- les processus utilisés et les changements aux processus
- les facteurs humains
- la supervision et les processus de gestion
- la gestion de l’eau
- la gestion des gaz à effet de serre
- la façon dont les contaminants et les facteurs de stress physique sont rejetés dans l’environnement
- les compromis associés à l’application d’une technique particulière (p. ex., les besoins énergétiques, la pollution de l’air et les gaz à effet de serre, la production de déchets, l’exposition des travailleurs et du public)
- d’autres facteurs propres au site, selon l’installation ou l’activité

L’analyse devrait également passer en revue les installations ou activités similaires les plus performantes afin de déterminer les technologies et techniques qui devraient être prises en compte dans le cadre de l’évaluation des MTEAR. L’analyse doit démontrer que les technologies et techniques sélectionnées représentent une conception optimisée pour atteindre les cibles de rejet dans l’environnement.

L’analyse devrait tenir compte des répercussions possibles de la technologie ou des techniques sur les changements climatiques. L’établissement de technologies ou de techniques qui constituent des MTEAR devrait tenir compte de la réduction des gaz à effet de serre rejetés dans l’environnement.

Les systèmes de traitement devraient être conçus de manière à tenir compte de la possibilité d’événements météorologiques extrêmes et devraient tenir compte des répercussions futures des changements climatiques sur ces événements (p. ex., événement à récurrence de 100 ans).

Cette analyse peut être étayée par des essais en laboratoire, à l’échelle du banc d’essai ou du projet pilote, pour confirmer l’efficacité du traitement et les concentrations prévues d’émissions ou d’effluents traités.

Les titulaires de permis d’installations nucléaires émettant des particules radioactives et des iodures radioactifs devraient envisager le recours à la norme CSA N288.3.4 pour la conception, la mise en service et l’entretien des systèmes de contrôle de la pollution atmosphérique.

Voici quelques exemples de techniques :

- des procédures améliorées pour le changement des filtres
- une dilution plus rapide grâce à l’utilisation de diffuseurs
- les rejets dans des cours d’eau rapides par rapport à des cours d’eau lents
- la réduction ou la prévention des rejets pendant les périodes écologiquement sensibles
- l’utilisation de cheminées plus hautes ou d’un diamètre réduit
- l’utilisation de meilleurs réactifs chimiques
- une plus grande certitude quant aux concentrations de gisement de minerai
- la réduction des erreurs humaines par l’amélioration des programmes de formation
- l’optimisation des conditions d’exploitation

Détermination des caractéristiques des rejets nominaux maximaux prévus

Pour ce qui est de la combinaison des technologies et techniques envisagées, la détermination des caractéristiques des rejets nominaux maximaux prévus comprend la concentration et les quantités qui pourraient être rejetées par l’installation ou l’activité.

Lors de la détermination des caractéristiques des rejets nominaux maximaux prévus, le demandeur ou titulaire de permis devrait tenir compte des aspects suivants :

- les caractéristiques des influents maximaux prévus
- l’efficacité prévue du traitement pour les opérations à grande échelle
- une marge de flexibilité opérationnelle

Analyse des avantages

Une analyse des avantages (p. ex., une analyse coûts-avantages ou une analyse des critères multivaleur) permet de sélectionner une technologie ou une technique appropriée.

Sélection de l’option MTEAR optimale

Sur la base des évaluations décrites ci-dessus, le demandeur ou le titulaire de permis devrait choisir l’option MTEAR convenant le mieux à l’installation ou à l’activité.

4.3.1 Documentation de l’évaluation des MTEAR et des résultats

Le demandeur ou le titulaire de permis devrait documenter les renseignements suivants sur l’évaluation des MTEAR et les résultats :

- un résumé des résultats de la caractérisation des sources de polluants, y compris :
  - la nature de la source
  - les concentrations moyennes et maximales prévues de l’influent
  - les quantités à traiter
- les cibles de rejet dans l’environnement fixées et la méthode utilisée pour les calculer
- un résumé des résultats de l’analyse des options technologiques, y compris une liste des technologies évaluées et de leur rendement prévu (en d’autres mots, l’efficacité prévue du traitement) pour traiter les contaminants et les facteurs de stress physique relevés
- une description des techniques à appliquer
- le cas échéant, un résumé des résultats de l’analyse coûts-avantages ou de l’analyse des critères multivaleur
- la conception finale proposée et sa justification en tant qu’option comme MTEAR
- le rendement prévu du traitement, les caractéristiques des rejets nominaux maximaux prévus et une comparaison avec les cibles établies de rejet dans l’environnement

Pour de plus amples renseignements sur la façon dont la CCSN tient compte des renseignements sur les coûts et avantages, voir le REGDOC-3.5.3, *Principes fondamentaux de réglementation*.

5. Limites de rejet autorisées

Les limites de rejet autorisées sont appliquées au point final de contrôle d’une installation ou d’une activité.

L’établissement de limites de rejet autorisées vise à restreindre la quantité ou la concentration de contaminants et de facteurs de stress physique qui peuvent être rejetés dans l’environnement. Conformément à cet objectif, une limite de rejet autorisée est basée sur les quantités ou les concentrations maximales proposées, y compris une marge offrant une flexibilité opérationnelle (c’est-à-dire le rejet nominal maximal prévu), comme décrit dans le fondement d’autorisation du titulaire de permis. Par conséquent, le dépassement d’une limite de rejet autorisée indique qu’il y a une perte de contrôle d’une partie du programme de protection de l’environnement ou des mesures de contrôle, et que le titulaire de permis fonctionne en dehors du fondement d’autorisation établi pour cette installation ou activité.

La mise en œuvre des limites de rejets autorisées garantit:

- l’application des mesures de contrôle acceptables (y compris les stratégies) pour la prévention de la pollution
- la protection de la santé humaine et de l’environnement
- que le titulaire de permis opère dans les limites indiquées dans le fondement de l’autorisation pour l’exploitation normale de cette installation ou activité.

Comme les limites de rejet autorisées représentent la limite supérieure des rejets acceptables, il est nécessaire de garantir que ces rejets ne posent pas de risque déraisonnable pour l’environnement ou pour la santé et la sécurité des personnes. Ceci est démontré par l’ERE spécifique au site.

Pour les nouvelles installations, ou les installations existantes qui subissent des modifications importantes nécessitant une modification du permis, les limites de rejet autorisées proposées sont soumises dans le cadre d’une demande de permis et sont approuvées par la Commission. Toute modification des limites de rejet autorisées pour une installation existante doit être approuvée par la CCSN.

Lorsqu’un permis est délivré, le titulaire de permis est autorisé à faire des rejets dans l’environnement conformément aux limites de rejet autorisées. L’autorisation de rejets doit être reçue de toutes les autorités compétentes concernées, et ce, avant tout rejet :

- une autorisation délivrée par d’autres autorités compétentes ne constitue pas une autorisation de la CCSN
- une autorisation délivrée par CCSN ne constitue pas une autorisation des autres autorités compétentes.

Les limites de rejet autorisées ne s’appliquent qu’au mode d’exploitation normale. Pendant les situations d’urgence, les limites de rejet autorisées ne s’appliquent pas et les procédures de gestion des urgences entrent en vigueur jusqu’au rétablissement du mode d’exploitation normale. Au cours de cette période, le personnel de la CCSN communique de façon continue avec le titulaire de permis, et une surveillance réglementaire accrue est exercée. La CCSN travaillera avec les autres autorités compétentes pour s’assurer que, dans la mesure du possible, les autorisations sont acceptables pour toutes les autorités compétentes concernées. La section 5.1 indique les procédures d’harmonisation des limites de rejet autorisées par la CCSN avec celles qui figurent actuellement dans les règlements fédéraux/provinciaux/territoriaux applicables à l’activité autorisée.

Les limites de rejet autorisées sont basées sur le rejet nominal maximal prévu, avec une marge incluse pour permettre une flexibilité opérationnelle. Cette approche établit les limites de rejet autorisées à des niveaux bien inférieurs aux dommages anticipés, mais si elles sont dépassées, cela indique clairement une défaillance du programme de protection de l’environnement pour le contrôle des rejets.

Pour les substances nucléaires, cette approche comprend la limitation de l’exposition et l’optimisation pour atteindre le niveau ALARA. La limitation est représentée par la limite de dose publique du *Règlement sur la radioprotection* de 1 mSv/an. Comme cette limite s’applique à la somme des expositions de tous les rejets autorisés, elle n’est pas utilisée comme base pour établir une limite de rejet autorisée pour une seule installation. La limite de rejet autorisée d’une installation est basée sur l’optimisation de la conception de l’installation et des systèmes de traitement par l’application de la méthode des MTEAR. Voir l’annexe B pour de plus amples informations sur le rôle des principes de radioprotection tels que l’optimisation et les contraintes de dose par rapport à l’établissement de limites de rejet autorisées pour les substances nucléaires.

Le dépassement d’une limite de rejet autorisée démontre un manque de conformité aux exigences et est sujet à des mesures d’application de la loi Celles-ci seront proportionnelles au niveau de rejet, aux risques associés pour la santé humaine et l’environnement, et aux antécédents en matière de conformité. Les mesures d’application peuvent comprendre n’importe lequel des outils d’application graduelle de la CCSN. Pour en savoir plus, veuillez consulter l’approche de la CCSN en matière de vérification de la conformité et d’application de la loi.

Remarque : La limite de rejet autorisée est fixée à un niveau qui garantit l’absence de risque déraisonnable pour la santé humaine et l’environnement et, par conséquent, qui protège la santé humaine et l’environnement. Ceci est soutenu par son application comme terme source dans l’ERE. La mise en œuvre des limites de rejet autorisées, qui comprend la manière d’intervenir en cas de dépassement de la limite autorisée et les mesures prises pour rétablir l’efficacité du programme de protection de l’environnement, permet d’atteindre cet objectif.

5.1 Exigences relatives à l’établissement et à la documentation des limites de rejet proposées

Le demandeur ou le titulaire de permis doit soumettre à la CCSN :

- l’emplacement des points de rejet contrôlé proposés
- la ou les limites de rejet proposées pour chaque point de rejet contrôlé proposé, et pour chaque contaminant ou facteur de stress physique
- la méthode utilisée pour établir la ou les limites de rejet proposées

La ou les limites de reje proposées pour chaque site :

- doivent être égales ou inférieures à toute limite de rejet applicable prévue par la législation en vigueur
- sont assujetties à l’approbation de la Commission (et font donc partie du fondement d’autorisation)

Pour les contaminants et les facteurs de stress physique qui ne sont pas visés par des limites de rejet établies, le demandeur ou le titulaire de permis doit utiliser les concentrations ou les quantités nominales prévues de rejets pour établir des limites de rejet proposées appropriées.

Pour toutes les substances nucléaires rejetées par l’installation ou l’activité, le demandeur ou le titulaire de permis doit démontrer que, d’après la ou les limites de rejet proposées, la dose efficace totale annuelle maximale prévue pour un membre du public est inférieure à la limite de dose réglementaire pour le public.

Afin d’établir la ou les limites de rejet qui seront proposées à la CCSN, le demandeur ou le titulaire de permis doit :

- déterminer les points de rejet où la ou les limites de rejet autorisées s’appliqueront
- déterminer le ou les rejets nominaux maximaux prévus
- indiquer chaque contaminant et facteur de stress physique qui nécessite une limite de rejet autorisée
- établir la ou les limites de rejet proposées
- démontrer que les limites de rejet proposées respectent la limite de la dose réglementaire pour le public et ne présentent pas de risque déraisonnable pour la santé humaine ou l’environnement

Orientation

Le demandeur ou le titulaire de permis devrait employer un processus systématique et structuré pour établir les limites de rejet proposées.

Déterminer les points de rejet où les limites de rejet autorisées s’appliqueront

La liste des points de rejet doit être conforme à la conception de l’installation et aux points de rejet contrôlés établis dans le programme de surveillance des effluents et/ou des émissions. Pour les substances nucléaires, lorsqu’il y a plusieurs points de rejet, des limites de rejet autorisées à l’échelle de l’installation et/ou de l’activité peuvent être appliquées.

Déterminer les rejets nominaux maximaux prévus

Déterminez les concentrations et les quantités maximales prévues pour chaque point de rejet contrôlé :

- pour une nouvelle installation ou activité, ou pour une installation ou activité existante qui subit des modifications importantes, cette information est documentée dans le cadre de l’évaluation et des résultats des MTEAR
- pour une installation ou une activité existante en mode d’exploitation normale :
  - cette information peut être documentée dans la documentation de conception approuvée pour un mode d’exploitation normale
  - sinon, le rejet nominal maximal prévu doit être établi en utilisant les données de rendement historiques pour chaque point de rejet contrôlé

- pour les substances nucléaires en particulier, le(s) rejet(s) nominal(aux) maximal(s) prévu(s) à l'échelle de l'installation et/ou de l'activité peuvent être établis selon la méthode suivante :
  i. pour chaque radionucléide/groupe de radionucléides, déterminer
     - un niveau qui représente le(s) rejet(s) maximal(s) à l'échelle de l'installation et/ou de l'activité en mode d'exploitation normale, sur la base des données historiques de rendement
     - leur contribution fractionnée à la dose totale
  ii. calculer la dose effective totale reçue par la personne représentative (ou le récepteur critique) en utilisant les valeurs de rejet maximales obtenues à l'étape i
  iii. calculer la dose correspondant au rejet nominal maximal prévu en appliquant un facteur à la dose calculée à l'étape ii, pour tenir compte de la flexibilité opérationnelle basée sur la compréhension du fonctionnement prévu de l'installation et/ou de l'activité, et sur le jugement professionnel
  iv. pour chaque radionucléide/groupe de radionucléides, recalculer la dose correspondant au rejet maximal prévu et la multiplier par sa contribution fractionnée à la dose totale identifiée à l'étape i, pour obtenir un rejet maximal prévu à l'échelle de l'installation et/ou de l'activité

Le demandeur ou le titulaire de permis peut utiliser la méthode décrite dans la norme CSA N288.8, *Établissement et mise en œuvre de seuils d'intervention pour les rejets dans l'environnement par les installations nucléaires* [5], pour une approche rétrospective, en utilisant une valeur en centile qui représente une perte de contrôle manifeste, et selon les connaissances propres au site et le jugement professionnel.

Pour les installations nucléaires autorisées où, en raison de la nature de l'exploitation (par exemple, recherche et développement, prestation de services à l'industrie nucléaire), les rejets dépendent du type de travail actif, lequel peut changer au fil du temps, une marge de flexibilité opérationnelle appropriée doit être considérée pour le calcul du rejet nominal maximal prévu afin de tenir compte des activités planifiées tout au long de la durée de vie de l'installation.

Indiquer chaque contaminant et facteur de stress physique qui nécessite une limite de rejet autorisée

Tous les contaminants et facteurs de stress physique qui correspondent à l'une ou l'autre des situations suivantes doivent être indiqués :

i. ils sont assujettis à des exigences fédérales, provinciales, territoriales ou municipales existantes en matière de rejets
ii. lorsque le ou les rejets nominaux maximaux prévus à l'installation ou à l'activité dépassent les exigences, les directives, les objectifs, les normes ou les critères de qualité de l'environnement fédéraux, provinciaux, territoriaux ou municipaux applicables et les plus scientifiquement défendables et qui ne sont pas couverts par i
iii. ils sont indiqués dans l'ERE comme nécessitant un contrôle
iv. Le demandeur ou le titulaire de permis doit démontrer qu'il a examiné la législation, la réglementation et les limites ou contrôles connexes existants applicables à l'installation ou à l'activité et dont il devait tenir compte pour faire sa proposition de limites de rejet autorisées (veuillez noter que cet examen est déjà requis pour les systèmes de gestion).

Une limite de rejet autorisé peut ne pas être requise si le demandeur ou le titulaire de permis est en mesure de démontrer que, pour les rejets contrôlés dans toutes les circonstances prévisibles (telles qu'identifiées dans l'ERE) :

- la dose annuelle efficace totale prévue pour le public ne dépasse pas 0,01 mSv/an pour la combinaison de toutes les substances nucléaires rejetées à leur rejet de conception maximal prévu de l'installation ou de l'activité autorisée dans des conditions d'exploitation normale

- en ce qui concerne une substance dangereuse, les rejets nominaux maximaux prévus sont inférieurs aux normes, lignes directrices ou objectifs fédéraux, provinciaux, territoriaux ou municipaux applicables (p. ex., ceux du Conseil canadien des ministres de l'environnement)

Si une limite de rejet autorisée n'est pas requise, le titulaire de permis ou le demandeur :

- est toujours tenu de démontrer chaque année (par la surveillance ou la modélisation) que la dose annuelle efficace totale ne dépasse pas la limite de dose publique réglementaire de 1 mSv, et que les limites de rejet autorisées ne sont toujours pas requises en confirmant que la dose reste inférieure à 0,01 mSv et toute contrainte de dose applicable prescrite par la CCSN (p. ex. lorsqu'il existe un potentiel d'exposition cumulative découlant de plusieurs activités autorisées)

  Remarque : Cette évaluation ferait partie de l'évaluation annuelle existante de la dose radiologique de l'installation, à l'aide du modèle d'évaluation de la dose publique propre au site. La détermination porterait sur l'ensemble de l'installation autorisée et/ou du site d'activité.

- peut être tenu d'effectuer une surveillance de routine des effluents et/ou des émissions, ainsi qu'une surveillance environnementale (comme décrit dans le REGDOC 2.9.1 [1])

Établir la limite de rejet proposées

Le demandeur ou le titulaire de permis doit établir les limites de rejets proposées comme suit :

- adopter les exigences gouvernementales préalablement déterminées applicables aux rejets

  Remarque : S'il existe d'autres exigences gouvernementales sur les rejets applicables à l'installation et/ou à l'activité, le demandeur ou le titulaire de permis peut harmoniser ses propres limites avec ces exigences (en particulier, avec tout processus ou procédure concernant les rapports) et les utiliser comme limites de rejet proposées. Notamment, les réglementations fédérales ou provinciales (y compris celles relatives à la qualité de l'air local au **point d'impact**), les règlements municipaux et les permis, les autorisations ou les licences provinciaux ou territoriaux.

  Remarque : Pour s'harmoniser avec les exigences relatives aux rejets visant à protéger la qualité de l'air local (p. ex., O. REG 419/05), les limites de rejets proposées pour les contaminants et/ou les facteurs de stress physique d'intérêt réglementaire peuvent être établies par rétrocalcul à partir du point d'impact, en utilisant les caractéristiques de rejet propres au site (p. ex., débits, hauteurs et températures des cheminées).

  Remarque : Les limites de rejets autorisées harmonisées avec les autres exigences gouvernementales peuvent changer de temps à autre, à mesure que ces dernières sont mises à jour. Le personnel de la CCSN doit être informé de ces changements en temps opportun afin de mettre à jour le manuel des conditions de permis. Les limites de rejets autorisées mises à jour entreront en vigueur à la date indiquée par l’autorité compétente.

Remarque : Lorsque les exigences fédérales, provinciales et territoriales en vigueur ne permettent pas une protection adéquate de l’environnement (comme indiqué par une ERE ou toute autre évaluation scientifiquement défendable), la CCSN consultera les autorités compétentes pour déterminer la limite de rejet autorisée la plus appropriée.

- pour chaque contaminant, lorsqu’il n’existe pas d’exigences en matière de rejets ou que l’on estime qu’elles ne permettent pas de protéger suffisamment l’environnement, choisir comme limite de rejet proposée la concentration des rejets nominaux maximaux prévus qui s’applique à la concentration moyenne mensuelle maximale.

  Remarque : Pour permettre une certaine flexibilité opérationnelle, une limite de rejet proposée dans l’eau peut être appliquée à un échantillon composite représentant 1,5 fois la concentration moyenne mensuelle maximale, ou à un « échantillon instantané » représentant 2 fois la concentration moyenne mensuelle maximale. L’application de ces facteurs est une approche réglementaire d’usage courant.

- lorsqu’une limite de rejet proposée doit être établie d’après la quantité de contaminants rejetée au cours d’une période donnée (c.-à-d. un débit ou une charge), multiplier la concentration des rejets nominaux maximaux prévus par le débit nominal maximal au cours de la période en question

  Remarque : Pour les substances nucléaires, une ou plusieurs limites de rejets autorisées à l’échelle de l’installation et/ou de l’activité peuvent être établies pour les installations ayant plusieurs points de rejet.

Remarque : Les limites de rejets autorisées basées sur le rejet nominal maximal prévu sont fondées sur la conception physique approuvée de l’installation, qui devrait tenir compte de la flexibilité opérationnelle basée sur l’exploitation prévue de l’installation et/ou de l’activité. Par conséquent, elles ne devraient pas changer au fil du temps, sauf en cas de modifications majeures apportées à l’installation ou à l’activité nucléaire susceptibles d’augmenter ou de modifier la nature des rejets dans l’environnement et les risques qui en résultent pour les récepteurs, ce qui dépasserait le fondement d’autorisation en place.

Remarque : Pendant la transition entre l’exploitation et le déclassement, s’il n’y a pas d’augmentation prévue des caractéristiques de rejet et que les mesures de contrôle existantes continuent à fonctionner dans les limites de rejets autorisées en cours, l’installation et/ou l’activité demeure dans les limites de son fondement d’autorisation. Cependant, si une modification majeure de l’installation et/ou de l’activité est proposée, susceptible de modifier les caractéristiques de rejet et de dépasser les limites de rejet autorisées en cours, le résultat pourrait se trouver hors du fondement d’autorisation existant, il faut demander une modification de permis, effectuer une évaluation des MTEAR et faire une mise à jour des limites de rejets autorisées afin qu’elles correspondent à la modification majeure des activités.

Démontrer que les limites de rejet proposées respectent la limite de dose réglementaire pour le public et ne présentent pas de risque déraisonnable pour la santé humaine ou l’environnement

Pour toutes les substances nucléaires rejetées par l’installation ou l’activité, la dose efficace totale annuelle maximale prévue (établie d’après les limites de rejet proposées) pour un membre du public doit être inférieure à la limite de dose réglementaire pour le public et démontrer que les rejets ont été optimisés (voir annexe B).

À cette fin, le demandeur ou le titulaire de permis devrait :

- obtenir les données de l’ERE la plus récente, s’ils sont disponibles
- utiliser ces données dans un modèle approprié de voie d’exposition et de transport dans l’environnement

Pour les substances nucléaires et dangereuses, le demandeur ou le titulaire de permis devrait utiliser les limites de rejet proposées de l’ERE pour démontrer que, au niveau des limites de rejet proposées, il n’y a pas de risque déraisonnable pour la santé humaine ou l’environnement.

Remarque : Une limite de rejet proposée permet au titulaire de permis à faire des rejets à hauteur de cette limite. Par conséquent, on s’attend à ce qu’il démontre que les rejets effectués selon la limite de rejet autorisée n’entraîneront pas de risque déraisonnable pour la santé humaine et l’environnement. Cela peut être évalué de manière conservatrice dans l’évaluation des risques pour l’environnement à partir d’un scénario selon lequel on suppose un rejet continu à la ou aux limites de rejets proposées. Si, en raison de la nature de l’installation et/ou de l’activité, on s’attend à ce que le rejet nominal maximal prévu ne soit atteint que pendant une période spécifique d’exploitation normale ou périodiquement pendant de courtes durées, le demandeur ou le titulaire de permis peut souhaiter modéliser cette situation dans l’ERE. Le dépassement des valeurs de rejet approuvées dans l’ERE signifie que l’on fonctionne en dehors du fondement d’autorisation, donc l’installation ou l’activité entre à ce moment dans une gestion adaptative progressive. Dans les scénarios où l’on prévoit des rejets accrus de manière périodique ou limitée dans le temps, la limite de rejet proposée peut inclure des limites temporelles.

Remarque : La dose efficace totale annuelle maximale prévue comprend l’exposition directe au rayonnement gamma.

Pour de plus amples renseignements sur le rôle et l’élaboration des modèles de voie d’exposition et de transport dans l’environnement, consulter ce qui suit :

- REGDOC-2.9.1, *Principes, évaluations environnementales et mesures de protection de l’environnement* [1]
- CSA N288.1, *Lignes directrices pour la modélisation du transport, du devenir et de l’exposition dans l’environnement des radionucléides associés à l’exploitation normale des installations nucléaires* [2]
- CSA N288.6, *Évaluation des risques environnementaux aux installations nucléaires de catégorie I et aux mines et usines de concentration d’uranium* [3]

5.2 Exigences concernant les interventions en cas de dépassement des limites de rejet autorisées

Lorsqu'un titulaire de permis apprend qu'une limite de rejet autorisée a été dépassée, il doit :

- limiter, dans la mesure du possible, l'effet et l'ampleur du dépassement
- mener une enquête pour établir la cause et déterminer l'ampleur du dépassement
- évaluer les effets potentiels sur la santé humaine et l'environnement
- déterminer et prendre toute mesure visant à rétablir l'efficacité du programme de protection de l'environnement ou des mesures de contrôle mises en œuvre et à prévenir toute récurrence (cela peut comprendre le recours à la gestion adaptative; voir la section 8)
- suivre les exigences de déclaration décrites dans le REGDOC applicables à l'installation ou à l'activité :
  - REGDOC-3.1.1, *Rapports à soumettre par les exploitants de centrales nucléaires* [8]
  - REGDOC-3.1.2, *Exigences relatives à la production de rapports, tome I : Installations de catégorie I non productrices de puissance et mines et usines de concentration d'uranium* [9]
  - REGDOC-3.1.3, *Exigences relatives à la production de rapports pour les titulaires de permis de déchets de substances nucléaires, les installations nucléaires de catégorie II et les utilisateurs d'équipement réglementé, de substances nucléaires et d'appareils à rayonnement* [13]

5.3 Exigences concernant la révision des limites de rejet autorisées

Les limites de rejet autorisées doivent être revues dans les cas suivants :

- une modification majeure des activités de l'installation, ce qui entraîne un changement du fondement d'autorisation
- des exigences gouvernementales nouvelles ou actualisées (p. ex., les exigences fédérales, provinciales, territoriales et municipales)

6. Seuils d’intervention pour la protection de l’environnement

Dans le cadre du fondement d’autorisation d’un site donné, le titulaire de permis doit revoir les seuils d’intervention périodiquement et les ajuster pour tenir compte de tout changement dans les activités, les conditions ou les processus du site. Toute révision des seuils d’intervention est soumise à l’examen et à l’approbation de la CCSN.

Le dépassement d’un seuil d’intervention oblige à prendre des mesures précises. Le dépassement d’un seuil d’intervention n’est pas considéré comme un manque de conformité, mais l’absence de réaction appropriée l’est. Lorsqu’un seuil d’intervention est dépassé, le titulaire de permis doit respecter :

- les étapes du paragraphe 6(2) du *Règlement sur la radioprotection*
- les exigences du code de pratique du titulaire de permis, conformément au paragraphe 4(2) du *Règlement sur les mines et les usines de concentration d’uranium*, le cas échéant
- les exigences supplémentaires qui peuvent être incluses dans le fondement d’autorisation du titulaire de permis.

En cas de dépassement d’un seuil d’intervention, la mise en œuvre réussie des activités de suivi requises (p. ex., la notification, l’enquête et les mesures correctives) est une démonstration claire de la tenue et de la gestion efficaces du programme de protection de l’environnement et des mesures de contrôle.

Les seuils d’intervention sont propres à chaque site et fondés sur des données opérationnelles. Pour de plus amples renseignements, voir :

- la section 6 sur l’établissement des seuils d’intervention
- pour les centrales nucléaires, le REGDOC-3.1.1, *Rapports à soumettre par les exploitants de centrales nucléaires* [8]
- pour les installations nucléaires de catégorie I (à l’exclusion des réacteurs de puissance) et les mines et usines de concentration d’uranium, le REGDOC-3.1.2, *Exigences relatives à la production de rapports, tome I : Installations nucléaires de catégorie I non productrices de puissance et mines et usines de concentration d’uranium* [9]
- la norme CSA N288.8, *Établissement et mise en œuvre de seuils d’intervention pour les rejets dans l’environnement par les installations nucléaires* [5]

Un seuil d’intervention est défini comme étant une dose précise de rayonnement ou un autre paramètre qui, s’il est atteint, peut indiquer une perte de contrôle d’une partie du programme de radioprotection ou du programme de protection de l’environnement d’un titulaire de permis, et déclenche l’obligation de prendre des mesures spécifiques [14].

Un seuil d’intervention est un indicateur d’une perte potentielle de contrôle d’une partie d’un programme ou de mesures de contrôle. Le dépassement d’un seuil d’intervention signale une réduction possible de l’efficacité du programme ou des mesures de contrôle et peut indiquer un écart par rapport à l’exploitation normale.

6.1 Exigences concernant l’établissement des seuils d’intervention

Le demandeur ou le titulaire de permis doit élaborer et établir des seuils d’intervention appropriés selon le type d’activité ou d’installation nucléaire.

6.1.1 Contaminants et facteurs de stress physique

Dans le cas des facteurs de stress physique et des contaminants rejetés dans l’environnement, le titulaire de permis doit déterminer et mettre en œuvre des seuils d’intervention conformément à la norme CSA N288.8, *Établissement et mise en œuvre de seuils d’intervention pour les rejets dans l’environnement par les installations nucléaires* [5].

6.1.2 Autres contrôles de protection de l’environnement

Le demandeur ou le titulaire de permis devrait établir et mettre en œuvre des seuils d’intervention pour d’autres contrôles de protection de l’environnement qui sont nécessaires afin d’assurer l’efficacité du programme de protection de l’environnement et des mesures de contrôle. Par exemple, des seuils d’intervention pourraient être établis pour les paramètres suivants :

- le débit (pour assurer un contrôle adéquat du débit dans un bassin hydrographique afin de prévenir les inondations en aval ou la perturbation du lit du cours d’eau)
- la charge hydraulique à travers les barrières naturelles ou artificielles (afin d’assurer un contrôle adéquat du confinement des contaminants et des facteurs de stress physique)

Remarque : Ces types de seuils d’intervention ont été généralement appliqués dans les mines et usines de concentration d’uranium; ils peuvent être appliqués dans d’autres installations nucléaires et pour d’autres contrôles environnementaux.

6.1.3 Documenter l’élaboration des seuils d’intervention

Le demandeur ou le titulaire de permis doit :

- documenter l’élaboration des seuils d’intervention conformément à la norme CSA N288.8, *Établissement et mise en œuvre de seuils d’intervention pour les rejets dans l’environnement par les installations nucléaires* [5]
- soumettre cette documentation et les seuils d’intervention proposés à la CCSN

Ce document fera partie du fondement d’autorisation de l’installation ou de l’activité nucléaire.

Les seuils d’intervention changent au fil du temps, car ils reflètent les conditions d’exploitation réelles. Le titulaire de permis doit soumettre à la CCSN toute modification des seuils d’intervention, ainsi que la documentation justificative.

6.2 Exigences concernant l’intervention en cas de dépassement des seuils d’intervention

Lorsqu’un seuil d’intervention est dépassé, le titulaire de permis doit :

- aviser la Commission et lui présenter un rapport selon ce qui est prescrit dans le permis ou le manuel des conditions de permis
- mener une enquête pour déterminer les raisons du dépassement du seuil d’intervention
- le cas échéant, prendre des mesures pour rétablir l’efficacité du programme ou des mesures de contrôle qui ont été mises en œuvre

6.3 Orientation concernant les seuils d'intervention

Les seuils d'intervention devraient être ajustés selon les modifications apportées aux activités ou aux processus du site, conformément au fondement d'autorisation du site en question. Le titulaire de permis devrait :

- examiner périodiquement les seuils d'intervention conformément à la norme CSA N288.8, *Établissement et mise en œuvre de seuils d'intervention pour les rejets dans l'environnement par les installations nucléaires* [5]
- revoir les seuils d'intervention le cas échéant, en tenant compte :
  - des données recueillies sur l'exploitation et le rendement de l'installation ou de l'activité nucléaire depuis le début de sa mise en service jusqu'à la date actuelle (méthode également appelée approche rétrospective)
  - des données sur l'exploitation et le rendement actuels de l'installation ou de l'activité nucléaire

Le cas échéant, le demandeur ou le titulaire de permis peut adapter l'approche basée sur le rendement décrite dans la norme CSA N288.8 [5] afin d'établir des seuils d'intervention pour d'autres contrôles de protection de l'environnement (p. ex., des barrières techniques ou naturelles, ou encore le contrôle du débit).

7. Mise en service d’un système de traitement

La mise en service est essentielle pour vérifier le rendement par rapport à la conception approuvée et pour s’assurer que les limites de rejet autorisées sont réalisables et sont fixées à un niveau qui protège l’environnement.

Tous les nouveaux systèmes de traitement doivent être mis en service pour vérifier ce qui suit :

- le système a été construit et fonctionnera conformément aux paramètres de dimensionnement avant de commencer les rejets dans l’environnement
- le système ne dépasse pas les caractéristiques des rejets nominaux maximaux prévus
- les seuils d’intervention et les limites de rejet autorisées, établis au préalable, sont appropriés

Dans la mesure du possible, la CCSN harmonise ce processus avec celui des autres autorités compétentes (p. ex., le ministère de l’Environnement, de la Protection de la nature et des Parcs de l’Ontario).

Remarque : La présente section s’applique aux activités autorisées et aux substances ou déchets dangereux qui ne sont pas des substances nucléaires, qui sont utilisés ou produits durant l’exécution d’une activité autorisée qui peut présenter un danger pour l’environnement ou pour la santé, la sûreté et la sécurité des personnes. Cela comprendrait une installation conventionnelle de traitement des eaux usées sur le site autorisé.

Exigences

Pour toute installation ou activité qui doit mettre en service un nouveau système de traitement, ou qui apporte une modification majeure à un système de traitement existant, le titulaire de permis doit soumettre un plan de mise en service à la CCSN.

Le titulaire de permis doit mettre en service le système de traitement et les mesures de contrôle conformément au plan de mise en service approuvé.

Après la mise en service du système de traitement, le titulaire de permis doit soumettre un rapport de mise en service qui :

- comprend une évaluation du rendement opérationnel du système de traitement par rapport aux limites de rejet autorisées et aux caractéristiques des rejets nominaux maximaux prévus pour garantir que le rendement opérationnel se situe dans les limites de rejet autorisées
- confirme que les seuils d’intervention proposés restent appropriés

Si le titulaire de permis détermine qu’une limite de rejet autorisée spécifique dans l’environnement ne peut être respectée, le titulaire de permis doit :

- aviser la Commission
- déterminer la nature du rendement ou du comportement imprévu
- évaluer si la limite de rejet autorisée peut être atteinte par une optimisation supplémentaire ou l’application de mesures d’atténuation ou de techniques supplémentaires en vue de réduire les rejets sous les limites de rejet autorisées

Si le titulaire de permis détermine que le rendement du système de traitement ne peut respecter une limite de rejet autorisée spécifique, il doit :

- établir une limite de rejet autorisée révisée, fondée sur la technologie disponible
- réévaluer l'ERE pour déterminer si ses prévisions demeurent valides
- Si la réévaluation de l'ERE :
  - indique un risque déraisonnable pour la santé humaine ou l'environnement, le titulaire de permis doit mettre en œuvre d'autres mesures ou techniques d'optimisation et d'atténuation et répéter les trois points énumérés ci-dessus
  - détermine qu'il n'y a pas de risque déraisonnable pour la santé humaine ou l'environnement, le titulaire de permis doit :
    - demander à la CCSN de modifier son fondement d'autorisation
    - présenter l'ERE révisée et les limites de rejet proposées

Orientation

Le demandeur ou le titulaire de permis devrait présenter un plan de mise en service à la fin de la phase de construction. Ce plan de mise en service devrait comprendre les renseignements suivants :

- le calendrier et les processus de mise en service
- les responsabilités
- le passage à l'étape suivante de mise en service (« dossier de transfert de responsabilité »)
- le rendement opérationnel
- l'évaluation du rendement
- le système de gestion (en particulier l'assurance de la qualité et le contrôle de la qualité – AQ/CQ)
- la sécurité (santé et sécurité au travail, radioprotection)
- la formation
- la tenue des dossiers
- le plan du site et les emplacements des points d'échantillonnage

Afin de confirmer le rendement du système de traitement, le titulaire de permis devrait évaluer le rendement opérationnel par rapport aux cibles environnementales établies à la section 4.2.1 (dans le cadre de l'évaluation des MTEAR).

Pour de plus amples renseignements sur les composantes d'un plan de mise en service et sur la façon de confirmer le rendement du système de traitement, voir l'annexe D.

Pour de plus amples renseignements sur la mise en service d'un système de traitement des eaux usées, voir les documents suivants :

- REGDOC-2.3.1, *Réalisation des activités autorisées : Programmes de construction et de mise en service* [15]
- orientation figurant dans le document du département de la Défense des États-Unis, *Planning and Commissioning Wastewater Treatment Plants* [16]

8. Gestion adaptative

La gestion adaptative consiste notamment à mettre en œuvre des mesures nouvelles ou modifiées d’atténuation pendant la durée de vie d’un projet afin de tenir compte des effets environnementaux imprévus [14].

La gestion adaptative présuppose que le titulaire de permis prend des mesures correctives pour atténuer un risque déraisonnable constaté ou potentiel pour l’environnement afin de l’amener à un niveau acceptable par la CCSN. Celle-ci s’attend à ce que le titulaire de permis adopte une approche proactive si un risque déraisonnable avéré ou potentiel pour l’environnement a été constaté.

Un plan de gestion adaptative est en un sens semblable à un plan de mesures correctives mis en œuvre en réponse à une non-conformité à l’égard du fondement d’autorisation.

8.1 Exigences de la gestion adaptative

La gestion adaptative est requise dans les situations suivantes :

- risque déraisonnable avéré ou potentiel cerné dans l’ERE ou relevé par la surveillance continue; par exemple, à la suite de :
  - modifications à l’exploitation ou à l’activité autorisée
  - avancées scientifiques dans la compréhension de la toxicité ou des effets physiques d’une substance
- modifications dans le statut réglementaire d’une substance (p. ex., classification, par Environnement et Changement climatique Canada, d’une substance comme étant toxique au sens de la *Loi canadienne sur la protection de l’environnement (1999)* exigences réglementaires nouvelles ou mises à jour

Lorsque la gestion adaptative s’impose, le titulaire de permis doit :

- aviser la Commission
- élaborer, documenter et mettre en œuvre un plan de gestion adaptative afin de :
  - réduire les facteurs de stress physique et les rejets de contaminants identifiés dans l’environnement
  - atténuer tout effet potentiel sur l’environnement
- fournir des mises à jour périodiques, le cas échéant, afin de refléter l’état de la situation

La période provisoire s’étend du moment à partir duquel la gestion adaptative est déclenchée jusqu’à l’achèvement de la mise en service du nouveau système de traitement ou d’autres mesures de contrôle. Au cours de cette période provisoire, les mises à jour périodiques, réalisées à la fréquence indiquée par la CCSN, doivent inclure les renseignements suivants :

- un résumé de la technologie et des techniques utilisées et leur rendement pour ce qui est de réduire les contaminants et les facteurs de stress physique
- pour chaque contaminant ou facteur de stress physique :
  - une évaluation des données de rendement historiques et actuelles concernant les effluents ou les émissions
  - une évaluation des tendances futures prévues du rendement en matière d’effluents ou d’émissions

- une mise à jour résumant les risques, y compris les risques résiduels, pour l’environnement
- l’état de la mise en œuvre du plan de gestion adaptative à long terme

La mise en œuvre de la gestion adaptative doit prendre en compte les effets potentiels des mesures d’atténuation sur le changement climatique afin de réduire les émissions de gaz à effet de serre.

Une fois le plan de gestion adaptative établi, il peut être intégré au programme de surveillance et de rapport de routine de l’installation.

8.2 Orientation concernant la gestion adaptative

Les demandeurs et les titulaires de permis sont encouragés à préparer des plans de gestion adaptative. Le personnel de la CCSN peut fournir des conseils propres à l’installation ou à l’activité en cause pour aider les demandeurs et les titulaires de permis.

8.2.1 Composantes d’un plan de gestion adaptative

Un plan de gestion adaptative devrait comprendre les éléments suivants :

- un plan provisoire de prévention de la pollution (PPPP)
- une évaluation des MTEAR afin de trouver et de mettre en œuvre une solution de traitement à long terme
- les échéanciers prévus pour la mise en œuvre du plan de gestion adaptative

8.2.2 Composantes d’un plan provisoire de prévention de la pollution

Le PPPP est axé sur les mesures d’atténuation à court terme, pendant que l’on procède à l’évaluation des solutions à long terme (en d’autres mots, il s’agit d’atténuer tout risque à court terme, jusqu’à ce que l’on mette en œuvre une solution de traitement viable à long terme). Le titulaire de permis devrait envisager le plein éventail des options de traitement qui ont été déterminées par l’évaluation des MTEAR.

Le PPPP devrait comprendre :

- une évaluation de tout processus en amont qui pourrait avoir un effet sur la concentration de chaque contaminant entrant dans le système de traitement
- une description de la technologie et des techniques qui ont été mises en œuvre afin de réduire les concentrations et les charges de contaminants dans l’environnement
- une description de toute technologie et technique qui a été évaluée, mais non encore mise en œuvre, avec un échéancier indiquant les dates prévues de mise en œuvre
- la technologie et les techniques qui seront évaluées afin d’assurer l’amélioration continue des mesures de contrôle des rejets dans l’environnement pendant la période d’évaluation des MTEAR
- toute modification, y compris toute étude de terrain spéciale, portant sur :
  - les programmes de surveillance des effluents ou des émissions
  - les programmes de surveillance de l’environnement

Au cours de la période provisoire, les mises à jour du PPPP devraient déterminer ce qui suit :

- les techniques actuelles d’amélioration continue qui sont appliquées

- les nouvelles techniques d’amélioration continue qui sont évaluées afin de réduire les niveaux de contaminants et les facteurs de stress physique dans l’environnement

Les mises à jour du PPPP pourraient être présentées sous forme de rapport autonome, ou dans le cadre d’un rapport de conformité périodique.

Appendix A: Rôle des niveaux de libération dans l’approche graduelle de l’application du cadre de protection de l’environnement

Les renseignements contenus dans la présente annexe doivent être consultés, comme indiqué dans les sections applicables du présent REGDOC. Les renseignements contenus dans la présente annexe s’appliquent aux installations nucléaires de catégorie I ou aux mines et usines de concentration d’uranium lorsqu’il s’agit d’évaluer si un contaminant radiologique doit être contrôlé au titre de la section 4.3 et de l’annexe B du présent REGDOC. En outre, les informations contenues dans cette annexe s’appliquent à toutes les autres installations nucléaires.

Les termes et les acronymes suivants sont fournis afin d’aider à comprendre les différents types de niveaux de libération.

- Quantité d’exemption : Comme il est précisé dans le *Règlement sur les substances nucléaires et les appareils à rayonnement*
- Niveaux de libération (NL)
  - Niveaux de libération inconditionnelle : Comme il est précisé dans le *Règlement sur les substances nucléaires et les appareils à rayonnement*
  - Niveaux de libération conditionnelle
    - niveaux de libération conditionnelle génériques : Comme il est précisé dans le tableau A.1 de la présente annexe
    - niveaux de libération conditionnelle propres à l’installation : Établis par la CCSN pour une installation ou une activité particulière

La présente annexe contient des renseignements sur l’application des niveaux de libération inconditionnelle et conditionnelle (libération conditionnelle générique et libération conditionnelle propre à la pratique), en ce qui concerne la nécessité de réaliser des évaluations des risques environnementaux propres au site et d’obtenir des autorisations de rejets opérationnels dans l’environnement. Comme il est décrit à la section 2, les titulaires de permis dont les rejets opérationnels courants de radionucléides respectent les niveaux de libération inconditionnelle ou les niveaux de libération conditionnelle propres aux radionucléides et aux conditions associées indiquées dans la présente annexe pourraient ne pas être tenus d’établir une évaluation des risques environnementaux propres au site ou des limites de rejet autorisées propres au site.

Afin de clarifier cette question et de faire en sorte que les avantages sociaux découlant de ces activités ne soient pas oblitérés par des exigences réglementaires excessives par rapport au risque radiologique connexe, la CCSN a élaboré un cadre décisionnel pour la protection de l’environnement décrit dans le REGDOC-2.9.1.

Exigences de protection de l’environnement pour les activités autorisées limitées à l’utilisation de sources scellées

Pour ce qui est des rejets de substances nucléaires dans l’environnement, les points suivants s’appliquent aux activités autorisées limitées à l’utilisation de sources scellées :

- il n’y a PAS d’interactions régulières avec l’environnement, ni de rejets dans celui-ci
- les épreuves d’étanchéité des sources scellées, conformément au Règlement sur les substances nucléaires et les appareils à rayonnement (RSNAR) et au Règlement sur les installations nucléaires et l’équipement réglementé de catégorie II, tiennent compte adéquatement du bris potentiel de

l’encapsulage des sources scellées, y compris les exigences réglementaires concernant les essais périodiques, les mesures d’atténuation et les rapports
- le *Règlement sur l’emballage et le transport des substances nucléaires (2015)* tient compte adéquatement des incidents dans le transport des sources scellées ou des matières radioactives non scellées qui pourraient être rejetées dans l’environnement

Compte tenu de ces caractéristiques, on tire les conclusions suivantes concernant les exigences de protection de l’environnement pour ces titulaires de permis :

- comme il n’y a pas d’interaction régulière avec l’environnement, et que les fuites et accidents sont couverts par la réglementation, il n’est pas nécessaire de réaliser une ERE propre au site

- comme il n’y a pas de rejets prévus, il n’est pas nécessaire d’établir des autorisations de rejets

Exigences de protection de l’environnement pour les titulaires de permis concernant l’utilisation de quantités limitées de substances nucléaires non scellées

Les critères suivants s’appliquent à l’évacuation ou aux rejets associés à l’utilisation de sources non scellées :

- les quantités d’exemption normalisées et les niveaux de libération inconditionnelle indiqués aux annexes 1 et 2, respectivement, du RSNAR
- les niveaux de libération conditionnelle génériques, documentés dans le tableau A.1, sous réserve que les rejets ne se fassent que par la voie indiquée (c.-à-d., les solides dans les décharges municipales, les gaz dans l’atmosphère, les liquides dans les réseaux d’égout municipaux)
- les niveaux de libération conditionnelle propres à la pratique, qui sont des niveaux de libération conditionnelle qui s’appliquent uniquement à une pratique ou une activité définie et qui ont été élaborés par la CCSN pour être appliqués à plusieurs titulaires de permis réalisant la pratique ou activité en question

Comme les activités ou les concentrations associées aux critères ci-dessus ont été établies à partir de modèles prudents d’évaluation du risque d’exposition du public (d’après les critères de dose associés au risque *de minimis* de ~ 10 µSv/an), il n’est pas nécessaire de procéder à une évaluation approfondie des risques propres à l’installation ou à l’activité. En d’autres mots, les calculs de dose associés à leur établissement servent d’ERE radiologique générique applicable à l’installation ou à l’activité (voir la sous-section A.1).

Les critères portant sur les sources non scellées servent également à déterminer si une autorisation de rejet ou d’élimination est requise, à éclairer la nature ou la complexité de l’autorisation et à soutenir la détermination des activités de vérification de la conformité connexes.

À la lumière de ces critères, lorsqu’un demandeur ou un titulaire de permis peut démontrer (c.-à-d., à l’étape de la demande de permis) que les rejets ne dépasseront pas les critères suivants :

- Critères i) : les quantités d’exemption normalisées et les niveaux de libération inconditionnelle déterminés dans le RSNAR, alors :
  - nul besoin d’autoriser un rejet dans une condition de permis ou dans le permis
  - nul besoin de surveiller ou de consigner les rejets au-delà de ce qui est requis par les exigences de tenue de dossiers des substances nucléaires indiquées dans le RSNAR
  - la CCSN pourrait demander d’être avisée de toute modification dans la pratique ou l’activité pouvant donner lieu à des rejets supérieurs aux quantités d’exemption indiquées ou aux niveaux de libération inconditionnelle.

- Critères ii) : les niveaux de libération conditionnelle génériques (voir le tableau A.1), alors :
  - une condition de permis est appliquée, utilisant les niveaux de libération conditionnelle génériques comme limite de rejet autorisée, sous réserve d'observer les voies de rejet indiquées (c.-à-d. dans l'atmosphère, les égouts municipaux, les flux de déchets solides municipaux)
  - la méthode de vérification de la conformité est déterminée par des spécialistes de l'autorisation utilisant une approche progressive et fondée sur le risque, appropriée pour l'installation ou l'activité. Les mécanismes potentiels comprennent :
    - un examen des dossiers de rejet ou d'évacuation lors d'une inspection
    - une confirmation simple, p. ex., par l'intermédiaire des rapports annuels de conformité indiquant que la quantité totale acquise/utilisée au cours d'une année est inférieure aux niveaux de libération conditionnelle générique correspondants
- Critère iii) : les niveaux de libération conditionnelle propres à la pratique et applicables à l'installation ou l'activité, alors :
  - une condition de permis est appliquée pour limiter les principaux paramètres de rejet aux niveaux et selon les conditions incorporées dans les calculs de dose au public utilisés pour établir les niveaux de libération conditionnelle propres à la pratique
  - un programme de surveillance devrait être requis, comprenant un rapport annuel sur les rejets et tout paramètre connexe (p. ex., les débits)

Remarque : La sous-section A.1 présente des éclaircissements concernant l'application des niveaux de libération conditionnelle lorsque les rejets contiennent plus d'un radionucléide.

Lorsqu'un demandeur ou un titulaire de permis manipule ou produit des activités suffisamment élevées de substances nucléaires non scellées dans des circonstances où des rejets possibles pourraient dépasser les critères ci-dessus (i à iii), des mesures de protection de l'environnement sont alors requises conformément aux REGDOC 2.9.1 et 2.9.2. De telles mesures de protection pourraient notamment comprendre une ERE propre au site, des limites de rejet radiologique, ainsi que des exigences en matière de surveillance et de rapports.

Remarque : Les niveaux présentés dans le tableau A.1 sont des niveaux préliminaires en dessous desquels aucune autorisation propre au site n'est requise. Les rejets ou l'évacuation en quantités supérieures à ces niveaux pourraient être acceptables, mais nécessitent une autorisation et des renseignements justificatifs additionnels propres au site et la prise en compte de la plage des mesures de protection de l'environnement documentées dans le REGDOC-2.9.1.

A.1 Base de calcul des niveaux de libération conditionnelle génériques

Afin d'assurer une application uniforme des exigences de protection de l'environnement pour ce qui est des rejets à risque extrêmement faible, la CCSN a établi des niveaux de libération conditionnelle (niveaux de libération conditionnelle) génériques. Ces niveaux ont été établis afin de déterminer les rejets présentant une exposition très faible et des risques connexes pour le public et l'environnement qui n'obligeraient pas le titulaire de permis à détenir une autorisation pour évacuer ou rejeter les matières par la voie indiquée.

Ces niveaux de libération conditionnelle ont été élaborés selon l'optique suivante :

- ils sont aussi simples que possible, mais aussi complexes que nécessaire
- ils respectent les pratiques nationales et internationales actuelles concernant l'élimination et les rejets de matières radioactives, y compris les exigences à ce sujet figurant dans le document de l'Agence

internationale de l’énergie atomique, *Prescriptions générales de sûreté, Partie 3 : Radioprotection et sûreté des sources de rayonnements : Normes fondamentales internationales de sûreté* [17]
- ils tiennent compte des méthodes actuellement disponibles et de l’expérience internationale concernant l’évacuation et le rejet des matières radioactives par les utilisateurs dans les hôpitaux, les universités, etc., conformément au document AIEA-TECDOC-1000, *Clearance of materials resulting from the use of radionuclides in medicine, industry and research* [18]
- ils tiennent compte de l’exposition probable des personnes et de l’environnement
- ils sont basés sur des scénarios d’exposition et des modèles prudents, mais raisonnablement plausibles, applicables aux conditions canadiennes
- ils constituent des documents officiels et au besoin ils améliorent les pratiques réglementaires actuelles

L’évacuation ou les rejets en quantités supérieures aux niveaux de libération conditionnelle requièrent des approbations réglementaires particulières.

Principaux concepts internationaux de radioprotection associés au calcul des niveaux de libération conditionnelle

Le cadre de radioprotection de l’AIEA et celui de la *Loi sur la sûreté et la réglementation nucléaires* s’appuient sur une structure hiérarchique incorporant les concepts d’exclusion, d’exemption, de libération (inconditionnelle ou conditionnelle) et d’autorisation de rejets (c.-à-d. rejet dans la terminologie des règlements pris en vertu de la LSRN) qui relèvent du domaine de la radioprotection.

On peut résumer comme suit les divers concepts de l’AIEA. L’exclusion désigne les sources et les situations d’exposition qu’il est impossible de contrôler. Par conséquent, ces situations sont complètement à l’extérieur du cadre législatif et ne nécessitent aucune considération légale (p. ex., l’exposition au rayonnement naturel de fond, au rayonnement cosmique, au potassium 40 présent dans les aliments, au rayonnement terrestre), comme il est indiqué à l’article 10 du *Règlement général sur la sûreté et la réglementation nucléaires* (RGSRN). Les exemptions visent les sources et les situations d’exposition où un contrôle est possible, mais n’est pas jugé nécessaire ou justifié et une décision doit être prise *a priori* pour exempter ces situations du contrôle réglementaire (p. ex., article 10 du RGSRN, paragraphe 5(1) du RSNAR). La libération peut être considérée comme une « exemption interne », c’est-à-dire qu’il s’agit d’une permission accordée pour que la matière découlant d’une activité prescrite puisse sortir du régime réglementaire sans nécessiter une exigence réglementaire ou une supervision additionnelle (paragraphe 5.1 du RSNAR).

L’autorisation de rejet est un concept distinct, mais connexe, qui permet un rejet dans l’environnement d’une substance tout en continuant d’assurer un contrôle et une surveillance réglementaires du rejet par le maintien d’exigences réglementaires additionnelles, p. ex., la réévaluation périodique de la pertinence des mesures de contrôle, la surveillance des rejets et, le cas échéant, la surveillance de l’environnement récepteur. Une autorisation de rejet n’est pas nécessaire pour les rejets répondant aux niveaux de libération inconditionnelle. À l’inverse, les niveaux de libération « conditionnelle » requièrent, par leur définition même, un ensemble défini de « conditions » qui limitent les rejets, dont le contrôle des voies de rejet, de sorte que le fondement des niveaux de libération conditionnelle demeure valide. Cela implique à son tour qu’une certaine forme d’« autorisation de rejet » est généralement requise, et les exigences nécessaires peuvent être incorporées selon une approche progressive, comme une condition du permis.

Le document TECDOC-1000 de l’AIEA présente :

- « …. une orientation sur les considérations réglementaires pour l’octroi de libérations et sur la nature et la portée des calculs de dose de rayonnement qui doivent être réalisés pour établir les niveaux de libération »
- « … des niveaux génériques de libération calculés selon une approche prudente… » [traduction]

Ces niveaux de libération conditionnelle génériques sont décrits comme étant des valeurs propres aux radio-isotopes, « exprimées en termes de taux de rejet de radionucléides dans l’environnement ou de concentrations d’activité dans les matières solides, en deçà desquels aucun contrôle réglementaire additionnel n’est requis ». Ces niveaux de libération conditionnelle sont des niveaux propres aux voies de rejet spécifiées, nommément les solides vers les décharges municipales, les déchets gazeux vers l’atmosphère et les déchets liquides solubles dans l’eau vers les réseaux d’égout.

Les niveaux de libération conditionnelle de la CCSN présentés dans le présent document ont été calculés selon la même méthode de base que le document TECDOC-1000 de l’AIEA, dont les principaux éléments sont présentés ci-dessous.

Critère de dose pour le calcul des niveaux de libération conditionnelle génériques

Les niveaux de libération conditionnelle ont la valeur suivante :

- 10 µSv/an pour un membre du public, soit la dose *de minimis* de l’AIEA
- 10 µGy/h pour le biote non humain

Pour un membre du public, c’est la même dose au public utilisée ailleurs dans le monde pour l’élaboration des quantités d’exemption et des niveaux de libération dans le document GSR Partie 3 de l’AIEA et adoptée dans la LSRN pour le *Règlement sur les substances nucléaires et les appareils à rayonnement* sous forme de quantités d’exemption et de niveaux de libération inconditionnelle, respectivement.

Pour ce qui est du débit de dose pour l’environnement et le biote non humain, soit 10 µGy/h, cette valeur a été adoptée comme étant représentative du niveau sans effet en dessous duquel les risques environnementaux seraient négligeables (Andersson et al. 2009). C’est le débit de dose utilisé par l’outil d’évaluation ERICA (Brown et al. 2008, 2016) pour calculer les critères préliminaires propres aux milieux, basés sur l’organisme limitant (c.-à-d. l’organisme le plus sensible). Ce débit de dose est le plus faible recommandé internationalement (c.-à-d. < que les valeurs de la CIPR, de l’AIEA, de l’UNSCEAR et du Département américain de l’Énergie), et est donc jugé comme étant une valeur de substitution préliminaire appropriée représentant l’exposition *de minimis* pour le biote non humain.

Scénarios d’exposition

Une fois les radionucléides rejetés, leur décroissance radioactive pendant le transport entre le point de rejet et le point d’exposition a été prise en compte. Pour ce qui est de l’activité rejetée dans l’atmosphère, l’accumulation et la décroissance de l’activité déposée sur le sol ont été calculées sur une période d’exploitation de 30 ans de l’installation. Le dépôt sur les cultures vivrières et fourragères, ainsi que le transfert vers le lait et la viande a été calculé selon le document de la Collection Sûreté n^{o} 19 de l’AIEA, *Generic Models for Use in Assessing the Impact of Discharges of Radioactive Substances to the Environment* [19]. Le transfert vers les cultures se produit seulement pendant les saisons de croissance, que l’on a présumées être de 30 jours par année pour le fourrage et de 60 jours par année pour les cultures vivrières. La décroissance entre le moment de la récolte et la consommation a été établie en supposant un temps de rétention de 14 jours pour les cultures vivrières, de 90 jours pour les aliments pour animaux entreposés et de 0 jour pour le fourrage. Le temps de décroissance entre la collecte du lait frais et sa consommation est de 1 jour, et pour la consommation de la viande, de 20 jours. Ces temps de décroissance sont conformes à ceux recommandés dans le document de la série de sûreté n^{o} 19 de l’AIEA [19].

Deux grandes catégories d’exposition ont été prises en compte :

- l’exposition externe due aux radionucléides présents dans l’air ou dans les matières incorporées dans les sols ou les sédiments, par exemple
- l’exposition interne par inhalation ou ingestion de radionucléides présents dans l’air ou incorporés dans l’eau ou les aliments, respectivement

L’importance relative des différentes voies d’exposition dépendait, dans les calculs, des points suivants :

- l’ampleur du rejet
- la voie de rejet
- les caractéristiques physiques et chimiques des radionucléides rejetés
- les caractéristiques de la décroissance radioactive

Évacuation dans les décharges municipales

Comme il est recommandé dans le TECDOC-1000, la CCSN a choisi d’adopter les niveaux d’exemption et de libération inconditionnelle dans le RSNAR comme niveaux de libération conditionnelle pour les rejets dans les décharges municipales. Ces valeurs sont basées sur les expositions les plus restrictives associées à des scénarios tels que l’exposition du public par altération de la source radioactive et par inhalation, ingestion et exposition cutanée.

Rejets dans l’atmosphère

Les limites autorisées de rejet de radionucléides dans l’atmosphère supposent que les rejets proviennent d’un évent situé sur le côté d’un bâtiment. On suppose également que le récepteur se trouve dans un bâtiment à 20 m de la source. En outre, on présume que le récepteur consomme tous les légumes et autres cultures à 100 m de la source des rejets atmosphériques, et que la viande et le lait consommés se trouvent à 800 m de la source des rejets. Les limites de rejet autorisées tiennent compte des voies d’exposition suivantes :

- inhalation de radionucléides rejetés dans l’air
- dose externe due aux nuages (immersion)
- dose externe due aux matières déposées sur le sol
- ingestion de radionucléides dans les aliments

Rejets dans les égouts

Pour ce qui est des rejets dans les réseaux d’égouts municipaux, les limites de rejet autorisées sont basées sur deux groupes principaux de voies : celles qui résultent de la rétention des radionucléides dans les boues d’épuration aux usines de traitement des eaux usées (UTEU) et celles qui résultent du rejet des effluents de l’UTEU dans un cours d’eau.

Dans le cas des boues d’épuration, on suppose que tous les radionucléides sont retenus dans les boues à l’UTEU. La concentration dans les boues est calculée selon l’hypothèse que la station d’épuration dessert une population de 20 000 personnes. Il s’agit d’une hypothèse prudente, car les grandes UTEU permettraient une plus grande dilution avec des déchets non contaminés par des radionucléides. On inclut deux voies d'exposition pour les travailleurs des UTEU :

- exposition externe aux boues
- inhalation d'une activité remise en suspension

Pour ce qui est des voies d'exposition liées aux rejets dans un cours d'eau, on suppose par prudence que tous les radionucléides reçus à l'UTEU sont éventuellement rejetés dans un cours d'eau sans qu'aucun radionucléide ne soit retenu dans les boues. Les voies suivantes sont incluses dans ce groupe :

- ingestion de radionucléides par l'eau potable
- ingestion de radionucléides par les poissons
- dose externe due aux radionucléides dans les sédiments

Les limites de rejet autorisées sont calculées séparément pour les deux groupes de voies, à savoir celles qui sont dues à la rétention des radionucléides dans les boues d'épuration et celles qui résultent du rejet des effluents de la UTEU dans un cours d'eau. Les limites sont calculées de manière que la dose annuelle efficace reçue par le récepteur soit de 10 µSv pour chacun des deux groupes de voies. La plus faible des deux limites ainsi calculées a été arrondie au multiple de 10 le plus proche et choisie comme niveaux de libération conditionnelle pour les rejets dans les égouts.

Le tableau A.1 présente les concentrations de radionucléides résultantes à l'entrée de l'UTEU. Ces valeurs ont été calculées pour une UTEU de référence desservant une population de 20 000 habitants, conformément au document TECDOC-1000 de l'AIEA. Le débit des influents (en m^3/an) pour cette UTEU de référence a été estimé en tenant compte des débits d'influents pour la période 2016 à 2018 pour trois UTEU à Toronto et cinq UTEU à Vancouver. Le débit d'effluents moyen annuel « par habitant » était d'environ 130 m^3/an, soit l'équivalent de 2,6 millions m^3/an pour une population de 20 000 personnes. La valeur dans la colonne 4 du tableau A.1 a été divisée par 2,6 millions m^3/an pour obtenir les concentrations résultantes.

Rejets contenant plus d'un radio-isotope

Lorsque plus d'un radionucléide est rejeté par une voie donnée (c.-à-d. les rejets dans les décharges municipales, les rejets dans l'atmosphère ou les rejets dans les réseaux d'égouts municipaux), la condition suivante s'applique :

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

Dans l'expression suivante :

- $Q_{i,k}$ représente l'activité ou les concentrations d'activité applicables, du radionucléide *i* qui est rejeté par la voie *k* au cours d'une année civile
- $NLC_{i,k}$ représente le niveau de libération conditionnelle correspondant pour le radionucléide *i* et la voie de rejet *k*, figurant dans le tableau A.1
- *n* est le nombre de radionucléides rejetés par la voie *k* au cours d'une année civile

Tableau A.1 : Niveaux de libération conditionnelle génériques pour les rejets de solides, de liquides et de gaz dans l’environnement, d’après une modélisation prudente de dose équivalant à une dose *de minimis* de 10 µSv/an (5 – 20 µSv/an)

Colonne 1	Colonne 2	Colonne 3	Colonne 4
Radionucléide	**Décharges municipales (Bq/g) Remarque 1 :**	**Activité annuelle rejetée dans l’atmosphère (MBq) Remarque 2 :**	**Activité annuelle rejetée dans les égouts municipaux (MBq) Remarque : 2, 3**
^{3}H	1 000 000	100 000	1 000 000
^{11}C	10	100 000	-
^{14}C	10 000	10 000	10 000
^{18}F	10	10 000	0,1
^{22}Na	10	1	0,1
^{24}Na	10	1 000	100
^{32}P	1 000	100	1
^{33}P	100 000	1 000	10
^{35}S	100 000	100	1 000
^{36}Cl	10 000	10	10 000
^{37}Ar	-	1,00 E+11	-
^{42}K	100	10 000	1 000
^{45}Ca	10 000	1 000	10 000
^{47}Ca	10	1 000	100
^{46}Sc	10	-	0,1
^{51}Cr	1 000	1 000	100
^{54}Mn	10	-	1
^{56}Mn	10	-	0,1
^{55}Fe	10 000	-	10 000
^{59}Fe	10	100	1
^{57}Co	100	1 000	1 000
^{58}Co	10	1 000	100
^{60}Co	10	1	0,1
^{63}Ni	100 000	-	10 000
^{64}Cu	100	-	1
^{65}Zn	10	10	1

Colonne 1	Colonne 2	Colonne 3	Colonne 4
Radionucléide	**Décharges municipales (Bq/g) Remarque 1 :**	**Activité annuelle rejetée dans l’atmosphère (MBq) Remarque 2 :**	**Activité annuelle rejetée dans les égouts municipaux (MBq) Remarque : 2, 3**
^{67}Ga	100	10 000	100
^{68+}Ge	10	-	0,1
^{75}Se	100	100	1
^{82}Br	10	-	0,1
^{83}Rb	100	1 000	1
^{86}Rb	100	-	10
^{82+}Sr	10	100	0,1
^{85}Sr	100	100	1
^{89}Sr	1 000	100	1 000
^{90+}Sr	100	1	1
^{88}Y	10	10	0,1
^{90}Y	1 000	10 000	10 000
^{99}Mo	100	1 000	100
^{99}Tc	10 000	10	10 000
^{99m}Tc	100	100 000	1 000
^{103}Pd	1 000	-	10
^{110m}Ag	10	-	0,1
^{109}Cd	10 000	100	10
^{111}In	100	1 000	100
^{124}Sb	10	-	0,1
^{125}Sb	100	100	1
^{123}I	100	10 000	1 000
^{124}I	10	100	10
^{125}I	1 000	100	100
^{131}I	100	100	10
^{127}Xe	-	100 000	-
^{133}Xe	-	1 000 000	-
^{125}Cs	10	-	100 000
^{134}Cs	10	-	0,1

Colonne 1	Colonne 2	Colonne 3	Colonne 4
Radionucléide	**Décharges municipales (Bq/g) Remarque 1 :**	**Activité annuelle rejetée dans l'atmosphère (MBq) Remarque 2 :**	**Activité annuelle rejetée dans les égouts municipaux (MBq) Remarque : 2, 3**
^{137}Cs	10	-	1
^{133}Ba	100	-	1
^{140}La	10	-	0,1
^{139}Ce	100	100	1
^{141}Ce	100	-	10
^{143}Ce	100	-	1
^{147}Nd	100	-	1
^{147}Pm	10 000	10 000	10 000
^{153}Sm	100	-	10
^{152}Eu	10	1	1
^{154}Eu	10	1	1
^{153}Gd	100	-	10
^{169}Er	10 000	10 000	10 000
^{170}Tm	1 000	1 000	100
^{169}Yb	100	100	1
^{177}Lu	1 000	1 000	10
^{177m}Lu	10	-	0,1
^{186}Re	1 000	1 000	10
^{192}Ir	10	-	1
^{198}Au	100	1 000	100
^{194}Hg	10	-	10
^{197}Hg	100	10 000	1 000
^{203}Hg	100	100	10
^{201}Tl	100	10 000	100
^{204}Tl	10 000	-	100
^{210+}Pb	10	-	1
^{210}Bi	1 000	-	10
^{208}Po	10	-	10
^{209}Po	10	-	10

Colonne 1	**Colonne 2**	**Colonne 3**	**Colonne 4**
Radionucléide	**Décharges municipales (Bq/g) Remarque 1 :**	**Activité annuelle rejetée dans l’atmosphère (MBq) Remarque 2 :**	**Activité annuelle rejetée dans les égouts municipaux (MBq) Remarque : 2, 3**
^{210}Po	10	-	10
^{223+}Ra	100	-	1
^{224+}Ra	10	-	0,1
^{226}Ra	10	1	1
^{228+}Ra	10	0,1	0,1
^{227+}Ac	0,1	-	1
^{230}Th	1	-	100
^{228}Th	1	-	100
^{228+}Th	1	0,1	0,1
^{229}Th	1	-	1
^{232}Th	1	0,1	1
^{232+}U	1	-	0,1
^{233}U	10	1	
^{235}U	10	1	
^{234}U	10	1	
^{238}U	10	1	
^{237}Np	1	-	10
^{238}Pu	1	0,01	1
^{239}Pu	1	-	1
^{240}Pu	1	-	1
^{241}Am	1	0,1	10
^{243+}Am	1	-	1
^{244+}Cm	10	0,1	0,1

Remarques :

1. Les conditions de permis normalisées comprennent une limite de 3 tonnes par bâtiment et par année, et l’obligation de démontrer l’uniformité de la distribution du radionucléide.

2. Les niveaux de libération conditionnelle s’appliquent à un site qui peut comprendre plusieurs bâtiments. Par exemple, un hôpital ou une université peut être considéré comme un site où il peut y avoir plusieurs points de rejet dans un réseau d’égouts ou dans l’atmosphère.

3. Les niveaux de libération conditionnelle pour les rejets dans les égouts ne s’appliquent qu’aux liquides solubles dans l’eau.

Appendix B: Imformation additionnelle

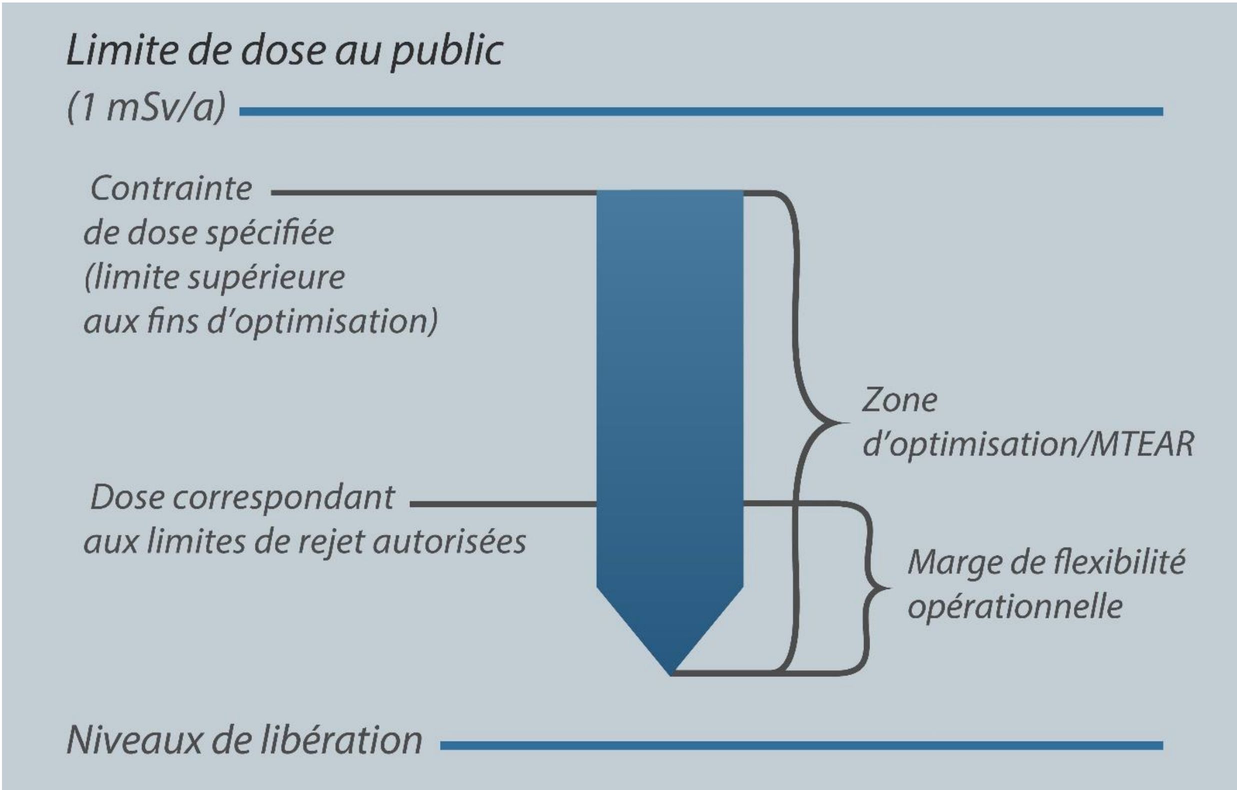
B.1 Principes de radioprotection et MTEAR

Optimisation et rejets autorisés dans l’environnement (limites de rejet autorisées)

En pratique, l’optimisation est une MTEAR en ce qui concerne la minimisation de la pollution par les contaminants et le contrôle des rejets dans l’environnement, en plus de veiller à ce que tout compromis associé à la dose aux travailleurs et à la dose au public soit équilibré (en d’autres mots, la limite de rejet pour une petite réduction de la dose au public ne se fait pas au détriment d’une forte augmentation de la dose reçue par les travailleurs). La dose associée au rejet optimisé final est simplement un artefact de l’optimisation. Ce n’est pas l’objectif de l’optimisation (les contraintes de dose sont parfois interprétées de manière inappropriée comme étant des limites de dose propres au site ou des objectifs pour établir des limites de rejet autorisées propres au site, plutôt que comme outils pour guider l’optimisation). L’optimisation de la protection peut être considérée comme un complément au concept de prévention de la pollution (un principe fondamental des mesures de protection de l’environnement décrites dans le REGDOC -2.9.1 [1]).

La figure B1 montre une relation générale entre l’optimisation et l’autorisation des rejets radioactifs dans l’environnement (c’est-à-dire les limites de rejet autorisées). L’optimisation (démontrée par l’application des MTEAR) permet d’établir des limites de rejet autorisées pour les substances nucléaires et dangereuses. En outre, l’optimisation exige l’application des MTEAR pour contrôler les rejets de telle sorte qu’elles représentent une dose au public propre au site, ou des doses limitées à une région inférieure à la limite de dose au public (contrainte de dose spécifiée), mais supérieure aux doses jugées *de minimis*. Sur le plan international, des doses efficaces d’environ 10 microsieverts (µSv) par an ont été utilisées pour calculer les niveaux de libération (inconditionnelle ou conditionnelle) représentant l’activité des radionucléides (activité totale ou concentrations) qui peut être libérée de tout contrôle réglementaire supplémentaire.

Figure B.1 : Relation entre l’optimisation et l’autorisation des rejets dans l’environnement [1]



Lorsqu’on applique le concept d’optimisation afin d’établir les limites de rejet autorisées, des doses modélisées d’environ 10 µSv/an sont recommandées comme niveau sous lequel une optimisation supplémentaire et l’application des MTEAR ne sont plus nécessaires. Cependant, il est nécessaire de faire une distinction entre, d’une part, ce critère de dose (c.-à-d. 10 µSv/an) appliqué à une évaluation de dose propre au site associée à une demande de permis et, d’autre part, son utilisation dans l’élaboration des niveaux d’exemption et de libération. Dans le premier cas, on a tendance à intégrer des scénarios de transport et d’exposition propres au site qui sont relativement réalistes (mais néanmoins prudents). Dans le deuxième cas, on est délibérément hyperprudents afin de garantir que l’exemption de l’obtention d’un permis ou de l’autorisation de rejets puisse être accordée en toute sécurité, dans un large éventail de scénarios englobant toute une plage de variables potentielles propres au site. Les rejets autorisés restent sous contrôle réglementaire (y compris la réévaluation périodique, les exigences de surveillance et les calculs annuels de la dose au public), tandis que les exemptions d’obtention de permis ou d’autorisation n’entraînent aucun autre contrôle réglementaire après le rejet (c.-à-d. qu’il n’y a pas d’exigence de permis pour la réception des matières et pas de surveillance environnementale), d’où la nécessité d’une grande prudence.

Ainsi, les titulaires de permis (autres que pour les installations de catégorie I et les mines et usines de concentration d’uranium dont les rejets opérationnels courants de radionucléides satisfont aux valeurs de libération conditionnelle propres aux radionucléides et aux conditions associées indiquées à l’annexe A)

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[1] Figure adaptée du guide de sûreté sur la radioprotection n° GSG 9 de l’AIEA, *Regulatory Control of Radioactive Discharges to the Environment*, Vienne, Autriche, 2018.

peuvent ne pas nécessiter d’autorisation réglementaire supplémentaire pour leurs rejets. Pour en savoir davantage, voir l’annexe A.

La conception approuvée de l’installation ou de l’activité aura démontré à la satisfaction de la CCSN que les MTEAR ont été appliqués en ce qui concerne la minimisation de la production de déchets et le contrôle des rejets. Les rejets maximaux associés à la conception optimisée approuvée (qui inclut l’ajout d’une marge de flexibilité opérationnelle) deviennent les limites de rejet autorisées (pour de plus amples renseignements, voir la section 5). La dose associée à ces rejets peut alors être déterminée par l’application d’un modèle de transport des radionucléides et de voies d’exposition qui est propre au site. Cette dose au public calculée peut être utilisée à des fins de communication sur les risques pour le public, et on peut indiquer que les rejets ont été limités à des niveaux représentant des expositions inférieures à la limite de dose réglementaire pour le public.

Comme la limite de rejet autorisée est basée sur le rejet maximal prévu (avec une marge de flexibilité opérationnelle), tout dépassement de cette limite représente un rejet à l’extérieur du fondement d’autorisation et démontre une non-conformité à l’égard du permis, ce qui indique donc un défaut de conception ou d’exploitation de l’installation ou de l’activité. Le titulaire de permis serait donc jugé non conforme en vertu de l’alinéa 12(1)f) du *Règlement général sur la sûreté et la réglementation nucléaires*. Cependant, comme la limite de rejet autorisée est basée sur la conception optimisée représentant une dose au public inférieure à 1 mSv/an, le dépassement ne représenterait pas nécessairement un dépassement de la limite de dose au public selon le *Règlement sur la radioprotection* et n’est en aucun cas destiné à remplacer cette limite de dose au public. Pour en savoir davantage, voir la section 5.

L’optimisation de la protection contre les rejets radioactifs ne consiste pas simplement à évaluer les risques radiologiques associés aux rejets en mode d’exploitation normale par rapport aux coûts des éventuelles réductions. On doit également tenir compte de l’effet des décisions en matière de gestion des déchets sur l’exposition des travailleurs et sur la sûreté de l’installation ou de l’activité dans son ensemble. Par exemple, une réduction des rejets peut entraîner une augmentation des déchets radioactifs entreposés sur le site, avec une augmentation concomitante de l’exposition professionnelle. Une telle réduction pourrait donc ne pas être la solution optimale.

Optimisation et contraintes de dose

Les contraintes de dose au public sont des estimations de la dose au public, inférieures à la limite réglementaire de dose au public, qui sont établies ou approuvées par la CCSN pour être utilisées dans le processus d’optimisation. La contrainte de dose pour chaque source particulière vise à garantir que la somme des doses dues aux activités prévues avec cette source et toutes les sources autorisées pouvant contribuer à l’exposition du public reste en deçà de la limite de dose (voir la figure 1).

Les contraintes de dose peuvent être génériques (c’est-à-dire applicables à un sous-secteur donné du cycle du combustible nucléaire) ou propres à une installation ou une activité réglementée. La CCSN peut spécifier une contrainte de dose générique pour un sous-secteur, ou approuver une contrainte de dose propre à une installation ou une activité sur la base de la démonstration, par le demandeur ou le titulaire de permis, de l’application des MTEAR en ce qui concerne la conception de l’installation et le contrôle des rejets. Dans les cas où plusieurs titulaires de permis opèrent à proximité les uns des autres (p. ex., dans des parcs d’énergie nucléaire ou de recherche nucléaire), la CCSN spécifiera une contrainte de dose propre à l’installation ou à l’activité comme limite supérieure pour le processus d’optimisation (voir la figure 1). Ce facteur garantit une répartition responsable de la limite de dose de 1 mSv/an pour le public, toutes sources confondues.

Pendant la phase de conception, l’examen de la conception des installations modernes intégrant les MTEAR, qui minimisent à la fois la production de déchets et contrôlent les rejets, sert à établir une plage de quantités et de concentrations nominales maximales de radionucléides qui peuvent être rejetées pendant l’exploitation normale. Pour chaque option de conception, les calculs de la dose au public propre au site, utilisant ces rejets nominaux maximaux, fournissent les doses équivalentes maximales associées aux différentes options de conception. Ces calculs alimentent le processus d’optimisation global qui tient compte des compromis coûts-avantages entre la dose aux travailleurs et celle au public (voir la figure 1). Les quantités et concentrations nominales maximales prévues correspondant à la meilleure option (en ce qui concerne l’optimisation), ainsi qu’une marge d’erreur pour assurer la souplesse opérationnelle, établissent les limites de rejet autorisées. La dose au public correspondant aux limites de rejet autorisées est déterminée par l’application de ces limites au modèle de transport et d’exposition dans l’environnement propre au site (p. ex., N288.1). Ainsi, plutôt que de définir expressément les contraintes de dose, la CCSN examine et approuve la conception de l’installation ou de l’activité et les contrôles des rejets afin de déterminer la pertinence d’appliquer les MTEAR dans le cadre du processus d’optimisation et d’accepter les doses au public ainsi obtenues.

B.2 Objectifs de rejet dans l’environnement, rejet maximal prévu par la conception, limites de rejet autorisées et seuils d’intervention

Le REGDOC 2.9.2 adopte un cadre internationalement reconnu pour le contrôle des rejets dans l'environnement, par l'application du principe de prévention de la pollution et de la MTEAR.

Dans ce cadre, pour les nouvelles installations ou les installations existantes qui subissent une modification majeure et qui nécessitent une évaluation selon la méthode MTEAR, des lignes directrices fondées sur le risque dans l'environnement récepteur (p. ex. contraintes de dose radiologique, lignes directrices sur la qualité de l'environnement du CCME, normes canadiennes de qualité de l'air ambiant) sont utilisées pour établir des objectifs de rejet dans l'environnement, en tenant compte d'un niveau acceptable de dilution dans l'environnement (selon les lignes directrices fédérales/provinciales applicables) afin de s'assurer que l'environnement demeure protégé. Il peut y avoir des cas où des limites technologiques d'autres juridictions applicables à l'installation existent déjà, et dans ces cas, elles devraient être considérées comme des cibles potentielles de rejet dans l'environnement. Dans ce cas, la plus restrictive des cibles basées sur l'exposition ou sur la technologie doit être retenue comme objectif de rejet dans l'environnement dans l'évaluation.

Les objectifs de rejet dans l'environnement sélectionnés sont utilisés comme base pour la conception du système de traitement. Dans le cadre de l'évaluation MTEAR, une analyse des options est effectuée pour identifier la technologie et les techniques les plus appropriées qui ont été démontrées à l'échelle industrielle pour atteindre les objectifs de rejet dans l'environnement. Ainsi, puisque le système de traitement est conçu pour atteindre les objectifs de rejet dans l'environnement, le système de traitement est conçu pour atteindre les objectifs en fonction du risque.

L'option de conception identifiée comme MTEAR peut permettre d'obtenir une qualité d'effluent ou d'émissions nettement meilleure pour certains contaminants dans leurs conditions de conception maximales (c'est-à-dire les concentrations et débits d'influent maximaux prévus). De même, l'option de conception peut être incapable d'atteindre les objectifs de rejet dans l'environnement pour d'autres contaminants, et le demandeur peut être limité par l'état actuel de la technologie et des techniques. Ce rejet résiduel mérite une évaluation des risques propres au site pour s'assurer qu'il n'y a pas de risque déraisonnable pour l'environnement et peut nécessiter une surveillance additionnelle (évaluée lors de l'établissement des limites de rejet proposées).

Le promoteur détermine les quantités et les concentrations maximales prévues des rejets de conception en fonction de l'option de conception MTEAR identifiée, en tenant compte d'une marge de flexibilité opérationnelle. Dans les cas où il existe déjà des limites de rejet fédérales, provinciales, territoriales et/ou municipales applicables, ces limites seront adoptées afin de s'harmoniser avec les autres organismes de réglementation, dans la mesure où elles sont protectrices. S'il n'existe aucune limite ou si la CCSN juge que les limites existantes ne sont pas protectrices (p. ex., sur la base d'une évaluation dans le cadre de l'évaluation des risques écologiques), les rejets maximaux prévus à la conception, qui font maintenant partie de la base d'autorisation de l'installation, sont alors établis comme limites de rejet proposées. Les limites de rejet proposées sont ensuite utilisées dans l'évaluation des risques environnementaux (ERE) pour confirmer que l'environnement sera protégé.

Étant donné que les limites de rejet autorisées représentent les concentrations et les quantités maximales pouvant être rejetées par l'installation dans des conditions normales d'exploitation, le dépassement d'une limite de rejet autorisée indique que le titulaire de l'autorisation fonctionne en dehors du fondement d'autorisation (c'est-à-dire la conception approuvée de l'installation) pour une exploitation normale, et indique une perte de contrôle évidente du programme de protection de l'environnement et/ou des mesures de contrôle. Un rejet en dehors du fondement d'autorisation indique une défaillance majeure des systèmes de contrôle.

Étant donné que les limites de rejet autorisées, qui sont basées sur le rejet maximal prévu à la conception, dépendent de la conception de l'installation, elles ne changent pas au fil du temps, sauf en cas de modification majeure de l'installation et/ou de l'activité nucléaire susceptible d'augmenter ou de modifier la nature des rejets dans l'environnement et les risques qui en résultent pour les récepteurs, qui seraient en dehors du fondement d'autorisation existant.

Il convient de noter qu'il existe une distinction claire entre les seuils d’intervention et les limites de rejet autorisées, comme décrit ci-dessous.

Les seuils d'intervention sont basés sur l'exploitation/les performances et représentent la limite supérieure de la performance opérationnelle actuelle (historique la plus récente), et sont donc censés être atteints périodiquement. Les limites de rejet autorisées, qui sont fondées sur le rejet maximal prévu à la conception, dépendent de la conception de l'installation, qui est elle-même fondée sur les risques.

Les seuils d'intervention sont basés sur l'historique d'exploitation le plus récent (par exemple, 5 ans) de l'installation, et évoluent donc au fil du temps, en augmentant ou en diminuant, en fonction des changements quotidiens de l'exploitation qui se trouvent **dans** le fondement d'autorisation actuelle. Les limites de rejet autorisées ne changent pas dans le temps, comme indiqué ci-dessus.

Le dépassement d'un seuil d'intervention signale une perte potentielle de contrôle (c'est-à-dire un feu jaune) ou une réduction de l'efficacité du programme et/ou des mesures de contrôle, et peut indiquer un écart par rapport au fonctionnement normal. Le dépassement d'une limite de rejet autorisée indique une perte de contrôle évidente (c'est-à-dire un feu rouge), et que l'installation fonctionne en dehors de sa conception approuvée, et donc de son fondement d'autorisation.

Dans cette approche, il y a une marge suffisante entre le déclenchement d'un seuil d'intervention et le déclenchement d'une limite de rejet autorisée. Les seuils d'intervention sont comparés aux résultats du programme de surveillance opérationnelle (c.-à-d. les concentrations des échantillons instantanés ou composites quotidiens ou hebdomadaires) qui correspondent au programme de surveillance des effluents/émissions du titulaire de permis. Les limites de rejet autorisées sont comparées aux résultats de la surveillance périodique moyenne (c.-à-d. les concentrations moyennes mensuelles). Cela permet de dépasser plusieurs seuils d'intervention avant de déclencher une limite de rejet autorisée. Cela donne également au titulaire de permis le temps de réagir à un dépassement du seuil d'intervention et de rétablir l'efficacité du programme avant qu'une perte totale de contrôle ne se produise. Si des semaines se sont écoulées et que le titulaire de permis a déclenché le seuil d'intervention à plusieurs reprises sans réagir, cela peut entraîner un dépassement de la limite de rejet autorisée, ce qui constitue en soi une démonstration de la perte de contrôle du programme de protection de l'environnement.

Appendix C: Établissement des cibles de rejets dans l’environnement

La présente annexe fournit de l’orientation concernant l’établissement des cibles de rejets dans l’environnement.

C.1 Introduction

Les cibles de rejets dans l’environnement s’appliquent pendant les phases de conception et de mise en service. Si ces cibles ne peuvent pas être atteintes, elles sont intégrées en tant que cibles ou objectifs dans le système de gestion de l’environnement (SGE). Les cibles de rejets dans l’environnement ne sont pas des limites de rejet autorisées, mais constituent plutôt des guides pour la conception et l’élaboration des concentrations de rejets nominaux maximaux prévus ou des quantités qui deviennent les limites de rejet autorisées.

Les cibles de rejets dans l’environnement sont utilisées comme critères pour guider la conception des systèmes de traitement des eaux usées ou des systèmes de contrôle de la pollution atmosphérique, afin de limiter la quantité et la concentration des contaminants et des facteurs de stress physique rejetés dans l’environnement Les cibles de rejets dans l’environnement assurent ce qui suit :

- les risques pour la santé humaine et l’environnement sont atténués
- des mesures de contrôle acceptables (y compris des stratégies de réduction) sont établies pour prévenir la pollution (p. ex., afin d’établir un niveau minimal de protection dans un secteur industriel donné)
- l’amélioration continue pour assurer la prévention et le contrôle proactifs de la pollution (p. ex., pour les mesures adoptées dans le SGE comme cibles ou objectifs d’amélioration continue)

À cette fin, des cibles de rejets dans l’environnement sont établies selon l’une des approches suivantes :

- une approche fondée sur l’exposition (pour respecter les recommandations de protection de la qualité de l’environnement à un endroit acceptable dans le milieu récepteur)
- une approche fondée sur la technologie (pour respecter des limites de rejet autorisées fondées sur la technologie ou des critères nominaux existants dans les exigences fédérales, provinciales, territoriales ou municipales, ou tel que recommandé par la CCSN et en consultation avec le demandeur ou le titulaire de permis)
- une combinaison de l’approche basée sur l’exposition et de l’approche fondée sur la technologie

Les cibles de rejets dans l’environnement les plus restrictives devraient être utilisées.

Remarque : Les cibles de rejets dans l’environnement fondées sur la technologie peuvent être équivalentes aux limites de rejet autorisées dans les exigences fédérales, provinciales, territoriales ou municipales existantes (p. ex., le *Règlement sur les effluents des mines de métaux et de diamant*). Dans la mesure où elles sont les plus rigoureuses, elles sous-tendent la conception des systèmes de traitement des eaux usées ou de contrôle de la pollution atmosphérique.

C.2 Aperçu du processus

Le titulaire de permis devrait établir des cibles de rejets dans l’environnement en utilisant un processus systématique et fondé sur des données probantes.

Voici un résumé d’un exemple de processus systématique et fondé sur des données probantes :

1. déterminer les points de rejet de l’effluent final ou de l’émission
2. déterminer les contaminants et les facteurs de stress physique qui nécessitent des cibles de rejets dans l’environnement
3. déterminer, le cas échéant, les exigences fédérales, provinciales, territoriales et municipales, et assurer l’harmonisation avec ces exigences
4. lorsque l’étape 3 ne s’applique pas :
   a. calculer les cibles de rejets dans l’environnement proposées pour chaque contaminant et facteur de stress physique, en utilisant l’une des approches suivantes :
      i. une approche fondée sur l’exposition pour les substances nucléaires
      ii. une approche fondée sur l’exposition pour les substances dangereuses
      iii. une approche fondée sur la technologie pour les substances nucléaires et dangereuses

Remarque : Dans le cas des substances considérées comme étant à la fois nucléaires et dangereuses (p. ex., l’uranium), calculer les cibles de rejets dans l’environnement proposées en utilisant toutes les approches applicables.

   b. sélectionner les cibles de rejets dans l’environnement les plus restrictives établies à l’étape à
5. documenter et justifier le choix des cibles de rejets dans l’environnement proposées

Les sections suivantes décrivent plus en détail chacune de ces étapes.

C.3 Identifier les points de rejet finaux

Le titulaire de permis devrait déterminer tous les points de rejet contrôlés (effluents ou émissions) depuis l’installation ou l’activité vers l’environnement.

C.4 Détermination des contaminants et des facteurs de stress physique qui doivent être contrôlés

Le titulaire de permis devrait procéder à une évaluation préliminaire, comme il est décrit à la section 4.3, afin de déterminer les contaminants et les facteurs de stress physique qui doivent être contrôlés, par exemple ceux qui :

- sont assujettis à des exigences fédérales, provinciales, territoriales ou municipales existantes
- dépassent potentiellement les critères fédéraux, provinciaux ou territoriaux de qualité de l’environnement, avant d’être traités
- déterminés comme dépassant les niveaux d’autorisation conditionnelle standard établis par la CCSN (voir l’annexe A)
- devraient faire l’objet d’un contrôle (selon l’ERE)

C.5 Calcul des cibles de rejets proposées dans l’environnement

Le titulaire de permis devrait calculer une cible de rejets dans l’environnement proposée pour chaque contaminant et facteur de stress physique qui a été déterminé.

Le titulaire de permis devrait utiliser une approche fondée sur l’exposition dans le cas des substances nucléaires, une approche fondée sur l’exposition dans le cas des substances dangereuses, ou encore une approche fondée sur la technologie, ou une combinaison de toutes les approches applicables.

C.5.1 Approche fondée sur l’exposition pour les substances nucléaires

Dans le cas des substances nucléaires, le titulaire de permis devrait établir des cibles de rejets dans l’environnement selon une approche structurée. Voici un exemple d’une telle méthode :

- déterminer une contrainte de dose appropriée pour une personne ou un groupe critique représentatif, d’après le rendement historique de l’installation ou de l’activité, ou pour des installations ou activités similaires
- pour chaque radionucléide qui pourrait être rejeté, calculer une cible de rejets dans l’environnement, à partir de la contrainte de dose jusqu’à la source de l’effluent ou de l’émission (rétrocalcul), en utilisant un modèle approprié de transport dans l’environnement et de voie d’exposition

Pour une orientation additionnelle sur les modèles appropriés de transport dans l’environnement et de voie d’exposition, voir les documents suivants :

- REGDOC-2.9.1, *Protection de l’environnement : Principes, évaluations environnementales et mesures de protection de l’environnement* [1]
- CSA N288.1, *Lignes directrices pour la modélisation du transport, du devenir et de l’exposition environnementale des radionucléides associés à l’exploitation normale des installations nucléaires* [2]
- CSA N288.6, *Évaluation des risques environnementaux aux installations nucléaires de catégorie I et aux mines et usines de concentration d’uranium* [6]
- AIEA, TECDOC 1714, *Management of Discharge of Low Level Liquid Radioactive Waste Generated in Medical, Educational, Research and Industrial Facilities* [12]

Remarque : Le personnel de la CCSN peut accepter l’utilisation d’autres méthodes d’après la nature de l’installation ou de l’activité nucléaire.

C.5.2 Approche fondée sur l’exposition pour les substances dangereuses

Pour les substances dangereuses, le titulaire de permis devrait établir des cibles de rejets dans l’environnement selon une approche structurée. Voici un exemple d’une telle méthode :

1. Pour chaque point de rejet et chaque contaminant ou facteur de stress physique devant faire l’objet d’un contrôle, déterminer le critère le plus restrictif pour chacun des éléments suivants :
- l’espèce ou les récepteurs humains les plus sensibles (génériques ou propres au site)
- l’utilisation finale la plus raisonnable (p. ex., eau potable, eaux à usage récréatif)
2. Déterminer le point précis dans l’environnement où les critères de qualité environnementale devraient être atteints
3. Trouver un modèle approprié de transport dans l’environnement et de voie d’exposition dont la complexité est déterminée par le récepteur ou l’utilisation finale, comme suit :
    - pour les rejets dans les eaux de surface et afin d’assurer la protection de la vie aquatique, de l’eau potable des utilisations récréatives, une approche simple par zone de dilution est acceptable
    - pour les rejets dans l’air ambiant, et afin d’assurer la protection de la santé humaine, une approche au point d’impact est acceptable
    - pour tous les autres rejets, y compris les rejets dans les eaux souterraines, et afin d’assurer la protection de l’eau potable ou d’autres utilisations finales, le titulaire de permis devrait proposer un modèle approprié

4. Calculer la cible de rejets dans l’environnement en partant du récepteur ou de l’utilisation finale et en remontant jusqu’au point de rejet final. Cette cible de rejets ne peut pas présenter une létalité aiguë au point de rejet (voir la section 3.1)

Les critères les plus restrictifs peuvent comprendre :

- les recommandations fédérales sur la qualité de l’environnement, par exemple :
  - CCME, Guide concernant l’application propre à un lieu des recommandations pour la qualité des eaux au Canada [20]
  - CCME, Protocole d’élaboration des recommandations pour la qualité des eaux en vue de protéger la vie aquatique [21]
- les normes, objectifs, critères ou lignes directrices des provinces ou territoires

L’espèce la plus sensible pour un site donné peut être identifiée comme composante valorisée et est généralement déterminée par une ERE.

Pour l’approche dite du point d’impact, le point d’impact doit être défini de manière à correspondre aux exigences fédérales ou provinciales (par exemple, celles du ministère de l’Environnement, de la Protection de la nature et des Parcs).

Pour de plus amples renseignements sur les rejets dans les eaux souterraines, voir la norme CSA N288.7, *Programmes de protection des eaux souterraines aux installations nucléaires de catégorie I et aux mines et usines de concentration d’uranium* [4].

C.5.2.1 Zones de dilution

Pour le calcul des cibles de rejets dans l’environnement :

- lorsqu’il existe des directives ou orientations fédérales, provinciales ou territoriales pour les zones de dilution, le titulaire de permis devrait s’y conformer
- lorsque de telles directives ou orientations n’existent pas pour les zones de dilution, le titulaire de permis devrait appliquer les règles générales concernant les zones de dilution figurant dans le tableau B.1

Tableau B.1 : Règles générales d’utilisation des zones de dilution pour le calcul des cibles de rejets dans l’environnement (adaptées du document *Calcul et interprétation des objectifs environnementaux de rejets pour les contaminants du milieu aquatique*, 2e édition [22])

Point de rejet	Facteur de dilution maximal dans la zone de dilution
Lac	1 sur 10
Cours d’eau lent	1 sur 100
Cours d’eau rapide	1 sur 100 (d’après le régime lent critique)
Eaux souterraines	Modélisé d’après la distance par rapport à l’utilisation finale désignée

Point de rejet	Facteur de dilution maximal dans la zone de dilution
Air ambiant	Modélisé d’après la distance entre la cheminée et le point d’impact, selon un modèle de dispersion acceptable (p. ex., le modèle de dispersion atmosphérique AERMOD)

Pour de plus amples renseignements sur la détermination de l’étendue spatiale de la zone de dilution initiale, propre au site), voir les directives provinciales sur les zones de dilution (p. ex., voir la référence [22], ainsi que le document du CCME intitulé *Guide concernant l’application propre à un lieu des recommandations pour la qualité des eaux au Canada* [20]).

C.5.2.2 Rejets dans les égouts

Les rejets dans les égouts sont considérés comme un cas particulier.

Pour les rejets dans les égouts :

- le titulaire de permis devrait utiliser les limites fixées par les règlements municipaux applicables, comme les cibles de rejets dans l’environnement
- dans le cas des substances pour lesquelles aucune limite n’est précisée par la municipalité, le titulaire de permis devrait utiliser une approche fondée sur l’exposition, lorsque les calculs tiennent compte des éléments suivants :
    - une zone de dilution appropriée dans le plan d’eau récepteur final est appliquée seulement au volume des effluents rejetés dans les égouts par le titulaire de permis
    - un facteur de dilution supplémentaire pour tenir compte de la collecte d’autres eaux municipales par l’UTEU municipale

    Remarque : Le calcul des cibles de rejets dans l’environnement ne devrait pas tenir compte des traitements réalisés par l’UTEU municipale.

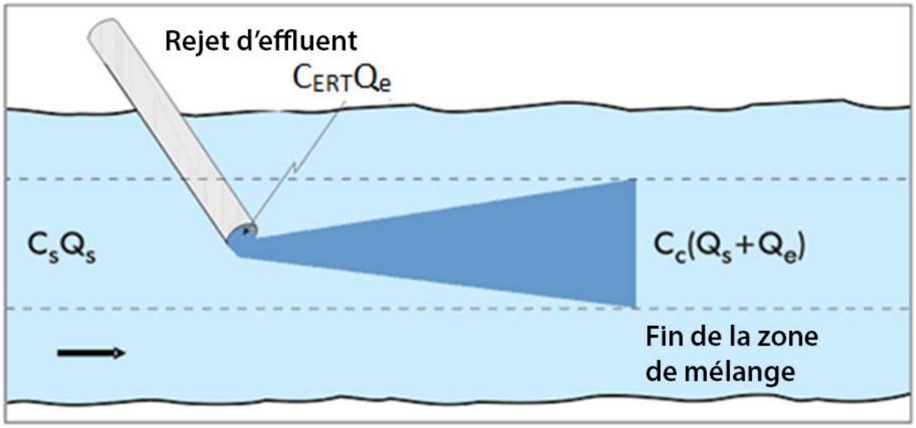
La zone de dilution :

- s’applique uniquement au volume contrôlé qui est réglementé par la CCSN
- ne s’applique pas à la collecte d’autres eaux municipales, car elles ne sont pas réglementées par la CCSN

C.5.2.3 Exemples de calculs d’objectifs de rejet dans l’environnement fondés sur l’exposition pour les substances dangereuses rejetées dans les eaux de surface à l’aide d’une approche de zone de dilution simple

Concernant les rejets dans les eaux de surface, dans le cadre de la protection de la vie aquatique, de la protection de l’eau potable ou de la protection des usages récréatifs, une simple approche par zone de dilution est acceptable. Un exemple de modèle de zone de dilution est fourni à la figure B.1.

Figure C.1 : Éléments du bilan massique de chargement



Sur la base de l'approche de la zone de dilution, le bilan massique suivant peut être calculé,

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

Où : C_c est la concentration correspondant au critère de qualité de l'eau
C_s est la concentration en amont ou de fond
C_{ERT} est la concentration de l'effluent correspondant à la cible de rejet dans l'environnement
Q_s est le débit en amont
Q_e est le débit de l'effluent

Le bilan massique ci-dessus peut ensuite être réorganisé pour isoler C_{ERT}, afin de recalculer l'ERT à partir des critères de qualité de l'eau appropriés,

où,

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

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

Un facteur de dilution peut être défini ainsi, $Fd = \frac{Q_e}{Q_s+Q_e}$ [4]

En remplaçant l'équation [1] et l'équation [4] par l'équation [3], il est possible d'obtenir une équation simplifiée qui est indépendante de l'effluent et du débit en amont, et qui peut être calculée en connaissant les concentrations en amont ou dans les eaux réceptrices de fond, les critères de qualité de l'eau appropriés pour l'utilisation désignée pertinente et le facteur de dilution correspondant.

$$C_{ERT} = \frac{C_c-C_s}{Fd} + C_s \qquad [5]$$

Le facteur de dilution doit être choisi en fonction des directives fédérales, provinciales ou territoriales existantes ou, en l'absence de telles directives, en fonction des règles générales relatives aux zones de mélange présentées dans le tableau B.1.

C.5.3 Approche fondée sur la technologie

Le titulaire de permis devrait définir des cibles de rejets dans l’environnement afin de garantir que des mesures de contrôle acceptables (y compris des stratégies de réduction) pour assurer la prévention de la pollution sont appliquées, en envisageant :

- toute limite ou toute cible de rejets basés sur la technologie et qui existe déjà dans d’autres exigences et orientations internationales, fédérales, provinciales, territoriales ou municipales
- s’il y a lieu, toute cible de rejets fondée sur la technologie établie par la CCSN pour des substances d’intérêt commun dans un secteur donné.
- le rendement historique de l’installation ou de l’activité, y compris les événements connus ou avérés de perte de contrôle

Remarque 1 : Les limites de rejet fondées sur la technologie sont incluses dans les lois fédérales et provinciales. Par exemple, le *Règlement sur les effluents des mines de métaux et de diamant* (DORS/2002-222) utilise des limites de rejet fondées sur la technologie pour établir un niveau de protection de base dans un secteur industriel donné.

C.6 Choix des cibles de rejets les plus restrictives dans l’environnement

Afin de s’assurer que tous les objectifs prévus sont atteints, le titulaire de permis devrait examiner les cibles de rejets dans l’environnement qui ont été calculées, et choisir les plus restrictives.

C.7 Documentation et justification du choix

Le titulaire de permis devrait documenter ce qui suit :

- les cibles de rejets dans l’environnement qui ont été choisies
- la méthode utilisée pour les établir
- la justification du choix des valeurs finales

Appendix D: Orientation concernant l’élaboration d’un plan de mise en service et la confirmation du rendement d’un système de traitement

Les systèmes de traitement comprennent notamment les systèmes de traitement et de contrôle des eaux usées et les systèmes de traitement et de contrôle de la pollution de l’air.

D.1 Orientation supplémentaire concernant l’élaboration d’un plan de mise en service d’un système de traitement

Comme il est décrit à la section 7, le demandeur ou le titulaire de permis soumet un plan de mise en service à la CCSN. Le plan de mise en service devrait contenir les renseignements suivants.

Calendrier et processus de mise en service

Le demandeur ou le titulaire de permis devrait établir un calendrier ou un échéancier pour la mise en service. Ce calendrier devrait :

- tenir compte des variations saisonnières et de leurs effets sur l’exploitation et les processus (p. ex., effets des niveaux de contaminants et des facteurs de stress physique; volume des effluents)
- indiquer les dates de mise en service des différents sous-systèmes (p. ex., sous-systèmes de traitement de l’eau, gestion des solides résiduels) et déterminer quels problèmes pourraient survenir (p. ex., retards dans les essais ou la livraison de pièces ou d’équipements spécialisés)

Le demandeur ou le titulaire de permis devrait décrire l’ensemble du processus de mise en service, par exemple :

- essais d’acceptation en usine
- inspection d’acceptation de l’installation (également appelée essai d’acceptation sur le site)
- essais de mise en marche
- essais fonctionnels sur système inactif
- formation opérationnelle sur système inactif
- transition de la phase inactive à la phase active
- formation opérationnelle sur système actif
- essais de rendement sur système actif

Description des responsabilités

Le demandeur ou le titulaire de permis devrait fournir une liste des titres des postes, une liste de tout le personnel externe participant aux activités de mise en service et une description de leurs responsabilités.

Par exemple, le demandeur ou le titulaire de permis pourrait inclure une description de l’équipe de mise en service, du personnel d’exploitation, de ses représentants, du gestionnaire de l’installation, du personnel du système de gestion (notamment les personnes responsables de l’AQ/CQ), et des organisations externes.

Transition à l’étape suivante de la mise en service (« dossier de transfert de responsabilité »)

Le demandeur ou le titulaire de permis devrait décrire le processus de transition, c’est-à-dire du passage de la phase inactive à la phase active de l’installation, puis de la phase active à la phase d’exploitation. La description devrait comprendre le contenu du dossier de transfert de responsabilité.

Un dossier de transfert de responsabilité comprend normalement ce qui suit :

- les données des manuels d’exploitation et d’entretien
- les procédures normales d’exploitation (PNE)
- les dessins et spécifications conformes à l’exécution
- les listes de contrôle de l’installation, les données et renseignements sur les produits, les dossiers de vérification du rendement
- les pièces de remplacement, outils spéciaux et matériaux d’entretien
- les échantillons et le fini des matériaux, et renseignements connexes
- les manuels et ressources de formation
- les résultats des essais d’acceptation sur le site et des essais d’acceptation en usine
- les certificats d’inspection et du fabricant
- le contrôle final du site

Rendement opérationnel

Le demandeur ou le titulaire de permis devrait décrire le rendement opérationnel des activités de mise en service, y compris :

- la vérification des processus, des systèmes et du fonctionnement des unités afin de s’assurer qu’ils fonctionnent tous correctement
- une évaluation continue des influents et des effluents, ou de la qualité des émissions, de l’efficacité de l’évacuation, des débits et des charges totales
- toute révision apportée aux manuels d’exploitation et d’entretien qui tiennent compte de l’expérience d’exploitation réelle
- la formation des opérateurs
- le génie-conseil
- l’examen des procédures de laboratoire
- les autres activités jugées appropriées pour l’installation ou l’activité

Évaluation du rendement

Le demandeur ou le titulaire de permis devrait décrire l’évaluation du rendement, y compris une évaluation du rendement opérationnel par rapport aux critères de rendement élaborés lors de la conception de l’installation ou de l’activité (y compris tous les critères de rendement, et non seulement ceux se rapportant à la qualité des effluents ou des émissions).

En ce qui concerne la qualité des effluents ou des émissions et les exigences réglementaires, les limites de rejet autorisées proposées et les cibles de rejets dans l’environnement devraient être utilisées comme critères d’évaluation du rendement.

Système de gestion (en particulier l’assurance de la qualité et le contrôle de la qualité)

Le demandeur ou le titulaire de permis devrait fournir une description de la façon dont le système de gestion (en particulier l’assurance-qualité et le contrôle-qualité) sera appliqué lors de la mise en service.

Remarque : Ce ne sont pas toutes les installations ou activités qui nécessitent un système de gestion complet.

Sécurité

Le demandeur ou le titulaire de permis devrait mentionner toutes les exigences pertinentes en matière de santé et sécurité au travail (SST) et de radioprotection lors de la mise en service. En particulier, il devrait indiquer et décrire tous les nouveaux aspects relatifs à la sécurité découlant de la mise en service et de l’exploitation éventuelle du nouveau système.

Formation

Le demandeur ou le titulaire de permis devrait décrire un plan de formation pour la mise en service et l’exploitation du système de traitement afin de s’assurer que le personnel dispose d’une formation appropriée. Pour de plus amples renseignements, veuillez consulter le REGDOC-2.2.2, *La formation du personnel* [23].

Tenue des dossiers

Le demandeur ou le titulaire de permis devrait fournir des références concernant la tenue des dossiers, par exemple :

- les PNE qui seront élaborées
- le processus de révision, de finalisation et de mise à jour des PNE pour chaque processus ou système, dans le cadre des manuels d’exploitation et d’entretien du système, afin de tenir compte de l’expérience d’exploitation réelle
- les résultats des essais d’acceptation sur le site et des essais d’acceptation en usine
- les dessins du site
- les rapports de vérification
- les renseignements sur les produits

Plan du site et emplacement des points d’échantillonnage

Le demandeur ou le titulaire de permis devrait fournir un plan du site qui comprend :

- un diagramme des processus du système de traitement
- l’emplacement des points d’échantillonnage des influents, des effluents ou des émissions (afin d’évaluer le rendement des unités opérationnelles pertinentes)

D.2 Orientation supplémentaire concernant la confirmation du rendement du système de traitement

Comme il est décrit à la section 7, le titulaire de permis confirme le rendement du système de traitement.

Confirmation que les seuils d’intervention demeurent appropriés

Le titulaire de permis devrait examiner les résultats du rendement de la mise en service pour confirmer que les seuils d’intervention peuvent continuer à indiquer une perte potentielle de contrôle du programme de protection de l’environnement ou des mesures de contrôle.

Si les seuils d’intervention ne sont plus appropriés, le titulaire de permis devrait les réexaminer conformément à la norme du Groupe CSA N288.8, *Établissement et mise en œuvre de seuils d’intervention pour les rejets dans l’environnement par les installations nucléaires* [5].

Le titulaire de permis peut utiliser l’approche prospective et devrait mettre à jour en conséquence la documentation sur les seuils d’intervention.

Évaluation du rendement opérationnel par rapport aux cibles environnementales

Le titulaire de permis devrait évaluer le rendement opérationnel par rapport aux cibles environnementales. Si certaines cibles environnementales ne peuvent être atteintes, le titulaire de permis devrait les intégrer en tant qu’objectifs d’amélioration continue dans son SGE.

Élaboration d’un rapport de mise en service

Le rapport de mise en service devrait comprendre les renseignements suivants :

- les données sur le rendement du traitement des influents, des effluents ou des émissions
- les rendements de traitement calculés
- la comparaison des données de rendement réel par rapport aux rejets nominaux maximaux prévus
- les tendances dans les données au fil du temps
- la comparaison des données sur le rendement par rapport aux cibles de rejets dans l’environnement
- la confirmation que les seuils d’intervention sont appropriés
- la confirmation que les limites de rejet autorisées sont respectées

Remarque : Le personnel de la CCSN peut réaliser une inspection de mise en service qui comporte le prélèvement d’échantillons indépendant des influents et des effluents afin de confirmer les résultats sur le rendement.

Glossaire

Les définitions des termes utilisés dans le présent document figurent dans le REGDOC-3.6, *Glossaire de la CCSN*, qui comprend les termes et les définitions figurant dans la *Loi sur la sûreté et la réglementation nucléaires* (LSRN), ses règlements d'application ainsi que les documents d'application de la réglementation et autres publications de la CCSN. Le REGDOC-3.6 est fourni à titre de référence et pour information.

Les définitions terminologiques ci-dessous sont soit nouvelles, soit révisées. Après la consultation publique, la version définitive sera soumise aux fins d'intégration dans la prochaine édition du REGDOC-3.6, Glossaire de la CCSN.

contrainte *(constraint)*
Définition extraite du *IAEA Safety Glossary*
Valeur prospective et liée à la source de la dose individuelle (voir contrainte de dose) ou du risque individuel (voir contrainte de risque) qui est utilisée dans les situations d'exposition prévues comme paramètre pour l'optimisation de la protection et de la sûreté de la source, et qui sert de limite pour définir la gamme des options d'optimisation. (Proposition, basée sur la version de 2018)

effluents à létalité aiguë *(acutely lethal effluent)*
Par létalité aiguë, on entend que l'effluent, à une concentration de 100 %, tue plus de 50 % des organismes d'essai qui y sont soumis pendant une période de 96 heures, lorsqu'il est testé conformément à la méthode d'essai de létalité aiguë appropriée précisée ci-dessous :

Lorsque la salinité de l'effluent est :

a) inférieure à dix parties par mille et que l'effluent est rejeté dans des eaux douces, la méthode d'essai spécifiée est la méthode de référence SPE 1/RM/13 [1] et — le cas échéant — elle est utilisée conjointement avec la procédure de stabilisation du pH SPE 1/RM/50 [2].
b) égale ou supérieure à dix parties par mille et que l'effluent est rejeté dans des eaux marines, la méthode d'essai spécifiée est la méthode de référence SPE 1/RM/10 [3].

Références :
1. Méthode d'essai biologique : essai de létalité aiguë d'effluents sur la truite arc-en-ciel (Méthode de référence SPE 1/RM/13, deuxième édition), décembre 2000 (avec modifications de mai 2007), publiée par le ministère de l'Environnement, avec ses modifications successives.
2. Procédure de stabilisation du pH pendant un essai de létalité aiguë d'un effluent d'eau usée chez la truite arc-en-ciel (SPE 1/RM/50), mars 2008, publié par le ministère de l'Environnement, avec ses modifications successives.
3. Méthode d'essai biologique : *Reference Method for Determining Acute Lethality Using Threespine Stickleback* (en anglais seulement) [SPE 1/RM10, deuxième édition], décembre 2017, publié par le ministère de l'Environnement, avec ses modifications successives.

exploitation normale *(normal operation)*
Exploitation d'une installation nucléaire dans des limites et conditions d'exploitation définies, y compris (le cas échéant) le démarrage, l'exploitation en puissance, la mise à l'arrêt, l'état d'arrêt, l'entretien, les essais et le rechargement de combustible. Pour les réacteurs nucléaires, l'exploitation normale correspond à un état de fonctionnement de l'installation.

Remarque : Les activités en mode d'exploitation normale de toute installation nucléaire correspondent à celles qui sont associées aux activités autorisées approuvées. Cela comprend l'exploitation normale de tout système de traitement pendant la remise en état ou le déclassement, comme défini dans les activités autorisées approuvées et les limites et conditions d’exploitation définies consignées dans le fondement d’autorisation de l’installation.

exposition prévue *(planned exposure)*
Exposition due à l’exploitation prévue d’une source ou à l’exécution d’une activité prévue entraînant l’exposition à une source.

- Comme des mesures de protection et de sûreté peuvent être mises en place avant le début de l’activité en question, il est possible de réduire l’exposition connexe et sa probabilité d’occurrence dès le début.
- Le principal moyen de contrôler l’exposition dans les situations d’exposition prévue repose sur une bonne conception des installations, des équipements et des procédures d’exploitation. Dans de telles situations, un certain niveau d’exposition est prévu.

limitation *(limitation)*
En ce qui concerne la protection de l’environnement, désigne un principe de radioprotection qui précise la valeur d’une quantité utilisée dans certaines activités ou circonstances et qui ne doit pas être dépassée, par exemple la limite de dose au public.

limite de dose réglementaire au public *(regulatory public dose limit)*
La limite de dose prescrite pour le grand public. Comme il est spécifié dans le *Règlement sur la radioprotection*, cette limite est de 1 millisievert (mSv) par année civile. Cette limite de dose protège le public contre les rayonnements résultant de l’exploitation normale d’une installation ou d’une activité nucléaire réglementée par la *Loi sur la sûreté et la réglementation nucléaires*.

limite de rejet autorisée *(licensed limit)*
Limite qui fait partie du fondement d’autorisation et qui, si elle est dépassée, représente une perte de contrôle d’une partie des programmes ou des mesures de contrôle du titulaire de permis. Le dépassement d’une limite de rejet autorisée indique que le titulaire de permis fonctionne à l’extérieur de son fondement d’autorisation pour ce qui est des conditions d’exploitation normale, mais n’implique pas nécessairement un risque déraisonnable pour l’environnement, pour la santé et la sécurité des personnes ou pour la sécurité nationale. Le dépassement d’une limite de rejet autorisée est un cas de non-conformité et entraîne une obligation pour le titulaire de permis de prendre des mesures précises. **Remarque :** Les limites de rejet autorisées peuvent comprendre toute limite précisée dans le fondement d’autorisation.

modification majeure *(major modification)*
Modification qui nécessite un changement au fondement d’autorisation (c.-à-d. une modification du permis) de l’installation ou de l’activité. Voici quelques exemples de modifications majeures :

- les modifications apportées à l’installation physique autorisée, ou aux processus de l’installation ou de l’activité, et qui sont susceptibles de modifier la nature des effluents et/ou des émissions et les risques qui en résultent pour les récepteurs (par exemple, la mise en service d’un système de traitement)
- des mesures prises en réponse à la gestion adaptative
- un résultat découlant d’un bilan périodique de sûreté (BPS)

optimisation *(optimization)*
En ce qui concerne la protection de l’environnement, désigne le processus visant à déterminer le niveau de protection et les mesures de sûreté qui rendent l’exposition ainsi que la probabilité et l’ampleur de l’exposition potentielle aussi faibles qu’il soit raisonnablement possible d’atteindre, compte tenu des facteurs économiques et sociaux.

période provisoire *(interim period)*
En ce qui concerne la protection de l'environnement, il s'agit du délai entre le déclenchement de la gestion adaptative et l'achèvement de la mise en service du nouveau système de traitement ou des autres mesures de contrôle.

point d'impact *(point of impingement, POI)*
Point le plus proche où la contamination atmosphérique émise par une source touche un bâtiment ou s'étend au-delà des limites de la propriété. Désigne tout point sur le sol ou sur un récepteur, par exemple les bâtiments voisins, où l'on s'attend à trouver la concentration la plus élevée d'un contaminant due à l'émission globale de ce contaminant par une installation ou une activité. **Remarque :** Dans le cas d'une installation, le point d'impact se situe à l'extérieur des limites de la propriété de l'installation.

rejet nominal maximal prévu *(maximum predicted design release)*
Caractéristiques des rejets maximaux (c.-à-d. les quantités, concentrations et volumes, plus la flexibilité opérationnelle) qui sont prévus, après traitement et atténuation par l'application des MTEAR.

seuil d'intervention *(action level)*
Un indicateur d'une perte potentielle de contrôle d'une partie du ou des programmes ou d'une ou de plusieurs mesures de contrôle du titulaire de permis. Le dépassement d'un seuil d'intervention indique une réduction potentielle de l'efficacité du programme ou des mesures de contrôle et un écart par rapport au mode d'exploitation normale. Le dépassement d'un seuil d'intervention n'est pas un cas de non-conformité, mais déclenche l'obligation de prendre des mesures spécifiques.

zone de dilution *(mixing zone)*
Zone dans laquelle un effluent rejeté subit une dilution initiale. Cette zone comprend la zone étendue dans laquelle une dilution secondaire se fait dans le plan d'eau ambiant. Une zone de dilution est une zone d'impact attribuée où les critères de qualité de l'eau peuvent être dépassés pourvu que les conditions de toxicité aiguë soient évitées. Aux abords de cette zone, qui tient compte du volume d'eau nécessaire pour assurer la dilution des effluents, les critères spécifiés de qualité de l'eau doivent être respectés. La prise en compte d'une zone de dilution repose sur le principe qu'une petite zone de dégradation peut exister sans pour autant porter préjudice à la durabilité de l'écosystème dans son ensemble.

Références

La CCSN pourrait inclure des références à des documents sur les pratiques exemplaires et les normes, comme celles publiées par le Groupe CSA. Avec la permission du Groupe CSA, qui en est l’éditeur, toutes les normes de la CSA associées au nucléaire peuvent être consultées gratuitement à partir de la page Web de la CCSN Comment obtenir un accès gratuit à l’ensemble des normes de la CSA associées au nucléaire.

1. Commission canadienne de sûreté nucléaire (CCSN). REGDOC-2.9.1, *Protection de l’environnement : Principes, évaluations environnementales et mesures de protection de l’environnement,* version 1.1, Ottawa, Canada, 2017.
2. Groupe CSA. CSA N288.1, *Lignes directrices pour la modélisation du transport, du devenir et de l’exposition dans l’environnement des radionucléides associés à l’exploitation normale des installations nucléaires.*
3. Groupe CSA. CSA N288.6, *Évaluation des risques environnementaux aux installations nucléaires de catégorie I et aux mines et usines de concentration d’uranium.*
4. Groupe CSA. CSA N288.7, *Programmes de protection des eaux souterraines aux installations nucléaires de catégorie I et aux mines et usines de concentration d’uranium.*
5. Groupe CSA. CSA N288.8, *Établissement et mise en œuvre de seuils d’intervention pour les rejets dans l’environnement par les installations nucléaires.*
6. Agence internationale de l’énergie atomique (AIEA). GSG-9, *Contrôle réglementaire des rejets radioactifs dans l’environnement : Guide général de sûreté*, Vienne, Autriche, 2018.
7. CCSN. REGDOC-2.3.3, *Bilans périodiques de la sûreté*, Ottawa, Canada, 2015.
8. CCSN. REGDOC-3.1.1, *Rapports à soumettre par les exploitants de centrales nucléaires*, Ottawa, Canada, 2016.
9. CCSN. REGDOC-3.1.2, *Exigences relatives à la production de rapports, tome 1 : Installations nucléaires de catégorie I non productrices de puissance et mines et usines de concentration d’uranium*, Ottawa, Canada, 2018.
10. CCSN. REGDOC-3.2.1, *L’information et la divulgation publiques*, Ottawa, Canada, 2018.
11. CCSN. REGDOC-2.6.3, *Gestion du vieillissement*, Ottawa, Canada, 2014.
12. AIEA. TECDOC 1714, *Management of Discharge of Low Level Liquid Radioactive Waste Generated in Medical, Educational, Research and Industrial Facilities*, Vienne, Autriche, 2013
13. CCSN. REGDOC-3.1.3, *Exigences relatives à la production de rapports pour les titulaires de permis de déchets de substances nucléaires, les installations nucléaires de catégorie II et les utilisateurs d’équipement réglementé, de substances nucléaires et d’appareils à rayonnement*, Ottawa, Canada, 2020.
14. CCSN. REGDOC-3.6, *Glossaire de la CCSN*, Ottawa, Canada, 2018.
15. CCSN. REGDOC-2.3.1, *Réalisation des activités autorisées : Programmes de construction et de mise en service*, Ottawa, Canada, 2016.
16. U.S. Department of Defense. Military Handbook: *Planning and Commissioning Wastewater Treatment Plants*, MIL-HDBK-353, États-Unis, 1996.
17. AIEA. GSR Part 3, *Radioprotection et sûreté des sources de rayonnements : Normes fondamentales internationales de sûreté*, Vienne, Autriche, 2014.

18. AIEA. TECDOC-1000, *Clearance of Materials Resulting from the Use of Radionuclides in Medicine, Industry and Research*, Vienne, Autriche, 1998.
19. AIEA. Collection Sûreté nº 19, *Generic Models for Use in Assessing the Impact of Discharges of Radioactive Substances to the Environment*, Vienne, Autriche, 2001.
20. Conseil canadien des ministres de l’environnement (CCME). Recommandations canadiennes pour la qualité des eaux : protection de la vie aquatique, *Guide concernant l’application propre à un lieu des recommandations pour la qualité des eaux au Canada*, 2003.
21. CCME. Recommandations canadiennes pour la qualité des eaux : protection de la vie aquatique, *Protocole d’élaboration des recommandations pour la qualité des eaux en vue de protéger la vie aquatique*, 2007.
22. Ministère du Développement durable, de l’Environnement et des Parcs du Québec. *Calcul et interprétation des objectifs environnementaux de rejet pour les contaminants du milieu aquatique*, 2e édition, 2007 (traduction, 2008).
23. CCSN, REGDOC-2.2.2, *La formation du personnel*, Ottawa, Canada, 2016.

Renseignements supplémentaires

La CCSN pourrait recommander d'autres documents sur les pratiques exemplaires et les normes, comme ceux publiés par le Groupe CSA. Avec la permission du Groupe CSA, qui en est l'éditeur, toutes les normes de la CSA associées au nucléaire peuvent être consultées gratuitement à partir de la page Web de la CCSN Comment obtenir un accès gratuit à l'ensemble des normes de la CSA associées au nucléaire.

Les documents suivants ne sont pas cités dans le présent document d'application de la réglementation, mais ils renferment des renseignements qui pourraient être utiles au lecteur.

- Agence internationale de l'énergie atomique (AIEA). *Clearance of Materials Resulting from the Use of Radionuclides in Medicine, Industry and Research*, AIEA-TECDOC-1000, 1998.
- AIEA. *Application of the Concepts of Exclusion, Exemption and Clearance*, Guide de sûreté de l'AIEA n° RS-G-1.7., 2004.
- AIEA. *Generic Models for use in Assessing the Impact of Discharges of Radioactive Substances to the Environment*, Collection Sûreté n° 19, 2001.
- Agence canadienne d'évaluation environnementale. *Glossaire des praticiens pour l'évaluation environnementale des projets désignés en vertu de la Loi canadienne sur l'évaluation environnementale (2012)*, Ottawa, Canada
- CCSN. Carte des processus (un diagramme détaillé des processus pour les nouvelles installations ou activités; pour les installations ou activités existantes qui subissent des modifications majeures; et pour les installations ou activités existantes en exploitation normale).
- Groupe CSA. CAN/CSA ISO 14001, *Systèmes de management environnemental — Exigences et lignes directrices pour son utilisation*, 2004 (1re édition).
  or
  Groupe CSA. CAN/CSA ISO 14001, *Systèmes de management environnemental — Exigences et lignes directrices pour son utilisation* (éditions suivantes).
- Groupe CSA. CSA N288.3.4, *Essais de performance des systèmes d'épuration d'air radioactif des installations nucléaires*, confirmée en 2018.
- Groupe CSA. CSA N288.4, *Programmes de surveillance de l'environnement aux installations nucléaires de catégorie I et aux mines et usines de concentration d'uranium.*
- Groupe CSA. CSA N288.5, *Programmes de surveillance des effluents aux installations nucléaires de catégorie I et aux mines et usines de concentration d'uranium.*
- Gouvernement du Canada. *Cadre d'application de la précaution dans un processus décisionnel scientifique en gestion de risque*, Ottawa Canada, 2003.
- AIEA. *Regulatory Control of Radioactive Discharges to the Environment*, Guide de sûreté de l'AIEA n° GSG-9, Vienne, Autriche, 2018.
- AIEA. GSR Part 3, *Radioprotection et sûreté des sources de rayonnements : Normes fondamentales internationales de sûreté*, Vienne, Autriche, 2014.
- United States Environmental Protection Agency (USEP). *Guidance on the Development, Evaluation, and Application of Environmental Models*, Washington, DC, États-Unis, 2009.

Séries de documents d'application de la réglementation de la CCSN

Les installations et activités du secteur nucléaire du Canada sont réglementées par la CCSN. En plus de la *Loi sur la sûreté et la réglementation nucléaires* et de ses règlements d'application, ces installations et activités pourraient devoir se conformer à d'autres outils de réglementation, comme les documents d'application de la réglementation ou les normes.

Les documents d'application de la réglementation préparés par la CCSN sont classés en fonction des catégories et des séries suivantes :

1.0 Installations et activités réglementées

Série 1.1 Installations dotées de réacteurs
1.2 Installations de catégorie IB
1.3 Mines et usines de concentration d'uranium
1.4 Installations de catégorie II
1.5 Homologation d'équipement réglementé
1.6 Substances nucléaires et appareils à rayonnement

2.0 Domaines de sûreté et de réglementation

Série 2.1 Système de gestion
2.2 Gestion de la performance humaine
2.3 Conduite de l'exploitation
2.4 Analyse de la sûreté
2.5 Conception matérielle
2.6 Aptitude fonctionnelle
2.7 Radioprotection
2.8 Santé et sécurité classiques
2.9 Protection de l'environnement
2.10 Gestion des urgences et protection-incendie
2.11 Gestion des déchets
2.12 Sécurité
2.13 Garanties et non-prolifération
2.14 Emballage et transport

3.0 Autres domaines de réglementation

Série 3.1 Exigences relatives à la production
3.2 Mobilisation du public et des Autochtones
3.3 Garanties financières
3.4 Délibérations de la Commission
3.5 Processus et pratiques de la CCSN
3.6 Glossaire de la CCSN

Remarque : Les séries de documents d'application de la réglementation pourraient être modifiées périodiquement par la CCSN. Chaque série susmentionnée peut comprendre plusieurs documents d'application de la réglementation. Le site Web de la CCSN offre la plus récente liste des documents d'application de la réglementation.

Comments received from public consultation / Commentaires reçus dans le cadre du processus de consultation

Comments received:
• during first round (March 29 to August 11, 2021): 49 comments from nine (9) reviewers
Commentaires reçus :
• lors de la première période (du 28 mars au 11 août 2021: 49 commentaires reçus de neufs (9) examinateurs

Table A: Comments received on the draft document

No.	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	CNSC Response
1.	Canadian Nuclear Association (CNA)	Comment on the overall document	"The CNA appreciates the opportunity to comment on this draft REGDOC. To ensure its requirements and operational impacts are fully understood, licensees would welcome the opportunity to review future drafts as well to offer constructive feedback before this document is submitted to the Commission for approval and publication. During a collective review of this initial version, subject matter experts from CNA, Cameco, Bruce Power, Ontario Power Generation, New Brunswick Power, Hydro Quebec, Canadian Nuclear Laboratories, Nordion and Orano Canada found: 1.There is a duplication of authority with provincial regulators in non-radioactive areas throughout this draft, which increases the potential for regulatory confusion. 2.The document extensively discusses action levels and references CSA N288.8, Establishing and implementing action levels for releases to the environment at nuclear facilities, though much of the discussion doesn't align. When N288.8 is updated, future misalignment with this REGDOC could occur. For clarity and simplicity, licensees suggest future drafts of this REGDOC should reference N288.8 where appropriate and eliminate any discussion on how action levels should be developed. 3.As currently written, the methodology used to derive the release limits is not clear. 4.Similarly, there a lack of clarity regarding the meaning of Environmental Release Targets and how they will be applied.	1. Regarding Duplication of Authority: Under the NSCA and corresponding regulations, the CNSC is mandated to regulate the release of both nuclear AND hazardous substances. The CNSC therefore has the authority and responsibility to do so. In doing so, the intent of this REGDOC is to reduce regulatory duplication where: • for those licensees with provincial permits, the most up-to-date permit should be submitted to CNSC, and release limits identified in those permits will be referenced as a Compliance Verification Criteria (CVC) and form part of the licensing basis • for those licensees with other applicable federal/provincial/municipal regulatory requirements (e.g., MDMERs, MIEPRs, MISA Requirements, Municipal Bylaws) they will also be referenced as CVCs • release limits in any permit or applicable federal/provincial/municipal regulatory requirement will be adopted by the CNSC as long as they are protective Clarity has now been provided throughout the REGDOC.

			5.Further guidance is required regarding the appropriate approach to release limits (risk-based/performance-based.)	2. Regarding Action Levels: Clause 6.1.1 makes clear reference to apply CSA N288.8 to establish and implement action levels for contaminants and physical stressors released to the environment. Text has been updated slightly as follows: "For contaminants and physical stressors released to the environment, the licensee shall establish ~~the need for action levels,~~ and ~~shall~~ implement ~~them~~ action levels in accordance with CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities* [5]." In addition, and as stated in this REGDOC, and in accordance with CSA N288.8, the action level is required to be below or equal to (i.e., when the action level and licensed release limit frequency of application varies, such as a weekly action level and a corresponding monthly licensed release limit) the licensed release limit. When establishing the licensed release limits this will trigger a check against any existing action levels for their suitability, in accordance with CSA N288.8 Clause 10.1(c), which states that, "The facility shall review the need for, and adequacy of the Als, c) following any change to the ARL, when available" CSA N288.8 Clause 8.6.3 states that, "When the release magnitude method is used and the AL is higher than the ARL, it should be adjusted downward to meet the ARL." While CSA N288.8 Clause 8.6.4 states that, "When the release frequency method is used and the upper value of normal operational release exceeds the ARL, the process for an unsatisfactory AL should be followed (Clause 8.9)"

				If an existing action level is above the licensed release limits this would be indicative of the following: i. sufficient overhead in the derivation of the maximum predicted design release wasn't provided ii. an action level that may be set too high (e.g., the factor applied in its derivation may be too high) and may not be suitable to meaningfully identify a *potential* loss of control, before one actually occurs). In this case the action levels would have to be adjusted to be at or below the licensed release limit. 3. Regarding licensed release limits methodology: Additional clarity has been provided throughout Section 5.1. 4. Regarding application of environmental release targets: Appendix B.2 has now been added which describes the relationship between environmental release targets, maximum predicted design release, and licensed release limits. 5. Regarding general approach to licensed release limits: Additional clarifications and guidance has been provided throughout the REGDOC
2.	CNA, Ontario Power Generation (OPG), Hydro-	Submit comments on section 1.2	**Industry Issue:** The Scope is unclear in several areas and reinforces industry's concerns in Theme #1 that this draft REGDOC too often duplicates the authority of	1) Use of the following language has been added throughout to clarify

	Quebec, Bruce Power, Canadian Nuclear Laboratories (CNL), NB Power and Cameco		provincial regulators in non-radioactive areas. For example: 1) The 2nd main bullet and its supporting sub-bullets on page 2 are unclear when they say: • "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 information in this document shall be applied" What if there is no guideline and those selected by licensees are ambiguous (i.e. contaminated sites, drinking vs regular water)? Is there a definition for hazardous substance? Does that definition precipitate federal/provincial guidelines licensees can follow? *Please see comment #28 on section 5.1 for a related example. 2) The 5th sub-bullet on page 2 is unclear when it says, "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." Is this only applicable for facilities or activities other than Class I nuclear facilities and uranium mines and mills? If it is more broadly applicable, this implies that monitoring of some kind would need to be in place for these release points since comparison to regulatory limits is a criterion for monitoring in N288.5. Some facilities currently do not monitor all release points and there is concern this could drive monitoring for insignificant release paths. 3) The Note 1 on page 2 does not mention whether this document applies to estimated emissions. **Suggested Change:** For clarity, CNSC staff is urged to amend the Scope to: 1) Include the following, "This REGDOC will not apply to hazardous substance that were identified to have a negligible contribution to environmental risk in the ERA and/or are regulated by provincial requirements." 2) Include a section for Class I nuclear facilities and a section for other facilities, similar to REGDOC 2.9.1. 3) Confirm if this document applies to estimated	"applicable and most scientifically defensible federal, provincial, ~~or~~ territorial, or municipal environmental quality guidelines, objectives, standards or criteria, as well as scientific literature." Definition for hazardous substance comes from *General Nuclear Safety and Control Regulations*, "hazardous substance or hazardous waste means a substance or waste, other than a nuclear substance, that is used or produced in the course of carrying on a licensed activity and that may pose a risk to the environment or the health and safety of persons." 2) Following text has been added to clarify that this section only applies to facilities other than Class I nuclear facilities and uranium mines and mills: "If the CNSC's review of the application for a licence other than a Class I nuclear facility and uranium mine and mill determines that the facility or activity has potential interactions with the environment and that additional consideration of environmental protection measures is warranted,.." 3) This document does apply to estimated emissions, as long as they are controlled and part of normal operations.

			emissions. **Impact on Industry:** As currently written, this draft REGDOC duplicates the authority of provincial regulators in non-radioactive areas. This increases confusion and the risk of regulatory non-compliance.	
3.	CAN, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 1.2	**Industry Issue: Major** As per Themes #3 and #6, the requirements and methodologies used to derive release limits are unclear, as are the applications of some passages to decommissioning activities. For example: 1) The Scope's 1st paragraph says this document "applies to nuclear facilities or activities that, under normal operation, release or intend to release nuclear substances or hazardous substances to the environment, either through direct releases to air, surface water, sewer, or through the ground, including where natural or engineered barriers for control are proposed or incorporated and require control." Does this mean that release limits are not required during decommissioning activities? Are facilities in decommissioning considered in "normal operation" as per figure 4C or with a "major modification" as per figure 4B? For a nuclear power plant, what is "normal operation"? Is it only applicable when the station is generating electricity, the core is fully loaded and the heavy water systems are pressurized? 2) Section 4.2 raises questions about how the concept of BATEA applies for decommissioning activities. The document says, "A BATEA assessment shall contain the following elements…identification of the maximum predicted design release characteristics." Predicting the releases from decommissioning of one-of-a-kind facilities will be difficult, if not impossible. Similarly, doing an assessment on different technologies and how it changes the emissions estimate will be near impossible. 3) Section 5 discusses Licenced Release Limits, but does not clarify the status of release limits that have already been established and agreed with the CNSC? Can these legacy limits continue to be used? **Suggested Change:** CNSC staff is urged to clarify the requirements and methodologies used to derive release limits and: 1) Clarify the applicability of the document to facilities undergoing decommissioning and what is meant by "normal	As defined in REGDOC 3.6, "normal operation" is *The operation of a nuclear facility within specified operational limits and conditions, including (where applicable) start up, power operation, shutting down, shutdown, maintenance, testing and refuelling. In nuclear reactors, normal operation is a plant state* Normal operations for any nuclear facility, are those associated with the approved licensed activities. In light of this, the REGDOC applies to decommissioning facilities and the normal operation of any treatment system(s) during decommissioning, as defined by their approved licenced activities, including the specified operational limits and conditions documented within the facility's licensing basis. If for a facility that is applying for a licence to decommission, the continued operation of the treatment system(s) form part of those decommissioning activities, and the releases to the environment will remain within the licensed release limits that applied during the licence to operate (i.e., remain within the current licensing basis for releases to the environment), then the facility is meeting this REGDOC. If a licensee would like to conduct decommissioning activities that would be outside of its current licensing basis, then it would be required to submit an application to amend the licence. If those new decommissioning activities, (e.g., remediation, construction of an on-site disposal/storage facility, or new/upgraded treatment system) would result in a change in the release

			operation."2) Amend the 1st sentence in 4.2 to read, "A BATEA assessment shall may contain the following elements:" 3) Confirm that legacy limits already established and agreed with the CNSC can continue to be used. **Impact on Industry:** Predicting the releases from decommissioning of one-of-a-kind facilities will be difficult if not impossible. Unclear expectations increase the risk of regulatory uncertainty and confusion.	characteristics and ensuing risk profile to the environment (i.e., be outside the current licensed release limits and hence outside the current licensing basis), then a BATEA assessment may be required. This may be due to the current system being over/under designed, and some contaminants may no longer require control, if no longer being released, while others may require some additional control). The licensee would ensure requirements as outlined in REGDOC 2.9.2. are being met. To clarify this, the following text has been added to Section 1.2 Scope, "This REGDOC also applies to refurbishment and decommissioning facilities, and the normal operation of any treatment system(s) during refurbishment and decommissioning." A note has also been added to the definition of normal operations, "Note: Normal operations for any nuclear facility, are those associated with the approved licensed activities. This includes the normal operation of any treatment system(s) during decommissioning, as defined by the approved licenced activities, and the specified operational limits and conditions documented within the facility's licensing basis."
4.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.1 and 2.1.1	**Industry Issue: Clarification** The 1st paragraph says, "Facilities and activities with radiation risks are required to be designed, built, authorized, operated and maintained in a manner that prevents or minimizes radioactive releases …" Should this be risk-based? **Suggested Change:** Clarify if this should be risk-based.	As per IAEA General Safety Requirements Part 3 (No GSR Part 3) – *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*, Requirement 1: Application of Principles of Radiation Protection Clause 2:10 states that, "For all exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that protection and safety is optimized"

				In addition, Clause 2:12 states that, "The application of the requirements for the system of protection and safety shall be commensurate with the radiation risks associated with the exposure situation." The text will be updated to read, "Facilities and activities with radiation risks are required to be designed, built, authorized, operated and maintained in a manner that prevents or minimizes radioactive releases to the environment, commensurate with the radiation risks associated with the exposure situation." Risk based, while respecting the principles of BATEA and ALARA.
5.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.1 and 2.1.1	**Industry Issue: Major** It is unclear from this draft which licensee will specify a constraint when there are multiple licensees in close proximity. **Suggested Change:** Provide guidance on how this could be accomplished (at the Bruce Power and Gentilly-2 sites, for example). **Impact on Industry:** Unclear expectations increase the risk of regulatory non-compliance.	Text moved to Appendix B, Optimization and dose constraints, "In situations where multiple licensees may be operating in close proximity (for example, nuclear research or energy parks), the CNSC may specify a facility- or activity-specific dose constraint as an upper bound for the optimization process." In these situations, the CNCS will specify the appropriate dose constraints. To improve clarity, the text will be updated to read, "In situations where multiple licensees may be operating in close proximity (for example, nuclear research or energy parks), the CNSC ~~may~~ will specify a facility- or activity-specific dose constraint as an upper bound for the optimization process."
6.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power	Submit comments on section 2.1 and 2.1.1	**Industry Issue: Major** As per Theme #3, licensees have concerns with maximum release limits throughout the document, including the following passages from section 2.1.1:• The 1st paragraph on page 6, which reads, "The maximum predicted	Section 5.1 provides the approach for establishing licensed release limits. Clarifications have been provided throughout the text.

	and Cameco.		design … establishes the licensed release limits." • The 1st full paragraph on page 8, which says, "The maximum releases associated with the approved optimized design (which includes the addition of a margin for operational flexibility) becomes the authorized release limits." Industry is concerned that:• Setting the authorized release limits as the initial design maximum value may be overly prescriptive and may not consider future operational states for the facility.• The level of effort and uncertainty involved in an estimate of the maximum release from a facility is significant. What about the fact that the maximum predicted release for normal operations may be below the action level which is related to an accident scenario?• It's unclear how authorized licensed release limits get authorized? Are they based on N288.8? Are they also applicable to non-radiological items? The CNSC has said the intent is not to replace or duplicate other legislation. How is applicability and adequacy determined?• Revision of release limits may also have negative impacts to public perception. > When applying optimization and setting authorized release limits, it is necessary to choose the time when doses are at the maximum value. The size of practice may change from year to year. Therefore, for optimization decisions, the relevance is the year when the practice reaches its maximum size. **Suggested Change:** For future drafts, CNSC staff is urged to: • Clarify the text throughout. For example, amend the 1st paragraph on page 6 to read, "The maximum predicted design quantities and concentrations corresponding to the year when the facility has reached its maximum size and is the best option (with respect to optimization), along with a margin of error to provide operational flexibility, establish the licensed release limits." • Clarify how licensed release limits get authorized. **Impact on Industry**: As written, this approach may be overly prescriptive and not consider future operational states for facilities. The level of uncertainty involved in estimating emissions from new facilities can be quite significant. Turning these estimates into regulatory limits which would be considered a violation of the licence if exceeded is a potential error trap. In addition, as written, the guidance could lead to a	When establishing the maximum predicted design release, it is up to the licensee or applicant to ensure enough supporting evidence has been provided and a sufficient margin for operational flexibility has been considered in the design of the maximum predicted design release to allow for all reasonably foreseeable activities associated with the licence. The following text has been included in Section 5 to clarify how licensed release limits are authorized. "For new facilities, or existing facilities undergoing major modifications that require an amendment to the licence, the proposed licensed 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 Commission." In addition, Section 7 provides the process for revising licensed release limits if they cannot be achieved during commissioning of the treatment systems.

			situation where the release limit is calculated to be below the action level. This would require lowering of the action level, which could then lead to unnecessary exceedances and increased administrative burden and regulatory oversight.	
7.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.1 and 2.1.1	**Industry Issue: Clarification** The 1st sentence beneath Figure 1 could be interpreted to require optimization beyond 10 uSv/year. Previous sections refer to 10 µSv/yr as the "de-minimus" dose, representing levels in which no further regulatory control is necessary. As written, this introduces the potential for misapplication of the optimization principle – or misinterpretations of the requirements by licensees or other stakeholders. **Suggested Change:** Revise to read, "…doses approximating 10 µSv/year are recommended as the level below which further optimization and application of BATEA is no longer necessary"	Text Moved to Appendix B Text will be updated to read, "When applying the concept of optimization to establish licensed release limits, modelled doses approximating 10 µSv/year are recommended as the ~~lower boundary for requiring~~ level below which further optimization and application of BATEA is no longer necessary."
8.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.1.2	**Industry Issue: Major** As currently written, page 8 of this section is unclear as to when mixing zone models apply. **Suggested Change:** For clarity, future drafts should state where mixing zone models apply, i.e. conventional or radiological effluent, thermal effluent. **Impact on Industry:** Unclear expectations and wording variations between related regulatory documents increase the risk of non-compliance	No Change. Section 2 of REGDOC 2.9.2 provides background into important concepts required to interpret the REGDOC, and does not provide requirements or guidance on when to apply mixing zone models. Requirements and Guidance on when to apply mixing zone models are specified throughout the REGDOC (Section 4, Section 5, Appendix C). In addition, examples of how to calculate environmental release targets using an exposure-based mixing zone approach has been provided in Appendix C.
9.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.1.2	**Industry Issue: Major** The EMS wording on page 9 is different than that in ISO 14001. Items identified through the ERA are not a requirement to be in the policy. **Suggested Change:** Revise future drafts to align with ISO 14001. Recommend it read, "An	Text moved to Section 3. Text will be updated to read, "An organization's environmental policy (documented in the EMS) includes the organization's commitment to ~~sustainable development,~~ continuous improvement, pollution prevention and to other specific commitments,

			organization's environmental policy includes a commitment to continuous improvement, pollution prevention and can include a commitment to sustainable development and adaptive management." **Impact on Industry:** Unclear expectations and wording variations between related regulatory documents increase the risk of non-compliance	which may include sustainable development and ~~(if it is identified as required through an ERA)~~ adaptive management.
10.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.1.2	**Industry Issue: Major** As per Theme #5, there is a lack of clarity regarding the term "environmental release targets" and how these targets will be applied throughout this draft REGDOC. This includes the passage on page 8 which reads, "The results of the ERA are used to identify what contaminants or physical stressors require mitigation measures and the environmental release targets used to inform the design of such mitigation measures (see appendix B)." Licensees do not understand what this means. There is no definition for release target so it is unclear how it relates to the ERA or the release limit. *Please see comments 28, 46 and 50 for related examples. **Suggested Change:** Clarify what the term "environmental release targets" means and how it relates to the ERA or the release limit. **Impact on Industry:** Unclear expectations increase the risk of regulatory non-compliance.	Appendix B.2 has now been created to clarify the relationship between environmental release target, maximum predicted design release, and licensed release limit. Text moved to Section 3. To prevent confusion, the text on page has been revised as follows: "The results of the ERA are used to identify ~~what~~ any contaminants or physical stressors which may require mitigation ~~measures~~, and may include the implementation of additional controls on releases to the environment. ~~and the environmental release targets used to inform the design of such mitigation measures (see appendix B)~~"
11.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.2	**Industry Issue: Major** The use of "maximum predicted design release" or the predicted design release could be interpreted as being the upper range of normal operations (e.g., 97.5th percentile of historical data). The maximum predicted design release value appears to be intended to be between the upper range of normal operations and the action level. The figures show that the upper range of normal operations, which is to be based on actual or predicted data (based on N288.8-17), is well below this "licensed release limit." This is a concern in 5.1 where an existing facility can identify the maximum predicted design release concentrations and quantities based on historical performance data and it is a concern for operations that use a batch release system whereby the concentrations released are very controlled and only released when acceptable.	As stated in this REGDOC, and in accordance with CSA N288.8, the action level is required to be below or equal to (i.e., when the action level and licensed release limit frequency of application varies, such as a weekly action level and a corresponding monthly release limit) the licensed release limit. When establishing the licensed release limits in accordance with REGDOC 2.9.2., this will trigger a check against any existing action levels for their suitability, in accordance with CSA N288.8 Clause 10.1(c), which states that, "The facility shall review the need for, and adequacy of the Als, c) following any change to the ARL, when available"

			Suggested Change: The licensed release limit should only be referred to as the licensed released limits or the authorized release limit to align with CSA N288.8-17 as per Theme #2. **Impact on Industry:** Confusion and uncertainty are created by introducing a term that is inconsistent with CSA standards.	CSA N288.8 Clause 8.6.3 states that, "When the release magnitude method is used and the AL is higher than the ARL, it should be adjusted downward to meet the ARL" While CSA N288.8 Clause 8.6.4 states that, "When the release frequency method is used and the upper value of normal operational release exceeds the ARL, the process for an unsatisfactory AL should be followed (Clause 8.9)" If an existing action level is above the licensed release limits this would be indicative of an action level that may be set too high (e.g., the factor applied in its derivation may be too high) and may not be suitable to meaningfully identify a *potential* loss of control, before one actually occurs). In this case the action levels would have to be adjusted to be below the licensed release limit. In addition, if the maximum predicted design release (including an appropriate overhead) exceeds the existing action levels, then the action level is clearly inappropriate as an early warning indicator.
12.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.2	**Industry Issue: Clarification** As per Theme #2, Figure 2 is very similar to Figure 1 in CSA N288.8-17 and should be referenced for consistency. There are two different regions in Figure 2 that describe normal operations – "upper value of normal operation" and "Normal Operation/region of optimization (BATEA/ALARA)," which may create confusion. Figure 2 shows that the "maximum predicted design release" should be the same as the licensed release limit." This is not practicable as the maximum of normal operations likely falls between the upper value of normal operations (e.g., 95th percentile) and the action level based on N288.8-17. This would result in a licensed limit below the action level. **Suggested Change:** Revise Figure 2 to align with Figure 1 in CSA N288.8-17 and reference this	These figures are not entirely the same. Appendix B.2 has now been created to describe the relationship between environmental release targets, maximum predicted design release, and licensed release limits. For clarity, the term "maximum predicted design release" has been removed from Figure 2.

			figure as it is very similar and set the "maximum predicted design release" between the upper value of normal operations (e.g., 95th percentile) and the action level.	
13.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.2.1	**Industry Issue: Clarification** This section incorrectly describes administrative levels as the upper range of normal operation when the level may be lower or higher than the upper value of normal operation when all factors are considered. **Suggested Change:** Amend the 2nd sentence in the 2nd paragraph to read, "Exceeding the upper value of normal operation triggers internal investigation by the licensee."	Section 2 provides background into relevant concepts required to interpret the REGDOC. To provide additional clarity, the text will be updated to read, "The applicant or licensee may also use the upper value of normal operation as or to inform internal control levels (may also be called internal investigation levels or administrative levels)."
14.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.2.2	**Industry Issue: Clarification** The order of 2.2.2 and 2.2.3 should be reversed to list in order of importance: 1) upper value of normal operation, 2) action levels, 3) license release limits. This could also apply to Section 5 and 6 of the document. **Suggested Change:** Discuss action levels before licensed release limits within the document. This would result to changes in Section 2.2.2 and 2.2.3 and Section 5 and 6.	No Change. This was discussed, however it was agreed to leave the discussion in the order of 1) licensed release limits, 2) action levels, and 3) upper value of normal operation, as it focuses on safety significant levels first and flows with the methodology outlined throughout the document. Section 5 and Section 6 will be left as is, as they follow the logic from BATEA to licensed release limits to action levels.
15.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.2.2	**Industry Issue: Clarification** Clarity is sought for the sentence, "Licensed Release limits are applicable under normal operation" **Suggested Change:** Please clarify what is meant by normal operation.	The term comes from CNSC Glossary (REGDOC 3.6) *The operation of a nuclear facility within specified operational limits and conditions, including (where applicable) start-up, power operation, shutting down, shutdown, maintenance, testing and refuelling. In nuclear reactors, normal operation is a plant state.* In addition, the following text has been added to provided for clarity,

				"During emergency events, licenced release limits do not apply and emergency management procedures take effect until normal operation is restored. During this period, CNSC staff are in on-going communications with the licensee and enhanced regulatory oversight is applied."
16.	Ecometrix	Submit comments on section 2.2.2	The licensed release limit is referred to as a "quantity" or "concentration". It is "set at the maximum predicted design release concentration and/or quantity." However, the maximum predicted design release is also characterized by "volume". An LRL may be set as an effluent concentration, but that would usually require an associated LRL for "volume" (= flow) since concentration in the environment depends on the release quantity (= flow x concentration). It is unclear if an LRL may be set for volume released (flow). Discussion of this issue would provide clarity.	The term "quantity" was used to capture the fact that volume could be a factor. Release of a specified "quantity" of substances such as kilograms or total Bq/year would require the incorporation of volume. For a licensed release limit that is based on the Maximum Predicted Design Release, this clarity is captured under Section 4, where it is stated that, "The maximum predicted design release characteristics include the location of the points of release, the maximum quantities and concentrations, and the anticipated volume and flow rate of nuclear and hazardous substances expected to be released to the environment"
17.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.2.3	**Industry Issue: Major** Licensees have concerns with the passages on page 13 which read, "Action levels are proposed by the licensee and submitted for review and approval by the CNSC … Any revisions to action levels are subject to CNSC review and approval." For changes to EALs and DRLs, current licence conditions handbooks (LCH) require the licensee to notify the CNSC (G.2. notification) and not obtain approval. An LCH should be the document that defines which items require CNSC acceptance and this requirement should not be in this REGDOC. **Suggested Change:** Licensees strongly urge staff to remove this requirement from the REGDOC. This section must align with licence conditions for both EALs and licenced release limits.	Section 7.2 of REGDOC 3.5.3, Regulatory Fundamentals, states that, "Licensees are expected to notify the CNSC of changes to operating processes, procedures or programs, or to submit written requests of such changes. In all cases, the CNSC assesses this information to ensure that operations remain within the licensing basis." The LCH would be the document that defines which items require CNSC acceptance. To provide additional clarity that is in-line with CNSCs Regulatory Fundamentals and to reduce unnecessary burden on both the licensees and the CNSC, the text will be updated to read,

			Impact on Industry: CNSC review and approval would take more time and reduce the flexibility for making changes.	"Any revisions to action levels ~~are~~ may be subject to CNSC review and approval."
18.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.2.3	**Industry Issue: Clarification** As per Theme #2, CSA N288.8 states the objective of the action level is to trigger an investigation to determine if a loss of control of the environmental protection program has occurred. Bullet 4 states it is a trigger for a specific action to be taken. **Suggested Change:** Amend text to reflect the objective of the action level as defined in CSA N288.8.	No Change. The language "triggers a requirement for specific action to be taken" comes directly from *Radiation Protection Regulations* and *Uranium Mines and Mills Regulations*.
19.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 2.2.3	**Industry Issue: Clarification** Section 2.2.3 (3rd bullet at the top of page 13) and Section 6 (page 29, 2nd paragraph) state that exceeding an action level "may indicate a deviation from normal operation." This is inconsistent with Figure 2 where the range of normal operation covers any action level exceedance below the licensed release limit. Although an action level exceedance could be a deviation from normal operation, this would have to also exceed the licensed release limit and, therefore, should more accurately be called a licensed release limit exceedance. **Suggested Change:** For clarity, delete the 3rd bullet in section 2.2.3 beneath "Exceeding an action level": Amend the 2nd sentence of the 2nd paragraph in section 6 to read, "Exceeding an action level signals a potential reduction in the effectiveness of the program and/or control measure(s)	No Change. An action level exceedance, may indicate a deviation in normal operation, and serves as a yellow light (warning) to conduct an investigation to determine whether a loss of control has or may potentially occur, before it does. This is consistent with Figure 2 and the color-coding in Figure 2.
20.	CNA, OPG, Hydro-Quebec,	Submit comments on section 3.1	**Industry Issue: Clarification** As per Theme #1, clarity is sought for the final bullet under Requirements,	In order to demonstrate mixed effluent as a whole is not acutely toxic, licensees are required to assess for acute

	Bruce Power, CNL, NB Power and Cameco.		which requires licensees to "ensure that releases are not acutely lethal, in accordance with federal, provincial and territorial requirements **Suggested Change:** Clarify if licensees would be required to demonstrate/test for lethality even if they are below the threshold? Being below the guidelines should be enough proof.	lethality for any effluents that are released to water frequented by fish and that contain hazardous substances that could be considered deleterious under the *Fisheries Act*. Text in REGDOC 2.9.1 states, "Meeting existing federal or provincial requirements for toxicity testing shall be considered as satisfying this requirement. Otherwise, the method(s), frequency of testing and actions to be implemented as a result of a test failure shall be developed during licensing and shall be informed by existing standard practices applied to other industrial sectors."
21.	OPG	Submit comments on section 3.2	**Industry Concern:** N/A The REGDOC does not clearly identify at what life stage of the facility's "normal operation" (i.e. construction, operations, or decommissioning) that License Release Limits will form part of the licence application. We understand that an existing DRL may apply from one stage to the next (such as from commercial operations to decommissioning) but it might not be clear if the "normal operation" decommissioning and refurbishment impacts must be considered at the time of application. This section notes the use of "adaptive management" plans for unmanaged risks, but examples identified do not mention refurbishment or decommissioning, which are neither unmanaged nor unknown. These activities are distinct overlays to commercial operations, with overlapping timelines and modified risks. **Suggested Change:** Clarify how important decommissioning and refurbishment activities are managed – is this "adaptive management", or are there distinct review steps, separate from the original licence review to consider? What is the scope of the review – is it adjunct to the existing limits, conditionally linked to operational status, etc.? Is this part of the licence for commercial operation? In addition, how "normal operation" can be defined while site is being end-stated. Can site use the existing operational limits (e.g., Action Level) until conditions stabilized from the operational phase to end of the stabilization	The requirement for adaptive management is clearly stated in Section 8. As defined in REGDOC 3.6, "normal operation" is *The operation of a nuclear facility within specified operational limits and conditions, including (where applicable) start up, power operation, shutting down, shutdown, maintenance, testing and refuelling. In nuclear reactors, normal operation is a plant state* Normal operations for any nuclear facility, are those associated with the approved licensed activities. In light of this, the REGDOC applies to refurbishment and decommissioning facilities and the normal operation of any treatment system(s) during refurbishment or decommissioning, as defined by their approved licenced activities, including the specified operational limits and conditions documented within the facility's licensing basis. For a refurbishment, with activities that are different than the facilities typical ones during a typical licence to operate, different licensed release limits may be appropriate. It is up to the licensee to propose and justify

			phase? **Impact on Industry:** Impacts from decommissioning and refurbishment activities are not necessarily equivalent or less than during commercial operations. There is some indication that when operating parameters change significantly (i.e., reduction of dilution flows and elimination of powerhouse steam supply) some emissions adversely change. This kind of review must be anticipated and managed.	these values during the licensing activity where the CNSC considers refurbishment. If for a facility that is applying for a licence to decommission, the continued operation of the treatment system(s) form part of those decommissioning activities, and the releases to the environment will remain within the licensed release limits that applied during the licence to operate (i.e., remain within the current licensing basis for releases to the environment), then the facility is meeting this REGDOC. If a licensee would like to conduct decommissioning activities that would be outside of its current licensing basis, then it would be required to submit an application to amend the licence. If those new decommissioning activities, (e.g., remediation, construction of an on-site disposal/storage facility, or new/upgraded treatment system) would result in a change in the release characteristics and ensuing risk profile to the environment (i.e., be outside the current licensed release limits and hence outside the current licensing basis), then a BATEA assessment may be required. This may be due to the current system being over/under designed, and some contaminants may no longer require control, if no longer being released, while others may require some additional control). The licensee would ensure requirements as outlined in REGDOC 2.9.2. are being met. To clarify this, the following text has been added to Section 1.2 Scope, "This REGDOC also applies to refurbishment and decommissioning facilities, and the normal operation of any treatment system(s) during refurbishment and decommissioning." A note has also been added to the definition of normal

				operations, "Note: Normal operations for any nuclear facility, are those associated with the approved licensed activities. This includes the normal operation of any treatment system(s) during refurbishment or decommissioning, as defined by the approved licenced activities, and the specified operational limits and conditions documented within the facility's licensing basis."
22.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 3.3	**Industry Issue: Major** There is a lack of clarity in this section. Specifically:1) On page 20, "unmanaged risk" requires further clarification as "evidence of significant increase in magnitude or spatial extent of a previously known risk" is an ambiguous definition. If significant risk is defined on the basis of statistical significance, then a very small statistically-significant change of no biological or ecological significance could result in unnecessary regulatory burden where no practical increase in risk exists.2) The timeline of "immediate" is extreme as per the final bullet under Requirements. Will the requirement to notify the Commission be included in REGDOC 3.1.1 and/or licence condition handbooks? **Suggested Change:** For future drafts, CNSC staff is urged to:1) Amend the note regarding unmanaged risk to read, "… 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." Define an "unmanaged risk" and provide more fulsome examples than those provided under the note on page 20. Also, define type of significance and provide criteria for determining the level of significance. 2) Revise the final bullet under Requirements to either "in a timely manner" or "upon completion of the ERA" rather than "immediately." **Impact on Industry:** As written, there is a potential for risks of no biological or ecological significance to be included as unmanaged risks where statistically-significance to be included as unmanaged risks where statistically-significant increases in risks have occurred. In addition, unclear	Changes partially accepted. 1) Text in the note has been updated to add "to an extent likely to have a measurable impact on the environment or on human health as identified in the ERA." The level of significance should be assessed and determined as part of the ERA, and will rely on the site-specific conditions and assessment results. 2) Text has been updated to remove "immediately" and replace with "upon completion of the ERA".

			expectations could lead to regulatory non-compliances, inconsistent application across the industry and additional administrative burden with no corresponding safety benefit.	
23.	OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 3.3	**Industry Issue: Major** These sections discuss new risks that may require adaptive management. Once a licensed limit is established, the document does not indicate how it can be removed if evidence suggests it is no longer needed. Also, an adaptive management plan should be allowed to be integrated into routine monitoring and reporting. **Suggested Change:** For future drafts, CNSC staff is urged to:• Add that new science or information or adaptive management may provide evidence to support the elimination of a licensed release limit.• Add the process to remove the limits.• Add the following phrase to both sections 3.3 and 8: "Once an adaptive management plan is established, it can be integrated in the facility's routine monitoring and reporting." **Impact on Industry:** As currently written, this creates regulatory burden to require managing a release limit that is no longer science-based.	Changes accepted. The following text has been added to Guidance in Section 3.3: "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 their environmental protection program." The following note has been added to section 3.3 and section 8.1, "Note: Once an adaptive management plan is established, it can be integrated in the facility's routine monitoring and reporting program"
24.	OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and	Submit comments on section 3.3	**Industry Issue: Major** As currently written, section 3.3 states a comprehensive BATEA assessment is not required for existing facilities under normal operation unless a new risk has been identified in the ERA that merits adaptive	A comprehensive BATEA Assessment follows those requirements as clearly articulated in Section 4 of the REGDOC.

	Cameco.		management. It is not clear what a comprehensive BATEA assessment is, or if this clause implies another form of BATEA assessment is required. Section 4 is also unclear on: 1) How to evaluate the BATEA assessment. What is considered "adequate?" 2) How to apply to hazardous contaminants and physical stressors that are regulated by other AHJs and already have limits in place. It is not clear how these regulatory limits should compare to 'environmental quality guidelines' and what exactly this is referring to. There are many limits to consider. Which one do licensees choose? **Suggested Change:** CNSC staff is urged to clarify section 3.3 to say that BATEA assessments are not required for existing facilities. In addition, amend section 4 to: 1) Define "adequate" outcomes and provide guidance for how to evaluate a BATEA assessment and criteria for how options should be assessed. 2) Clarify what is considered an environmental quality guideline. **Impact on Industry:** Unclear expectations could lead to regulatory non-compliances, inconsistent application across the industry and additional administrative burden with no corresponding safety benefit.	1) To provide clarity, the term "comprehensive" has been removed, and the text now reads, "For an existing facility or activity under normal operation, a ~~comprehensive~~ BATEA assessment is not required unless a new risk has been identified in the ERA that merits adaptive management" It is up to the applicant or licensee to submit the information required under Section 4 and provide justification as to why the selected option is considered BATEA. For additional clarity, the following text in section 4 has been removed, "~~The outcome of the~~ BATEA assessment ~~determines what is "adequate", based on the weight of evidence and in consultation with CNSC staff.~~" 2) As previously stated, the intention of this REGDOC is to reduce regulatory duplication by harmonizing with existing licensed release limits under other jurisdictions (i.e., other applicable federal, provincial, territorial, and/or municipal requirements), unless those licensed limits are not deemed protective. Additional text has been included throughout to provide clarity.
25.	OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco	Submit comments on section 4.1	**Industry Concern: Clarification** The note on page 22 creates unnecessary confusion when it says, "Demonstration of a technology or technique as a best practice on a similar industry or activity indicates that the technology or technique is economically achievable." It is not the CNSC's responsibility to deem something "'economically achievable."	The note has been modified as follows: "Note: Demonstration of a technology or technique as a best practice on a similar industry or activity may indicate~~s~~ 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

			Suggested Change: CNSC staff is urged to delete the note and avoid confusion. Perhaps it could cross-reference REGDOC-2.9.1.	similar or better outcome is achieved."
26.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 4.2	**Industry Issue: Major** As per Theme #5, the draft does not clearly identify how environmental release targets fit with existing or proposed thresholds and limits. Nor does it explain the intended purpose of these additional thresholds. If these targets are only part of the BATEA assessment process, perhaps this REGDOC should include a figure separate from Figure 2 to compare to relevant limits for context. The statement in Appendix B.1 which says, "Environmental release targets are not licensed release limits but are guides in the design and development of the maximum predicted design release concentrations or the quantities that become the licensed release limits" is inconsistent with Figure 2. That Figure shows the conceptual relationship of licenses release limits and that the license release limit is the same as the maximum predicted design release. **Suggested Change:** For future drafts, CNSC staff is urged to clarify 4.2, Appendix B.1 and Figure 2 to include how environmental release targets fit into the hierarchy of licensed release limits, action levels, maximum predicted design release concentrations and normal operational conditions. **Impact on Industry:** Unclear expectations increase the risk of regulatory non-compliance and administrative burden for licensees with no corresponding safety benefit.	To prevent confusion, the term "maximum predicted design release" has been removed from Figure 2. Additional clarity has now been provided by creating Appendix B.2, which discusses the relationship between the environmental release target, the maximum predicted design release, and the licensed release limit.
27.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 4.3	**Industry Issue: Clarification** The last two bullets on page 22 are unclear when they say: • "identified as potentially exceeding federal, provincial, or territorial environmental quality guidelines before consideration of treatment • "identified within the ERA as meriting control" Where pre-existing limits are in place for hazardous substances, is the intention for the ERA to evaluate these limits? The ERA is designed to evaluate the effects on ecological receptors and human health, not to evaluate the existing regulatory action levels or licensed release limits.	To provide additional clarity, text will be updated as follows: "•identified as potentially exceeding applicable and most scientifically defensible federal, provincial, ~~or~~ territorial, or municipal environmental quality guidelines, objectives, standards or criteria, before consideration of treatment • identified within the ERA as meriting control where a risk or potential risk has been identified during the review of

			Suggested Change: CNSC staff is asked to clarify the intention of these bullets.	the ERA"
28.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 5	**Industry Issue: Major** License release limits do not ensure "the protection of human health and environment" but rely on federal, provincial, territorial, and municipal requirements that use technology-based approaches, as noted in Section B.5.3. These approaches may include some risk and is why environmental effects monitoring programs are carried out as part of the MDMER. **Suggested Change:** The section overstates the protection that license release limits offer. For future drafts, staff is asked to remove the 2nd bullet that states the implementation of license release limits ensures. **Impact on Industry:** Without changes, this section creates confusion for the public and unreasonable expectations for licensees.	The ERA is one tool to "ensure" that human health and the environment is protected. It does so by assessing the risk to human and ecological receptors. The EP principles, design, the controls, the monitoring and the mitigation and corrective actions all work together to "ensure" environment is protected. In other words, the environmental protection program and its components. The REGDOC states that, "The implementation of licensed release limits ensures: • the protection of human health and the environment" This is true, as its implementation does. Exceeding a limit, investigating corrective and preventative actions, adaptive management if it is triggered, are all part of the implementation of licensed limits and its purpose. In addition, the licensed release limit should be set at a level that "ensures" <u>no unreasonable risk</u> to human health and the environment and as a result the limit is therefore protective of human health and the environment. That doesn't mean it's guaranteed that there will be no residual risk, or even an unreasonable risk. The following text has been added: "Note: The licensed release limit is set at a level that ensures no unreasonable risk to human health and the environment and as a result is therefore protective of human health and the environment. This is supported by its

				application as a source term in the ERA. 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." Based on the adequate precaution to control releases to the environment under the NSCA.
29.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 5	**Industry Issue: Clarification** Licensees also found:1) Guidance is lacking on how to develop licensed release limits for hazardous contaminants and physical stressors.2) There is a lack of clarity on the criteria for determining when an ERA is "protective." Can an ERA be protective if screening criteria is not available? Is this equivalent to an HQ above 1.0? What about where the HQ is over 1 but further assessment shows no biological impact of the level of the substance? Additionally, the evaluation of the protectiveness of various provincial or federal criteria as having "no unreasonable risk" is far beyond the scope of the ERA. Some licensees use these criteria to evaluate the presence of risk but the evaluation of the criteria themselves is the job of government, not industry. 3) A lack of clarity regarding the 3rd bullet, which reads, "that the licensee is operating within the licensing basis for normal operation for that facility or activity."4) The 2nd sentence in the 3rd paragraph confusing when it says, "Exceeding a licensed release limit signals a loss of control of the environmental protection program and/or control measure(s) and that the licensee is operating outside the licensing basis". How is this different than action levels if they both have the same purpose? **Suggested Change:** For added clarity, staff is urged to:1) Clarify what an "applicable" standard guideline or objective for hazardous contaminant is and provide guidance for when there is no guideline or objective available for a particular contaminant. 2) Provide a common methodology or criteria for determining when the ERA is considered "protective." Liaise with the CSA to consider it for inclusion in N288.6 3) Provide clarification as to the purpose and added benefit of licensed release limits considering EALs and DRLs are	1) Clarity has been provided throughout the REGDOC on how to develop licensed release limits for non-radiological contaminants and physical stressors. 2) The ERA and its results, are one tool for supporting whether the environment is protected, along with other components of the environmental protection program. This is described in REGDOC 2.9.1 and is not in the scope of this REGDOC. 3) The licensed release limit as defined in this REGDOC is in-line with international best practices (IAEA, No. GSG-9: Regulatory Control of Radioactive Discharges to the Environment), taking into account pollution prevention, and optimization of protection. Current practice of using DRLs that are based on the public dose limit of 1 mSv/yr, does not meet international best practices. This deficiency in CNSCs regulatory framework was identified by the IAEA Integrated Regulatory Review (2019) and acknowledged by the CNSC. 4) As licensed release limits are based on the approved design of the facility, 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 that would be outside the

			currently in place.4) Clarify that release limits should be risk based. Licensees already have performance-based limits that provide an indication of a potential loss of control event – action levels. It is unclear why another limit that does the same thing is needed.	existing licensing basis. This differs from action levels, which would be expected to change from time to time as a result of operational changes that occur within the existing licencing basis. 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 (i.e., 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. There is a clear distinction between action levels licensed release limits: •Action levels are operational/performance-based, and represent the upper bound of current operational performance and thus are expected to periodically be activated. Licensed release limits based on the maximum predicted design release are based on the design of the facility, which itself is risk-informed. •Action levels are based on the most recent (5-year) operating history of the facility, and therefore change over time either increasing or decreasing. Licensed release limits do not change over time as stated above. •Exceeding an action level signals a potential loss of control (i.e., 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 (i.e., red light), and that the facility is

				operating outside of its approved facility design. •In this approach, there is sufficient margin between triggering an action level and triggering a licensed release limit. Action levels are compared to the operational monitoring program results (e.g., daily or weekly grab sample concentrations) that correspond to a licensee's effluent/emission monitoring program. Licensed release limits are compared to periodic average monitoring results (e.g., monthly average concentrations). This allows for several action level exceedances to occur, before triggering a licensed release limit. It also allows time for the licensee to respond to an action level exceedance and restore the effectiveness of the program before a 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. The following Note has been added to clarify this, "Note: As licensed release limits are based on the approved design of the facility, 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 that would be outside the existing licensing basis."
30.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power	Submit comments on section 5.1	**Industry Issue: Major** Industry has questions with the note on page 27, which says, "The applicant or licensee may use the methodology described in CSA N288.8, Establishing and implementing action levels for releases to the environment	For increased clarity the text has been revised as follows, "• for an existing facility or activity under normal operation: o this information may be documented in the approved

	and Cameco.		from nuclear facilities [5], for a retrospective approach, using a percentile that represents a clear loss of control (for example, 99.99%)" If licensees are sampling every 8 hours for five years, one sample would represent 0.01% of samples. Most samples are taken weekly, so the example percentage in this note (99.99% cut-off for Loss of control) is slightly incongruent to industry's understood mandate to report once every five years an exceedance of the AL. This approach may also put the release limit below the action level since the action level is 99.7 percentile times a factor. It also implies that the licensed release limit could be exceeded, even if there is no loss of control as it is based on historical data. Is the expectation that these limits will be exceeded? How does the maximum probable emission rate factor into the development of these proposed new limits? **Suggested Change:** CNSC staff is urged to clarify the intent of this note and provide more guidance on an appropriate methodology, with examples, for developing license release limits. Staff should also confirm the release limits as risk-based, which would decrease potential overlap with action levels. **Impact on Industry:** As written, this section could lead to a situation where the release limit is calculated to be below the action level. This would require lowering of the action level which could then lead to unnecessary exceedances and increased administrative burden and regulatory oversight.	design documentation for normal operation o otherwise, the maximum predicted design release should be established by using historical performance data for each controlled release point o for nuclear substances specifically, facility-wide and/or activity-wide maximum predicted design release(s) 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, and • their fraction contribution to the total dose 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 maximum predicted design release 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, back calculate from the dose corresponding to the maximum predicted design release and multiply by its fraction contribution to the total dose identified in step i, to obtain a facility-wide and/or activity-wide maximum predicted design release 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 [5], for a retrospective approach, using a percentile that represents a clear loss of control, and as informed by site-specific knowledge and professional judgement. For those licensed nuclear facilities where, due to the

				nature of the operation (e.g., 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 maximum predicted design release to account for anticipated operations throughout the lifetime of the facility." In addition, licensed release limits are based on the optimized facility design which considers pollution prevention, and is risk-informed and in alignment with IAEA General Safety Guide, No. GSG-9: Regulatory Control of Radioactive Discharges to the Environment (2018), taking into account pollution prevention, and optimization of protection. As stated in this REGDOC, and in accordance with CSA N288.8, the action level is required to be below or equal to (i.e., when the action level and licensed release limit frequency of application varies, such as a weekly action level and a corresponding monthly release limit) the licensed release limit. When establishing the licensed release limits in accordance with REGDOC 2.9.2., this will trigger a check against any existing action levels for their suitability, in accordance with CSA N288.8 Clause 10.1(c), which states that, "The facility shall review the need for, and adequacy of the Als, c) following any change to the ARL, when available" CSA N288.8 Clause 8.6.3 states that, "When the release magnitude method is used and the AL is higher than the ARL, it should be adjusted downward to meet the ARL" While CSA N288.8 Clause 8.6.4 states that, "When the release frequency method is used and the upper value of normal operational release exceeds the ARL, the process for an unsatisfactory AL should be followed (Clause 8.9)"

				If an existing action level is above the licensed release limits this would be indicative of an action level that may be set too high (e.g., the factor applied in its derivation may be too high) and may not be suitable to meaningfully identify a *potential* loss of control, before one actually occurs). In this case the action levels would have to be adjusted to be below the licensed release limit.
31.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 5.1	**Industry Issue: Major** This section is also unclear in the following ways: 1) The statement under Guidance on page 26 which reads, "The list of points of release should be in alignment with those established in the effluent and/or emissions monitoring program" contradicts an earlier statement in section 5.1 that licence release limits should be for controlled release points. Stormwater releases or effluents that are mainly groundwater contamination are not controlled and these should be excluded from having release limits, as was done for action levels. 2) As per Theme #1, the statement on page 26 that says, "All contaminants and physical stressors should be identified that are: …identified as potentially exceeding federal, provincial, or territorial environmental quality guidelines" could be controversial because there are many limits in many jurisdictions. 3) Also on page 26, further clarification is needed for how to combine all nuclear substances at a licensed facility when determining if the maximum predicted total effective annual dose to the public does not exceed 0.01 mSv/year. 4) Regarding the 3rd bullet on page 26: If the intention is use these requirements to establish release limits, then "and adopt" should be deleted. It is unclear what two options the "or" between bullets 3 and 4 applies to. 5) Regarding the 4th bullet on page 26, proposed licensed release limits may not always be applicable. 6) The bullet on page 27 which reads, "otherwise, the licensed release limits should be established by using historical performance data" is unclear. The methodology for setting of release limits is too vague. Are the Licensed Release Limits applicable to each effluent stream like the EAL (CSA N288.8) or by facility?	1) Agreed, following text added, "The list of points of release should be in alignment with those controlled release points established in the effluent and/or emissions monitoring program" 2) Additional clarity provided to be consistent with comment 29. Text for second bullet now reads, "identified as potentially exceeding applicable, to the facility and/or activity, and most scientifically defensible federal, provincial, territorial, or municipal environmental quality guidelines, objectives, standards or criteria" 3)The site-specific public dose model would be used to demonstrate this. Determination would be for the total site. The following text has been provided to add clarity, • "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 ~~is~~ below 0.01 mSv and any applicable CNSC prescribed dose constraint (e.g., where potential for cumulative exposure from multiple licensed activities exists).~~and therefore does not exceed the regulatory public dose limit of 1 mSv~~

			7) On page 28, the criteria for "unreasonable risk" are unclear. **Suggested Change:** For clarity, staff is urged to: 1) Amend the statement under Guidance on page 26 to read, "The list of points of release should be in alignment with those controlled release points established in the effluent and/or emissions monitoring program." 2) Clarify how a facility ensures is selecting the appropriate guidelines? What will be in place to ensure facilities in the same regions follow the same guidelines? 3) Clarify how to combine all nuclear substances for determining if licensed released limits are required or not. Is this for the total site, or for each facility on the site? 4) Amend the 3rd bullet on page 26 to read, identify any other governmental requirements (for example, existing federal, provincial, territorial, and municipal requirements) or 5) Amend the 4th bullet on page 26 to read, "establish the proposed licensed release limit, if applicable, based on the maximum predicted design release concentration or quantity" 6) Provide clarity on whether the licensed release limits are specific to effluent stream or facility. 7) Define what is considered "unreasonable risk." Provide a common methodology and liaise with the CSA to consider for inclusion in N288.6. **Impact on Industry:** Unclear expectations could lead to regulatory non-compliances, inconsistent application across the industry and additional administrative burden with no corresponding safety benefit.	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 site." 4) Bullets outlining the methodology for licensed release limits have been re-arranged and streamlined for clarity as follows, "To establish the proposed licensed release limit(s), the applicant or licensee shall: •identify the release points where licensed release limit(s) will apply •identify the maximum predicted design release(s) (MPDRs) •identify each contaminant and physical stressor that requires a release limit •establish the proposed licensed release limit(s) •demonstrate that the proposed licensed release limits respect the radiological regulatory public dose limit, and do not pose an unreasonable risk to human health or the environment" As part of streamlining, some text was moved and additional text provided as follows, "**Establish the proposed licensed release limit** The applicant or licensee should establish the proposed licensed release limits as follows: •adopt those applicable governmental requirements on releases that were previously identified Note: Where other government requirements on releases that are applicable to the facility and/or activity exist, the applicant or licensee may

				harmonize with those requirements (in particular, with any reporting processes and procedures) and use these values as the proposed licensed release limit(s). Some examples include federal or provincial regulations (including those for local air quality at the point-of-impingement (POI)), municipal by-laws, and provincial or territorial permits, authorizations, or licences. Note: To harmonize with requirements on releases to protect local air quality (e.g., O. REG 419/05), proposed licensed release limits for those contaminants and/or physical stressors of regulatory interest may be established by back calculating from the POI, using site-specific release characteristics (e.g., flow rates, stack heights, stack temperature). Note: 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 in a timely manner to update the licence conditions handbook. The updated licensed release limits will be in effect in accordance with the date specified by the respectable jurisdiction. Note: 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."

				5) Clarified by adding "radiological" regulatory public dose limit. 6) The following text has been added as well as note for clarity, • "identify the maximum predicted design release concentrations and quantities for each controlled release point" • "Otherwise, the licensed release limits should be established by using historical performance data, for each controlled release point" In addition, for nuclear substances the following guidance has been provided, "for nuclear substances specifically, facility-wide and/or activity-wide maximum predicted design release(s) can be established through the following methodology… **Note:** For nuclear substances, facility-wide and/or activity-wide licensed release limit(s) may be established for those facilities with multiple release points." 7) No Change. The determination of "unreasonable risk" is made by the Commission based on the evidence provided for a licensing decision.
32.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 5.1	**Industry Issue: Major** As per Theme #1, guidance is lacking in this section on how to develop licensed release limits for hazardous contaminants and physical stressors. If there are limits established by other AHJs, is a licensed release limit required? CSA N288.8 Clause 5.4.2 excludes contaminants from requiring an EAL that are already controlled by other AHJs. If these contaminants	Under the NSCA and corresponding regulations, the CNSC is mandated to regulate the release of both nuclear AND hazardous substances. The CNSC therefore has the authority and responsibility to do so. In addition, under Section 12(1) of the *General Nuclear Safety and Control Regulations* Every Licensee shall,

			still require a Licensed Release Limit, provide guidance on what these values should be, for example flow, hydraulic head, hazardous contaminants, noise, wildlife-vehicle collisions. It seems that a license release limit would be required for all Constituents of Potential Concern as defined in the ERA if hazardous substances are above guidelines and objectives, which are often out-of-date. A license limit should be based on current science and not an out-of-date federal or provincial guideline. **Suggested Change:** Provide guidance for developing licensed release limits for hazardous contaminants and physical stressors that (i) are already governed by other AHJs or (ii) do not have standard guidelines or objectives available. Add to the subsection "Identify each contaminant and physical stressor that requires a license release limit" that all available scientific information should be used in the decision to determine if a licensed release limit is required, if the guideline is determined to be not based on current science. **Impact on Industry:** As written, this section could lead to inconsistent application across the industry and additional administrative burden for licensees with no corresponding safety benefit. It could also create regulatory uncertainty if licensees must comply with guidelines and standards that are based on current science.	(f) take all reasonable precautions to **control the release of radioactive nuclear substances or hazardous substances** within the site of the licensed activity and into the environment as a result of the licensed activity; In light of this, when a CNSC licence is issued, the licensee is authorized to release to the environment in accordance with the licensed release limits. As stated in the REGDOC, the applicant or licensee shall identify any other governmental requirements on releases that are applicable to the facility and/or activity, and adopt those as the CNSC licensed release limits. This ensures regulatory harmonization, and reduces regulatory duplication. Additional clarity has been provided by updating the text – see Comment 31 #1 and #4.
33.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 5.1	**Industry Issue: Major** This draft indicates a licensed limit may not be required where the applicant/licensee can demonstrate that maximum predicted design release is lower than applicable federal/provincial/territorial or municipal standard, guidelines or objectives.In the April 9, 2021 information session, it was noted that the most sensitive species used to derive that limit may actually be considered, not the benchmark itself. **Suggested Change:**As per Theme #1, update the text to note that, where provincial standards/benchmarks apply, a licence limit is not required if the applicant or licensee can demonstrate that the maximum predicted design release or the derived value is lower applicable the provincial value. If a provincial guideline is in place, that should be the standard to which the effluent limit is compared against. For example, if a provincial value has	Text is now consistent with text in Section 4.3, and disposition to Comment 29. Text has been updated in the second bullet as follows: "for a hazardous substance, the maximum predicted design release 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)"

			been updated and is based on the best-available scientific information that should take precedent over outdated research from other jurisdictions. The value itself must be considered, not the most sensitive species used to derive the guideline or benchmark. **Impact on Industry:** It creates regulatory uncertainty when the best available science is not the basis for licensed limits and licensees must comply with inconsistent requirements.	
34.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 5.1	**Industry Issue: Clarification** As per Theme #3, the methodology for setting of release limits is too vague as described on page 27. If you based the limit on historical releases but the work in the facility changes (i.e. new experiment for example) then the limits would need to change if the work changes. This would be very difficult if the release limit was in the licence approved by the commission. **Suggested Change:** Clarify the methodology.	For new facilities, the physical design of the treatment facility and the corresponding maximum predicted design release characteristics are submitted as part of a licence application and form part of the licencing basis for the specific activities for which the applicant is seeking a licence to conduct. If there would be a change in those licenced activities, and that change would result in releases that are no longer within the facilities licensing basis, then the licensee at that time would have to apply for a licence amendment to modify the activities being conducted. This would then trigger an assessment of whether the existing treatment system is adequate for the protection of human health and the environment, and whether the current licensed release limits are adequate. For existing facilities, in all cases the design documentation for the treatment facilities should be available and should identify what the treatment system was designed to treat to (as the treatment systems would have been designed to treat something). This is standard engineering practice. In some cases where this information may not be available (for example for legacy sites), historical releases can be used to identify a licensed release limit that would be indicative of a clear loss of control of the environmental protection program, and hence identify

				the level of control for which the treatment system has been designed to achieve. As licensed release limits are based on the approved design of the facility, 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 that would be outside the existing licensing basis. This differs from action levels, which would be expected to change from time to time as a result of operational changes that occur within the existing licencing basis. The following Note has been added to clarify this, "Note: As licensed release limits are based on the approved design of the facility, 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 that would be outside the existing licensing basis."
35.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco.	Submit comments on section 5.1	**Industry Issue: Major** As per Theme #2, the section on page 27 under "Establish the licensed released limit to be proposed" indicates: 1) An applicant or licensee may use historical performance data to establish a release limit. The 1st Note indicates that the applicant or licensee may use the methodology in CSA N288.8 for a retrospective approach, using a percentile that represents a clear loss of control. CSA N288.8 uses both a percentile and a factor in deriving the action level. The note also uses an example of a percentile that represents a clear loss of control (99.9%). Dependent on the analysis, hitting this value does not represent a clear loss of control given the use of factors in CSA N288.8. The Note also suggests that nuclear operations would be held to a more stringent standard than non-	See Comment 32 1) For increased clarity the text has been revised as outlined in the disposition to Comment 30. 2) As stated in this REGDOC, and in accordance with CSA N288.8, the action level is required to be below or equal to (i.e., when the action level and licensed release limit frequency of application varies, such as a weekly action level and a corresponding monthly release limit) the licensed release limit.

			nuclear facilities. 2) Regarding the 2nd Note, applying factors of 1.5 and 2 to the maximum monthly mean of federal and provincial limits to achieve grab sample and composite sample maximums may not be achievable using the monthly maximum predicted design release concentration, particularly a batch treat and release process, whereby the concentrations are approved prior to release, and have action levels in place that are a factor (such as five, but factors can vary) above the upper range of normal (e.g., 95th to 99.7th percentile). Setting the maximum monthly mean concentration as the licensed release limit, based on the maximum predicted design release concentration, could result in a license release limit that is below the action level. Is "maximum monthly mean concentration" referring to the predicted maximum mean concentration? Furthermore, the operational flexibility calculation only applies to waterborne releases. There is no guidance on how the operational flexibility would be calculated for atmospheric releases. **Suggested Change:** For future drafts, CNSC staff is urged to:1) Delete the note. Otherwise, revise it to read, "for a retrospective approach, using a percentile and a factor that represents a clear loss of control …" As shown in Figure 3, the licensed limit must be above the approved action levels, which are derived using a combination of historical performance data and a corresponding factor. The use of the factor is necessary to have a limit above the established action level and to address situations where strong performance has resulted in low concentrations of parameters in treated effluent.2) Further detail and example calculations should be added and referenced to the second bullet and its Note. A release limit should be a factor above the maximum predicted design release concentration that is also above the action level, particularly in the scenario that licensed release limits are based on historical performance data. Ideally, the maximum monthly mean concentration should be at or above the action level and the maximum grab and composite samples should be above the maximum monthly mean concentration by a factor of 1.5 and 2 to align with the hierarch established for existing license limits from provincial and federal authorities.	When establishing the licensed release limits in accordance with REGDOC 2.9.2., this will trigger a check against any existing action levels for their suitability, in accordance with CSA N288.8 Clause 10.1(c), which states that, "The facility shall review the need for, and adequacy of the Als, c) following any change to the ARL, when available" CSA N288.8 Clause 8.6.3 states that, "When the release magnitude method is used and the AL is higher than the ARL, it should be adjusted downward to meet the ARL" While CSA N288.8 Clause 8.6.4 states that, "When the release frequency method is used and the upper value of normal operational release exceeds the ARL, the process for an unsatisfactory AL should be followed (Clause 8.9)" If an existing action level is above the licensed release limits this would be indicative of an action level that may be set too high (e.g., the factor applied in its derivation may be too high) and may not be suitable to meaningfully identify a *potential* loss of control, before one actually occurs). In this case the action levels would have to be adjusted to be below the licensed release limit.

			Impact on Industry: Inconsistency with CSA N288.8 and regulatory uncertainty. REGDOCs should not create regulatory requirements that exceed legal requirements	
36.	CNA	`	**Industry Issue: Major** The list used to determine each contaminant and physical stressor requiring a licensed release limit is far-reaching and may not indicate a loss of control of part of the environmental protection program or control measures. Examples:• Absence of an "or" in the list, it incorrectly assumes that all parameters with guidelines are required to be monitored. • The April 9th information session discussion confirmed that if release concentrations (based on normal operation predictions) were lower than guidelines then no licensed limits would be required. The ERA is the most efficient way to determine the contaminants and physical stressor that require a licensed release limit because it considers applicable guidelines and is only based on required monitoring data. Therefore, the first and second point of the list to the right are already captured by the third and eliminate the potential for unnecessarily expanding the scope for licensed release limits. **Suggested Change:** Delete first two bullets in the Identify each contaminant and physical stressor that requires a licensed release limit section. **Impact On Industry:** Regulatory burden is created to impose release limits in the absence of a loss of control.	There are instances where a substance has a legal limit within a jurisdiction even though it is not identified in the ERA as requiring control. This is still a legally required limit. Thus to avoid confusion, the CNSC will harmonize with these limits. To provide clarity and transparency the bullets are necessary. The information provided at the April 9th information session is clearly stated in the REGDOC in the following text, "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 maximum predicted design release 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 maximum

				predicted design release is lower than the applicable federal, provincial, territorial or municipal standards, guidelines or objectives (for example, Canadian Council of Ministers of the Environment)" To provide additional clarity, "or" has been added to the end of the first and second bullet.
37.	OPG	Submit comments on section 5.1	**Industry Concern:** Considering the 5.1 section on "Identify other requirements of other jurisdictions", the licensee is expected to demonstrate, where existing provincial requirements do not adequately protect the environment, alternative limits, demonstrated through the ERA, to be protective. The coordination of regulator interests here will be problematic when applying for a permit, and the CNSC may be over-reaching if this creates regulatory conflicts. If wishing to pursue more stringent limits based on an alternative review process, it would be more beneficial if the CNSC coordinates with the provincial regulator to align themselves as a reviewer of the permit application. Note: Per 2.2.2, "The CNSC will work with other jurisdictions to ensure that, to the extent possible, authorizations are acceptable to all applicable jurisdictions." **Suggested Change:** Applicants and licensees should be able to reference a pre-screened list of alternative guidelines and limits, prior to ERA review. This may include lists similar to the MECP Air Contaminants Benchmark list, but which would define alternative limits for contentious hazardous substances considered sufficiently protective to federal regulators. **Impact on Industry:** Risk and uncertainty are created in the regulatory process, if existing provincial, protective limits may be invalidated by an alternative risk assessment process. Contradictions, outside the control of the licensee, need to be resolved prior to starting reviews, as much as possible.	The Note in this section, for which the comment is referring to, is intended to refer to those instances where existing federal, provincial, territorial or municipal requirements exist and apply to the facility under their specific jurisdiction, but for which the CNSC does not find adequately protective based on well defined scientific evidence, including the results of an ERA or other assessment. An example is uranium under the Saskatchewan *Mineral Industry Environmental Protection Regulations*, whereby the authorized concentrations for uranium in effluent is well above that which has been identified through the PSL2 assessment as being non-protective, as a result of past effects identified in the downstream environment of uranium mines and mills. Additional text has been added to the note as follows, "Where existing requirements do not adequately protect the environment (as supported through an ERA or other scientifically defensible assessment), CNSC will engage with the applicable jurisdictions, when determining the most appropriate licensed release limit. ~~the applicant or licensee should propose licensed release limit(s) based on the maximum predicted design release concentration or quantity that have been demonstrated through the ERA to be protective.~~"

38.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco	Submit comments on section 5.1	**Industry Issue: Major** The bolded font in this section indicates that the proponent/licensee must demonstrate that the proposed licensed release limits respect the regulatory public dose limit and do not pose an unreasonable risk to human health or the environment. When completing risk assessments, mean annual values are used to assess potential risk to human health or the environment. Given existing controls, these values are well below established action levels and regulatory limits. Other factors will also contribute to the risk evaluation including treated effluent flow volume, historical effluent releases, assumptions surrounding receptor characteristics, etc. In some cases, potential risks may exist in the absence of any treated effluent release. Further, in many cases, ERAs are completed using probabilistic assessments that use mean values as opposed to single data points. Further, licensed limits are values that a licensee will not operate at continuously; therefore, demonstrating a long-term risk at these values is not reflective of an actual operating scenario. Other processes, such as action levels, would prevent a licensee from continuously releasing treated effluent at the licensed limit. Risk assessments that assume mean values at the licensed limit would imply that many values are above the licensed limit, which could not happen. Unreasonable risks identified under these assumptions, would not represent valid operational scenarios and therefore should not form the basis of a licensed limit. **Suggested Change:** The approach must be modified to reflect that the continuous release at the licensed limit is not a realistic or authorized operating scenario. The determination of an unreasonable risk should not be based on this assumption, as existing controls and regulatory limits would prevent this from occurring. Further clarification is required to note that potential risks are not solely connected to the licensed limit, and that many other factors can influence the assessment. **Impact on Industry:**	A licensed release limit is an authorization that the licensee can release up-to the limit at all times. Therefore, the licensee must demonstrate that a release at the licensed release limit will not result in an unreasonable risk to human health and the environment. As the licensed release limit, in the majority of cases, represents the maximum predicted design release, then the effects to the environment due to a release at this level is required to be assessed. This may be assessed in the ERA by assuming a continuous release at the licensed release limit(s). In some scenarios the applicant or licensee may wish to model the expected evolution of the source term up-to the licensed release limit, if due to the nature of the facility and/or activity, the maximum predicted design release is only expected to be reached during a specific period of normal operations. For a new facility this should be assessed in the original ERA submitted to support a licence to construct. For an existing facility undergoing a major modification, or for an existing facility where there is a major revision to the ERA model, the effects to the environment due to a release at the licensed release limits should be reassessed in their ERA. The above has now been added in Section 5.1 to provide clarity. In addition, the following text has been provided to allow flexibility in how the licensed release limit is applied, "Note: A licensed release limit is an authorization that the licensee can release up to the limit. Therefore, the applicant or licensee is expected to demonstrate that

			Licensees cannot comply with unrealistic risks used in assessments that do not represent valid scenarios.	releases at the proposed licensed release limit will not result in an unreasonable risk to human health and the environment. This may be assessed conservatively in the ERA through a scenario whereby a continuous release at the proposed licensed release limit(s) is assumed. If, due to the nature of the facility and/or activity, the maximum predicted design release 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 in the ERA. Exceeding the approved ERA release values means operating outside of the licensing basis, which results in the facility or activity entering adaptive phased management. In scenarios where periodic or time-limited higher releases are anticipated, the proposed licensed release limit may incorporate temporal limits." If the maximum predicted design release would result in an unreasonable risk to the environment, then additional controls and mitigation would be required as per the process outlined in this REGDOC, and demonstrated in Figure 4b, to reduce the maximum predicted design release, and hence the corresponding licensed release limit. For a new facility, this is captured under the process for the licence application and would be re-assessed during commissioning. For an existing facility, this is captured under the process for responding to a licensed release limit exceedance, Section 5.3, Section 3.3, and Section 8 of the REGDOC. Average values in-line with actual operating performance and anticipated future performance based on current operating conditions should still be considered in the ERA. Along with an additional bounding scenario

				whereby releases are set at the licensed release limits.
39.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco	Submit comments on section 6.1.1	**Industry Issue: Major** Guidance is required on how to "establish the need" for action levels for physical stressors and hazardous contaminants. If licensees are meeting the requirements of other AHJ, then action levels should not be required. **Suggested Change:** Provide guidance as to how to establish the need for action levels for physical stressors and hazardous substances. **Impact on Industry:** Unclear expectations could lead to regulatory non-compliances, inconsistent application across the industry and additional administrative burden with no corresponding safety benefit.	The text has been updated to provide clarity by reducing the existing ambiguity. For contaminants and physical stressors released to the environment, the licensee shall establish ~~the need for action levels,~~ and ~~shall~~ implement ~~them~~ action levels in accordance with CSA N288.8, Establishing and implementing action levels for releases to the environment from nuclear facilities [5].
40.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco	Submit comments on section 6.1.2	**Industry Issue: Clarification** Clarity is sought for the requirement to "establish and implement action levels on other environmental controls that are necessary to ensure the effectiveness of the environmental protection program and control measures" **Suggested Change:** Clarify if licensees have gaps needing to be addressed/ scope of work to implement.	No change. This requirement is not meant to address 'gaps' of current licensees, but to capture those cases where licensees have implemented action levels on environmental controls other than contaminants and physical stressors.
41.	CNA OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco	Submit comments on section 7	**Industry Issue: Clarification** Clarity is sought on the following items on the commissioning of a treatment system: 1) Does this section apply to conventional or non-licenced facilities on a licenced site such a new sewage treatment facility. 2) There is an incomplete reference in third last paragraph. 3) The definition of major modification within the glossary doesn't provide sufficient clarity. **Suggested Change:** For future drafts, CNSC staff is asked to: 1) Clarify the intent of the section for conventional or non-licensed facilities.	The following clarifications have been provided below: 1) This REGDOC applies to licensed activities, and to hazardous substances or hazardous waste, other than nuclear substances, that is used or produced in the course of carrying on a licensed activity that may pose a risk to the environment or the health and safety of persons. This would include conventional sewage treatment facility that is on the licensed site. The following Note has been included to clarify this.

			2) Amend the 3rd last paragraph to read, "… Appendix B section 4.2.1." 3) Expand upon the definition of "major modification."	"Note: This section applies to licensed activities, and to hazardous substances or hazardous waste, other than nuclear substances, that is used or produced in the course of 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." 2) The section referenced is the requirement in section 4.2. For clarity, the text has been updated to read " "To confirm the performance of the treatment system, the licensee should assess the operating performance against the environmental targets established in section 4.2.1 (as part of the BATEA Assessment). 3) Additional text has been provided for clarity within the definition. A modification that requires a change ~~in~~ to the licensing basis (i.e., a licence amendment) 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 increase or change the nature of releases to the environment and the resulting risks to receptors • a response to adaptive management • a result of a periodic safety review (PSR)
42.	CNA OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco	Submit comments on appendix A	**Industry Issue: Clarification** Industry reviewers found: 1) Bracketing is incorrect and the first sentence indicates this appendix is not relevant to class 1 uranium mines and mills. Even with the correct brackets that align with the text in Section 2, it still says licensees need to	Clarification has been provided. 1) This Appendix does apply to Class I nuclear facilities and uranium mines and mills, when assessing whether a radiological contaminant

			meet conditions in this appendix. It is unclear if this appendix is applicable to Class 1 facilities or not.
			2) Inconsistent terminology for clearance levels leads to confusion and uncertainty.
			
			Suggested Change:
			For future drafts, CNSC staff is urged to:
			1) Delete bracket: As described in section 2 licensees (other than Class I facilities and uranium mines and mills) whose routine operational releases of radionuclides meet …"
			2) Add a hierarchy or simple figure outlining the various clearance level terms (CL; Standard Conditional CL, Unconditional CL, Conditional CL, Generic Conditional CL, Practice-specific CL) and how they relate to each other.
				requires control as per Section 4.3. Text has been provided upfront to state that, "The information in this appendix should be consulted as referred to in the applicable sections of this REGDOC. 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 REGDOC. In addition, the information in this appendix applies to all other nuclear facilities."
				
				2) A simple hierarchy has now been included. And the word "Generic" has now been included in the caption of Table A.1
				
				The following terminology and acronyms are provided to assist in understanding the different types of clearance levels.
				
				• Exemption Quantity (EQ): As specified under the *Nuclear Substances and Radiation Devices Regulations*
				
				• Clearance Levels (CLs)
				
				    • Unconditional Clearance Levels (UCLs): As specified under 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

43.	Gilles Provost, Ralliement contre la pollution radioactive	Commentaires sur l'annexe A.1	1) Je trouve exagérément permissive la dose de minimis de l'AIEA, sur laquelle se fonde votre calcul des rejets radioactifs admissibles sans permis. Cette dose de 0,01 milliSievert/an n'est certainement pas négligeable puisqu'elle est à peine 100 fois plus petite que la dose maximale de 1milliSievert pour le public, toutes sources confondues. Et il faut tenir compte du fait que les citoyens sont exposés simultanément à bien d'autres sources de radiation ionisantes. 2) Le tableau A- 1 qui énumère les quantités de radioisotopes qui peuvent être rejetées dans l'environnement sans le moindre permis sont aussi déraisonnablement élevées, en partie parce qu'elles se fondent sur la dose de minimis de l'AIEA. 3) Je trouve particulièrement permissives les rejets maximaux autorisés pour le tritium, plus élevés que ceux de la centaine d'autres radioisotopes présents dans le même tableau. Pourtant, le tritium est un des isotopes les plus mobiles et les plus facilement incorporés dans les organismes vivants. Son rayonnement en outre particulièrement dommageable pour les cellules dans lesquelles il s'est intégré et dans lesquelles il peut persister plus d'un an. 4) Ce REGDOC autoriserait, sans le moindre permis, de déverser chaque année dans un égout municipal assez de tritium pour générer mille milliards de désintégrations (1 000 000 000 000 becquerels). Cela permet, sans permis, un déversement continu de 32 000 becquerels à la seconde alors que l'eau cesse d'être potable à 7 000 becquerels par litre. Aucun autre radioisotope du tableau A-1 ne bénéficie d'une limite aussi laxiste pour les rejets à l'égout! 5) De même, le règlement autoriserait de placer sans permis dans n'importe quelle décharge municipale jusqu'à trois tonnes par année de déchets solide contenant un million de becquerels de tritium par gramme. Là encore, on atteint un rejet total annuel de 3 mille milliards de becquerels (3 000 000 000 000 Bq). À ce rythme, on aura dépassé en 30 ans la quantité totale de tritium que contiendront les centaines de milliers de tonnes de déchets radioactifs en vrac que devrait recevoir en 50 ans le monticule de l'Installation de gestion des déchets près de la surface que le Gouvernement veut construire à Chalk River ! Aucun autre radioisotope du tableau A-1 ne bénéficie d'une limite aussi laxiste pour les rejets dans les décharges publiques!	Vous trouverez les réponses à chacun des commentaires ci-dessous : 1)La dose *de minimis* est internationalement reconnue comme une dose qui correspond à un risque négligeable et qu'il n'est pas nécessaire de réglementer. 2)Voir la réponse à la question 1. 3)Les niveaux de libération conditionnelle correspondent aux concentrations qui contribueraient à ce qu'une dose soit jugée *de minimis*. Les niveaux de libération conditionnelle du tritium sont supérieurs à ceux d'autres radionucléides, parce qu'il faut être exposé à une plus forte concentration de tritium pour recevoir une dose jugée *de minimis*. 4)Voir la réponse à la question 3. 5)Voir la réponse à la question 3. De plus, ce REGDOC est axé sur le contrôle des rejets dans l'environnement par voie aérienne et par voie aquatique. Pour obtenir de plus amples renseignements sur les exigences réglementaires en matière de gestion des déchets radioactifs, veuillez consulter la série de REGDOC 2.11.

44.	OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco	Submit comments on appendix B	The CNSC received this comment from Ontario Power Generation (OPG), Hydro-Quebec, Bruce Power, Canadian Nuclear Laboratories (CNL), NB Power and Cameco. **Industry Concern: Clarification** On page 45, it is not clear how the environmental release targets that may be based on technology would be any different than the release limits themselves and am unsure the purpose for them. **Suggested Change:** Clarify	Licensed release limits may end up being equal to the environmental release target. Appendix B.2 has now been created to clarify the relationship between environmental release target, maximum predicted design release, and licensed release limit. Clarification has been added in Section B.1 through the addition of the following Note. Note: Environmental release targets that are technology-based may be equivalent to licensed release limits in existing in federal, provincial/territorial or municipal requirements (e.g., Metal and Diamond Mining Effluent Regulations). Provided they are the most stringent (in comparison to the exposure-based approach), they are used to inform the design of the wastewater treatment systems or air pollution control systems. In addition, Examples of how to calculate environmental release targets using an exposure-based mixing zone approach has been provided.
45.	CAN, CNA OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco	Submit comments on section B.1	**Industry Issue: Clarification** The 2nd bullet is unclear regarding expectations for setting environmental release targets: it excludes the consideration of BATEA when the CNSC could specify release targets. Establishing environmental release targets is part of the BATEA assessment, but it is not mentioned in Appendix B. **Suggested Change:** Amend the 2nd bullet to read, "a technology-based approach "	Clarification has been added. "or as specified by the CNSC" has now been included within the brackets as an example of technology-based criteria used in the technology-based approach. The second bullet now reads, "•a technology-based approach (to meet technology-based licensed release limits or design ~~requirements~~ criteria existing in federal, provincial/territorial or municipal requirements~~),~~ or as specified by the CNSC)"

46.	CNA, OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco	Submit comments on section B.4	**Industry Issue: Clarification** The list in Appendix B.4 does not align with the referenced list in Section 4.3 (page 22). **Suggested Change:** Delete third bullet	No change. The third bullet should have also been guidance in Section 4.3. Third bullet has now been added to Section 4.3 with the following text, • identified as exceeding standard conditional clearance levels established by the CNSC (see appendix A)
47.	CNA OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco	Submit comments on section B.5.2	**Industry Issue: Major** The releases to sewer Note states that the treatment provided by the municipal wastewater treatment plant should be not considered. This is not a realistic scenario and is very conservative, particularly if the release to sewer, other inputs, and the output from the municipal discharge is known. The environmental release targets can consider mixing zone dilution factors; similarly, the know information related to the collective discharges to the sewer system and municipal treatment prior to release to the environment should be considered. **Suggested Change:** The text should be revised to include information that is known about the releases to sewer and municipal treatment to ensure that environmental release targets are realistic. **Impact on Industry:** Regulatory burden is created when unrealistic scenarios are used to calculate releases to the environment.	No Change. Third party wastewater treatment plants are not regulated by the CNSC. The treated effluent from a third party is not a release that is controlled by the applicant or licensee. For this reason, only control measures of the applicant or licensee or considered acceptable.
48.	CNA OPG, Hydro-Quebec, Bruce Power,	Submit comments on section B.5.3	**Industry Issue: Major** Technology-based licensed release limits established by the CNSC are not needed when licence release limits are based on an ERA and could be	This section is specific to identifying environmental release targets using a technology-based approach.

	CNL, NB Power and Cameco		inconsistent with site specific risk. **Suggested Change:** Revise second bullet to "When necessary, the CNSC may develop technology-based licensed release limits for substances of common concern within a sector. **Impact On Industry**: Creates regulatory uncertainty.	Clarity will be provided by removing Note 2 and updating the second bullet with the following text, "• when necessary, any technology-based licensed release limits established by the CNSC for substances of common concern within a sector"
49.	CNA OPG, Hydro-Quebec, Bruce Power, CNL, NB Power and Cameco	Submit comments on Glossary	**Industry Concern: Major** "maximum predicted design release" is "[t]he residual release characteristics (that is, quantities, concentrations and volumes) that are anticipated, following treatment and mitigation through the application of BATEA, to the maximum expected pollutant source characteristics." **Suggested Change:** Revise definition to read, "[t]he maximum release characteristics (that is, quantities, concentrations and volumes) that are anticipated, following treatment and mitigation through the application of BATEA, **Impact on Industry:** Creates regulatory uncertainty when compliance with two documents is based on inconsistent concepts	Definition will be updated to read "The ~~residual~~ maximum release characteristics (that is, quantities, concentrations and volumes) that are anticipated, following treatment and mitigation through the application of BATEA~~, to the maximum expected pollutant source characteristics~~."

D. APPENDIX D. HIGHLIGHTS OF CHANGES TO REGDOC-2.9.2

Canada's Nuclear Regulator

Environmental Protection

Controlling Releases to the Environment

REGDOC-2.9.2

February 2024

DRAFT

Canadian Nuclear Safety Commission
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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 (BATEA)
- 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 ~~advised or~~ permissible within the limits of this regulatory document. "Can" is used to express possibility or capability.

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

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Controlling Releases to the Environment

1. Introduction

1.1 Purpose

Environmental protection for nuclear facilities and activities 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 intend to release nuclear or hazardous substances to the environment. It applies to those from direct releases to air, surface water, sewer, or through the ground, including where natural or engineered barriers for control are proposed or incorporated. This REGDOC 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 (ERA), and to develop and implement an environmental management system (EMS). 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 does 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 they meet 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 interaction 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's (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 REGDOC focuses on controlling releases to the environment under normal operations.

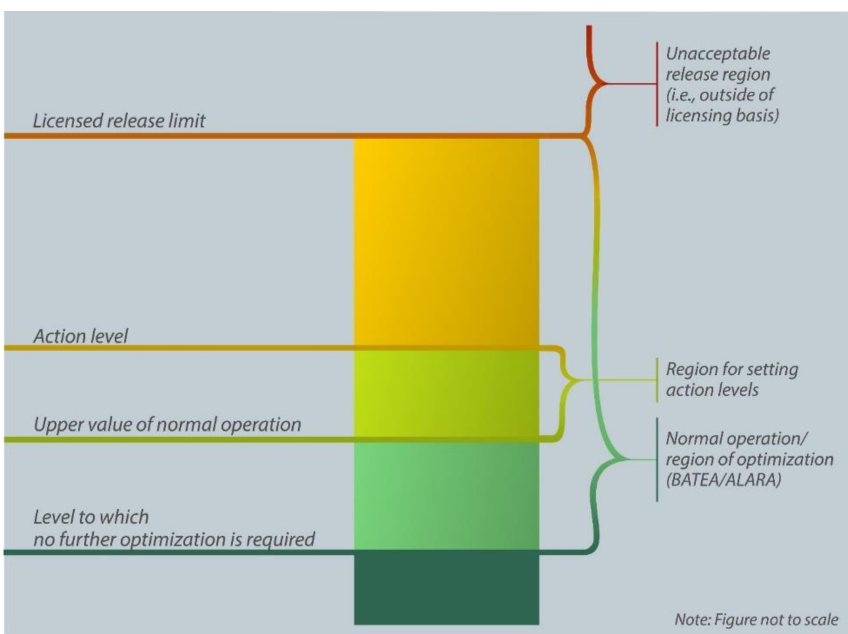
Paragraph 12(1)(f) of the *General Nuclear Safety and Control Regulations*, deals with "reasonable precautions" regarding control of releases. REGDOC-2.9.1 [1] specifies that reasonable precaution in the context of controlling releases involves the application of best available technology and techniques economically achievable (BATEA) and the application of the as low as reasonably achievable (ALARA) principle. Thus, licensees are required to control releases to limits specified within regulation and demonstrate the application of BATEA and ALARA. Hereafter, the term BATEA is considered to refer to both nuclear and hazardous substances with ALARA utilized 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).

The figures below are conceptual and are not necessarily to scale. The actual range between the values depends on the site-specific design and operation of the facility or activity, and 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 CNSCs 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.

Specific to releases to the environment, licensed release limits are part of the licensing basis and, if exceeded, represents a loss of control of part of the licensee's environmental protection program(s) or control measure(s). Exceeding a licensed release 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 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 their 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 released 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 one individual sample.

Exceeding a licensed release limit (that is, a red light) signals that the licensee is operating outside the 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 indicate an unreasonable risk to the environment or to the health and safety of persons.

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 ~~and represent~~, are derived using the ~~upper bound of~~ current ~~operational performance,~~upper value of normal operation, and lie within the maximum upper-end of normal operation (that is, licenced 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 ~~thus~~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 ~~be~~ 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

~~Action levels are based on the most recent (e.g., 5-year) operating history of the facility, and therefore change over time. Action levels may increase or decrease, depending on the day-to-day changes of the operation that lies within the current licensing basis.~~

~~For more information on action levels, see section 6.~~

~~2.1.3~~1.1.1 ~~Overview of upper value of normal operation~~

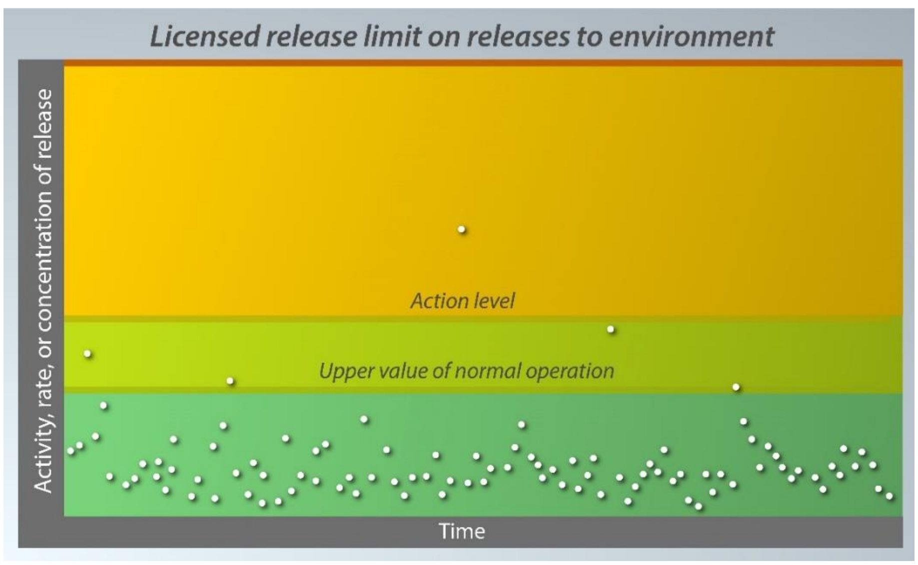
The upper value of normal operation ~~represents the expected upper bound release,~~is based on the predicted or current operating conditions, and is typically determined using either:

- 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 below shows operational performance data that demonstrates the relationship between the upper value of normal operation~~ for a sample nuclear or hazardous substance~~, the action level ~~for environmental releases~~, 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 ~~operational~~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~~. Several action level exceedances may occur before triggering a licensed release limit. It also allows time for the licensee to respond to an action level exceedance and restore the effectiveness of the program before a complete loss of control occurs. If weeks have gone by and the licensee has triggered the action level repeatedly~~, designed in accordance with ~~little response, this may result in exceeding the licensed release limit,~~CSA N288.5, *Effluent monitoring programs at Class I nuclear facilities* *and* ~~is in itself a demonstration of loss of control of the environmental protection program.~~*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 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)
- licence 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 ~~clearly~~ 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 ERA or similar documentation~~, which is~~ submitted ~~as part~~in support of a licence application~~ and forms part of the licensing basis~~.

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.

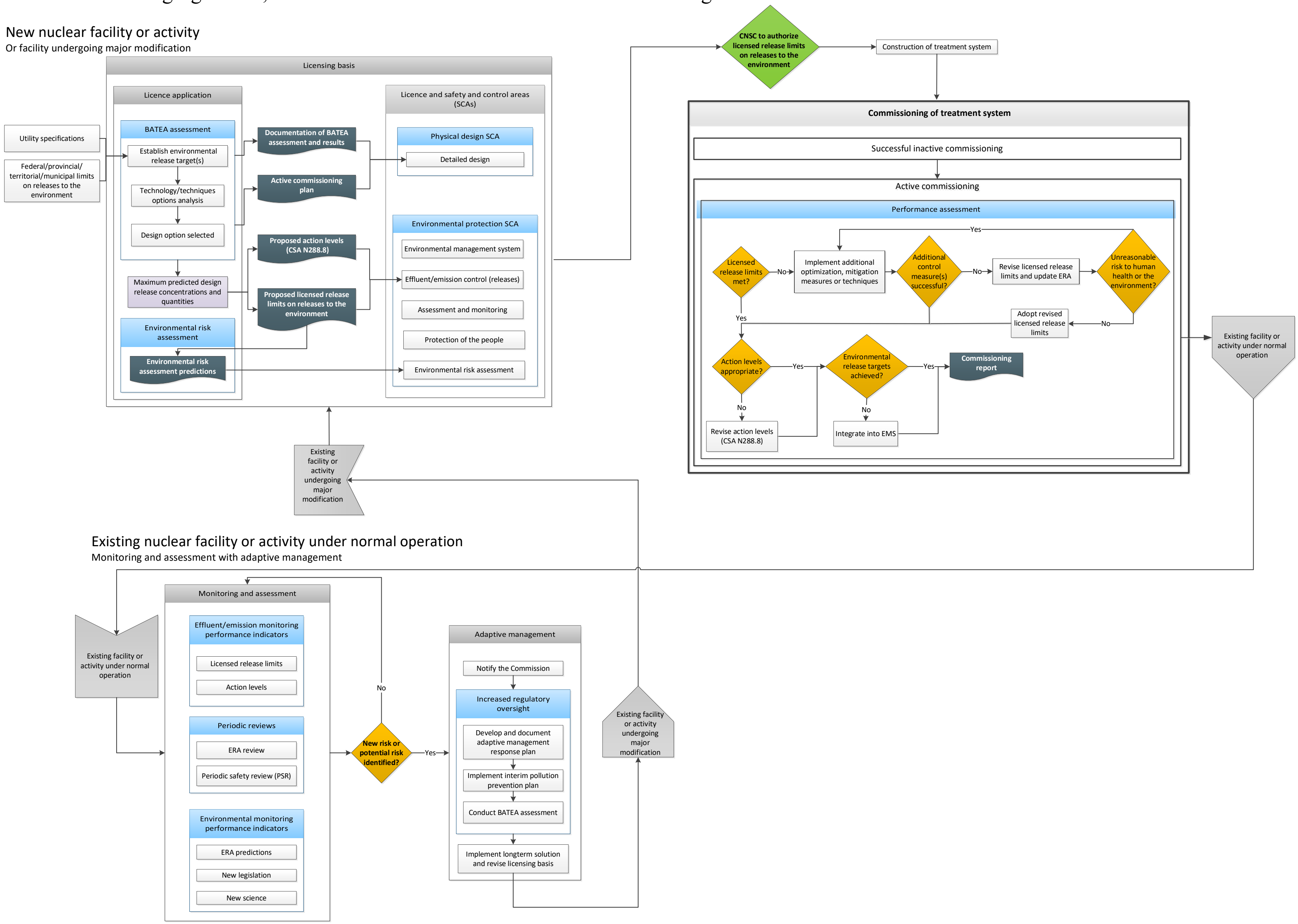


Figure 3a: Information on control measures for releases to the environment to be submitted for a new facility or activity applying for a licence to construct, or an existing facility undergoing a major modification and requiring a licence amendment

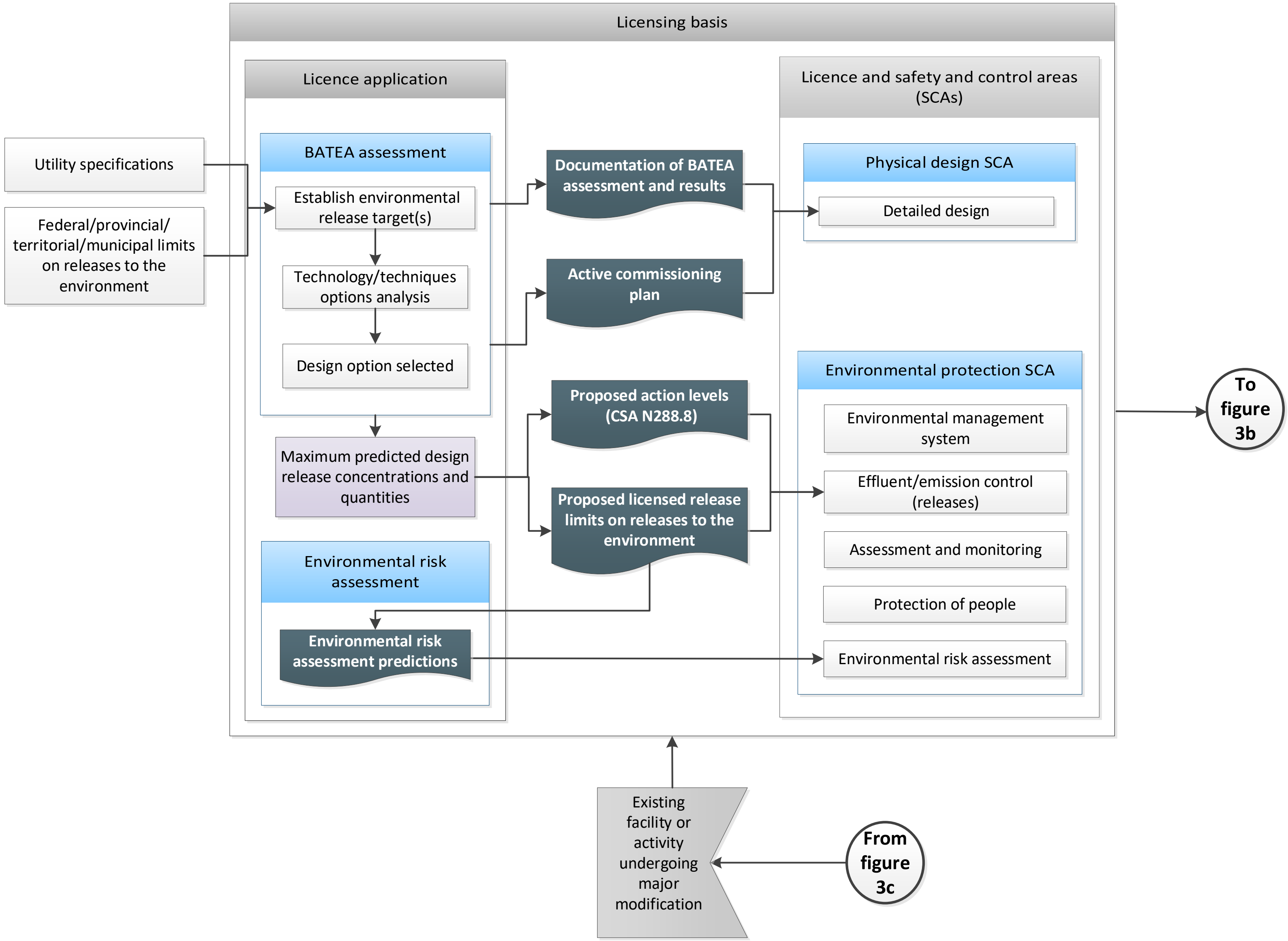


Figure 3b: Commissioning treatment system(s)

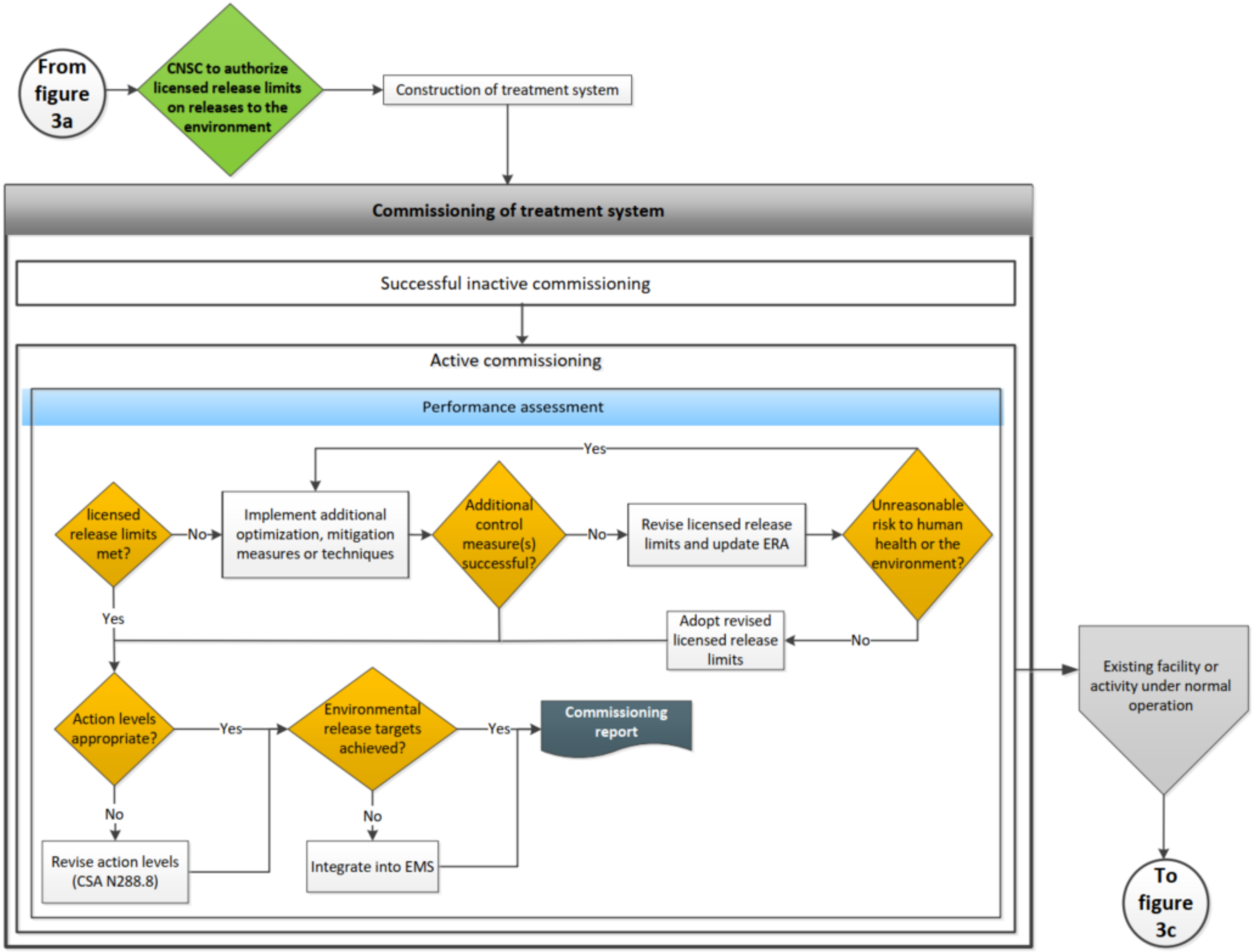
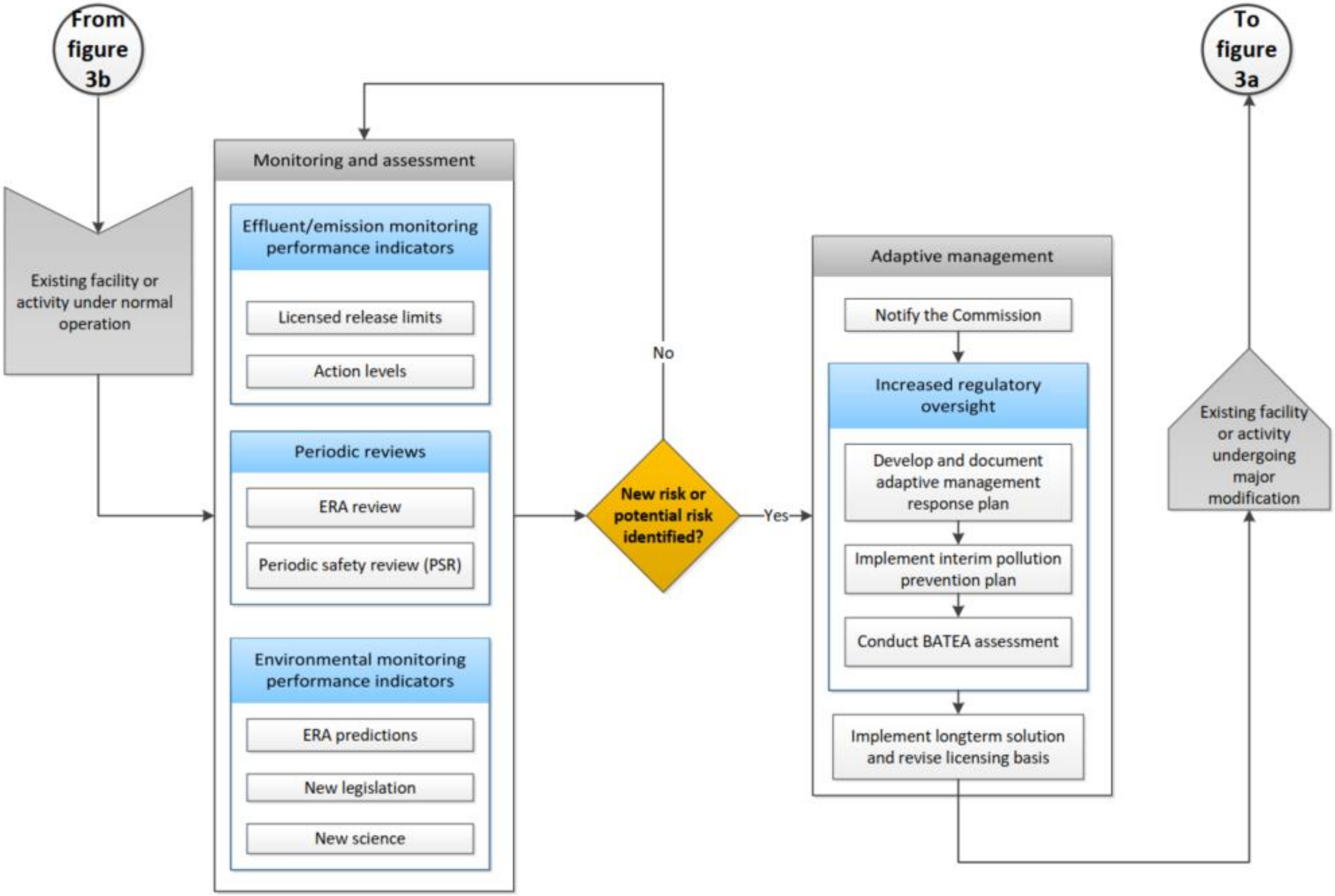


Figure 3c: The part of the overall process for establishing control measures that is specifically for a nuclear facility or activity under normal operation



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 ~~the~~ an environmental risk assessment (ERA ~~are~~) can be used to identify any contaminants or physical stressors which may require mitigation including implementation of additional controls on releases to the environment. ~~The~~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~~, in accordance with federal, provincial and territorial requirements~~

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 ~~effluent~~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)
- if a previously unmanaged risk is identified in the ERA, and adaptive management is required to restore the effectiveness of the environmental protection program, upon completion of the ERA, notify the Commission

  Note: Some examples of unmanaged risks are those ~~arising~~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 ~~the environment~~ecological or ~~on human~~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 their environmental protection program.

BATEA during operations is considered as part of a facilities commitment to pollution prevent and continuous improvement as part of their environmental policy and as managed through their EMS. Like applying the ALARA concept, 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), but applies to those 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)

~~The maximum predicted design release characteristics~~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~~. The maximum predicted design release~~, 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 on 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 (ERT) 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 utilized:
- dose constraints, concentrations, or total loadings identified in federal and/or provincial regulations as being 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, CCME 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 licence 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-year 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 maximum predicted design release characteristics (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 that 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, ~~and includes a margin providing operational flexibility (i.e.,~~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 ~~described in~~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~~ for that facility or activity.~~.

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 ~~licenced~~licensed release limits represent the upper~~ bound~~-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 ~~is~~can be demonstrated through ~~the~~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 are applicable 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 enhanced regulatory oversight is applied. ~~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 licenced release limits with those currently in federal/provincial/territorial regulations that are applicable to the licenced activity.~~

~~The licenced release limits are based on the predicted maximum design release with a margin incorporated to allow for operational flexibility. The approach establishes licensed release limits at levels well below anticipated harm, but if exceeded clearly indicate a failure in the environmental protection program for control of releases.~~

~~For nuclear substances, this 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 licenced 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.~~

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

Note: The licensed release limit is set at a level that ensures no unreasonable risk to human health and the environment, and as a result is protective of human health and the environment. ~~This is supported by its application as a source term in the ERA.~~ 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)

~~The~~ **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 maximum predicted design release(s) ~~(MPDRs~~characteristics (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 ~~limits~~limit(s) will apply

The list of ~~points 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(s) characteristics

Identify the maximum predicted design release ~~concentrations and quantities~~characteristics (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 ~~maximum predicted design release~~MPDRCs should be established by using historical performance data for each controlled release point
  - for nuclear substances ~~specifically~~, facility-wide and/or activity-wide ~~maximum predicted design release(s)~~MPDRCs can be established through the following methodology:
    1. 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~~, and~~
       - ~~their fraction contribution to the total dose~~
    2. calculate the total effective dose to the representative person (or critical receptor) using the maximum release values obtained in step i
    3. calculate the dose corresponding to the ~~maximum predicted design release~~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 contribution to the total effective dose identified in step iii

~~iv.~~v. for each radionuclide/radionuclide group, back calculate from the dose corresponding to the ~~maximum predicted design release~~MPDRCs, and multiply by its fraction contribution to the total dose identified in step ~~i~~iv, to obtain a facility-wide and/or activity-wide ~~maximum predicted design release~~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~~, using~~. This approach could use a percentile that represents ~~a clear loss~~the upper value of ~~control,~~normal operation and ~~as~~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 ~~maximum predicted design release~~MPDRCs to account for anticipated operations throughout the ~~lifetime~~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 ~~MPDR~~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. that are identified within the ERA as requiring control.~~

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 ~~maximum predicted design release~~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 ~~maximum predicted design release~~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 those applicable governmental requirements on releases that were previously identified

- where other government requirements on releases that are applicable to the facility and/or activity exist, 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 (POI)), 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 REGDOC.
- 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 POI, 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 ~~in a timely manner to~~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 ~~respectable~~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-annually averaging period). This should be done for each contaminant~~,~~ requiring proposed release limits (where ~~existing~~ requirements on releases do not exist, ~~or~~ are deemed to not be adequately protective of the environment, ~~set the proposed release limit as the maximum predicted design release concentration that applies to the maximum monthly mean concentration~~

- ~~To allow for operational flexibility, a proposed release limit~~or where the applicant or licensee chooses not to adopt, for ~~waterborne~~the purposes of harmonization, those applicable governmental requirements on releases ~~may be applied~~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 ~~a~~ uncertainty in sampling results, a proposed release limit corresponding to an individual grab sample or an individual composite sample ~~at 1.5 times the maximum monthly mean concentration, or to a "grab sample" at 2 times the maximum monthly~~may be established. A proposed release limit that applies to an individual composite sample can be established by multiplying the maximum mean concentration~~. The application of these factors~~ 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 ~~maximum predicted design release~~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 ~~use~~assess the proposed release limits ~~in the~~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 (ECCC) 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 ~~in the ERA~~ through a scenario whereby a continuous release at the proposed release limit(s) is assumed. This may be used by any industrial facility that has a very stable, continuous release over their operational lifetime, or for low-risk facilities that wish to conservatively demonstrate their releases are protective.

If, due to the nature of the facility and/or activity, the ~~maximum predicted design~~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 ~~in the ERA. Exceeding the approved ERA release values means operating outside of the licensing basis, which results in the facility or activity entering adaptive phased management.~~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 REGDOC 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~~ and operationally based.~~. 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~~ appropriate to~~, as control measures, on the operational parameters of the~~ type of~~ 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 whether the licensed release limit can be met through further optimization or application of additional mitigation measures or techniques to reduce releases below the licensed release limits

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, then 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 EP Framework

The information in this appendix should be consulted as referred to in the applicable sections of this REGDOC. 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 REGDOC. 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 (CLs)
  - 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

EP 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 conditional clearance levels 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 conditional clearance, 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 μSv/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): if 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 NSRDRs
  - 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): if 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, e.g., via the annual compliance reports that the total quantity acquired/used over one year is less than the corresponding generic CCL

- Criterion iii): the 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 conditional clearance levels (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* 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” which 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 µSv/year for a member of the public and
- 10 µGy/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 µGy/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 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 metres (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 two 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 µSv from each of the two groups of pathways. The smaller of the two 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 m^3/year) for this reference WTP was estimated by considering Canadian WTP influent rates for 2016 – 2018 for three WTPs in Toronto and 5 WTPs in Vancouver. The “per capita” annual average inflow rate was approximately 130 m^3/a, which is equivalent to 2.6 million m^3/a for a population of 20,000. The values in column 4 of table A.1 were divided by 2.6 million m^3/a to obtain the resultant concentrations.

Releases containing more than one radioisotope

When more than one radionuclide is released via one 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 one 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 one calendar year

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

Column 1	Column 2	Column 3	Column 4
Radionuclide	**Municipal landfill (Bq/g)** **Note: 1**	**Annual activity released to atmosphere (MBq)** **Note: 2**	**Annual activity released to municipal sewer (MBq)** **Note: 2, 3**
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

Column 1	Column 2	Column 3	Column 4
Radionuclide	**Municipal landfill (Bq/g)** **Note: 1**	**Annual activity released to atmosphere (MBq)** **Note: 2**	**Annual activity released to municipal sewer (MBq)** **Note: 2, 3**
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

Column 1	Column 2	Column 3	Column 4
Radionuclide	**Municipal landfill (Bq/g)** **Note: 1**	**Annual activity released to atmosphere (MBq)** **Note: 2**	**Annual activity released to municipal sewer (MBq)** **Note: 2, 3**
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

Column 1	Column 2	Column 3	Column 4
Radionuclide	**Municipal landfill (Bq/g)** **Note: 1**	**Annual activity released to atmosphere (MBq)** **Note: 2**	**Annual activity released to municipal sewer (MBq)** **Note: 2, 3**
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	

Column 1	**Column 2**	**Column 3**	**Column 4**
Radionuclide	**Municipal landfill (Bq/g)** **Note: 1**	**Annual activity released to atmosphere (MBq)** **Note: 2**	**Annual activity released to municipal sewer (MBq)** **Note: 2, 3**
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

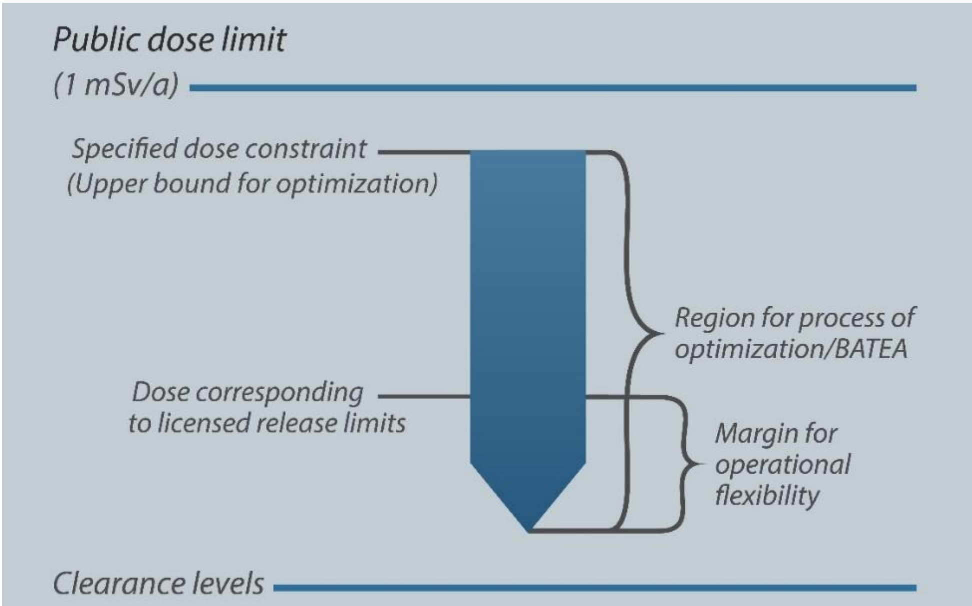
B.1 ~~Radiation~~ Optimization of Protection ~~Principles~~ and ~~BATEA~~Pollution Prevention

~~Optimization and authorized releases~~**The radiation protection principle of optimization of protection can be considered as complementary to the** ***~~environment (licensed release limits)~~***

environmental protection principle of pollution prevention. In practice, ~~optimization~~ the application of BATEA is ~~BATEA regarding~~part of optimization of protection that is specific to the minimization of contaminant pollution ~~and controls~~through the control on ~~the~~ 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). ~~Optimization of protection can be considered as complementary to the concept of pollution prevention (a core principle of the environmental protection measures described in REGDOC-2.9.1 [1]).~~

Figure B1 shows a general relationship between optimization and the authorization of radioactive releases to the environment (that is, licensed release limits). Through optimization ~~(demonstrated by the application of BATEA),~~, 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 (μSv) 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[1]



When applying the concept of optimization to establish licensed release limits, modelled doses approximating 10 µSv/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 µSv/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

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

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 ~~quantities and concentrations~~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 take into account a margin for operational flexibility to account for anticipated operations throughout the remaining lifecycle of the facility.

The MPDRCs are used 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 ~~will~~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 ~~maximum predicted design releases~~MPDRCs, which now form part of the licensing basis of the facility, are then 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 ~~the~~ a scenario using environmental risk assessment (ERA) methodology to confirm that the environment will be protected.

Since the licensed release limits represents 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 ~~maximum predicted design release~~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.

~~It should be noted that there is a clear distinction between action levels and licensed release limits as described below.~~

Action levels are operationally/performance-based~~ and represent~~, are derived using the ~~upper bound of~~ current ~~(most recent historical) operational performance, and thus are expected to periodically be reached.~~upper value of normal operation and lie within the maximum upper-end of normal operation (that is, licenced release limit). Licensed release limits that are based on the maximum predicted design release depend on the design of the facility~~, which in itself is risk-informed~~ and represent the maximum upper-end of normal operation over the entire lifecycle of the facility.

~~Action levels are based on the most recent (e.g., 5-year) operating history of the facility, and therefore change over time, either increasing or decreasing, depending on the day-to-day changes of the operation that lies **within** the current licensing basis. Licensed release limits do not change over time as stated above.~~

~~Exceeding an action level signals a potential loss of control (i.e., 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 (i.e., red light), and that the facility is operating outside of its approved facility design, and hence its licensing basis.~~

~~In this approach,~~ For existing facilities, there ~~is~~should be sufficient margin between ~~triggering an action level and triggering a licensed release limit.~~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 ~~compared to the operational monitoring program results (i.e.,~~based on a prospective approach to account for operational uncertainty (in accordance CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities* [7]). In 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~~. Licensed release limits~~, designed in accordance with CSA N288.5, *Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills* [4], are ~~compared to periodic average~~assessed against the action levels to determine whether an action level has been reached. Monitoring results ~~(i.e., monthly~~ averaged over a longer period (for example, weekly, monthly or bi-annual average concentrations~~). This allows for several action level exceedances to occur before triggering a licensed release limit. It also~~) 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 ~~an~~the triggering of these action ~~level exceedance~~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 ~~concentrations or the quantities~~(s) characteristics (MPDRCs) 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:

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 ~~based on~~. 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 release point and contaminant or physical stressor identified as requiring control, identify the most restrictive criteria for each of the following:
   - most sensitive species or human receptors (generic or site-specific)
   - most reasonable 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 ~~ambient~~ air for the protection of human health, a 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 ~~(e.g., Ontario Ministry of Environment and Climate Change).~~.

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 Mixing zones~~

C.5.2.1 Dilution Factors

For calculating the environmental release targets:

- where federal, provincial, or territorial guidance exists for ~~mixing zones~~dilution factors, the licensee should follow that guidance
- where such guidance does not exist ~~for mixing zones~~, the licensee should apply the general ~~mixing zone~~ 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 Environmen*t, 2nd Edition [25])

Release point	~~Maximum mixing zone~~ 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
~~Ambient~~ 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 ~~aerial~~spatial extent of the initial mixing zone (also called a dilution zone), see provincial mixing zone guidance (for example, reference [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.

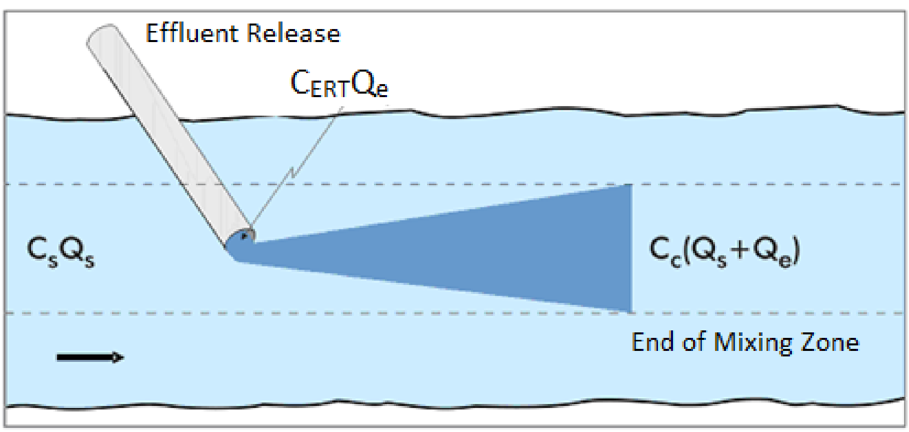
The licensee should use an exposure-based approach, where the calculation considers:
- an appropriate mixing zone in the final receiving waterbody applied only to the volume of effluent released prior to mixing with cooling water discharge
- additional dilution provided by the volume of cooling water discharge

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

~~C.5.2.3~~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 B.1.

Figure C.1: Elements of the loading mass balance



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

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

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,

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

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

A dilution factor can be defined as, $Fd = \frac{Q_e}{Q_s+Q_e}$ [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.

$$C_{ERT} = \frac{C_c-C_s}{Fd} + C_s \qquad [5]$$

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 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 releases~~MPDRCs
- 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* [27], which includes terms and definitions used in the *Nuclear Safety and Control Act* (NSCA) and the regulations made under it, and in CNSC regulatory documents and other publications. REGDOC-3.6 [27] 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* [27].

action level *(seuil d'intervention)*
An indicator of a potential loss of control of part of a licensee's program(s) or control measure(s). Exceeding an action level signals a potential reduction in effectiveness of the program and/or control measure(s) and may indicate a deviation from normal operation. Exceeding an action level is not a non-compliance, but triggers a requirement for specific action to be taken.

acutely lethal effluent *(effluents à létalité aiguë)*
Acutely lethal, in respect of an effluent, means that the effluent at 100% concentration kills more than 50% of the test organisms subjected to it for a period of 96 hours, when tested in accordance with the appropriate acute lethality test method specified below:

Where the salinity of the effluent is:
a) less than ten parts per thousand and the effluent is deposited into fresh waters, the specified test method is Reference Method EPS 1/RM/13 [1] and – if applicable – used in conjunction with the Procedure for pH Stabilization EPS 1/RM/50 [2].
b) equal to or greater than ten parts per thousand and the effluent is deposited into marine waters, the specified test method is Reference Method EPS 1/RM/10 [3].

References:
1. Biological Test Method: Reference Method for Determining Acute Lethality of Effluents to Rainbow Trout (EPS 1/RM/13 Second Edition), December 2000 (with May 2007 amendments), published by the Department of the Environment, as amended from time to time.
2. Procedure for pH Stabilization During the Testing of Acute Lethality of Wastewater Effluent to Rainbow Trout (EPS 1/RM/50), March 2008, published by the Department of the Environment, as amended from time to time.
3. Biological Test Method: Reference Method for Determining Acute Lethality Using Threespine Stickleback (EPS 1/RM10 Second Edition), December 2017, published by the Department of the Environment, as amended from time to time.

constraint *(contrainte)*
From the *IAEA Safety Glossary*
A prospective and source related value of individual dose (see dose constraint) or of individual risk (see risk constraint) that is used in planned exposure situations as a parameter for the optimization of protection and safety for the source, and that serves as a boundary in defining the range of options in optimization.

interim period *(période provisoire)*
With respect to environmental protection, the time from when adaptive management is triggered through to the completion of commissioning of the new treatment system or other control measures.

licensed limit *(limite autorisée)*
A limit that 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 ~~release~~ 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 ~~release~~ limit is a non-compliance and triggers a requirement for the licensee to take specific action.
Note: The licensed ~~release~~ limits may include any limits specified in the licensing basis.

licensed release limit *(limite de rejet autorisée)*
A limit that is part of the licensing basis and, if exceeded, represents a loss of control of part of the licensee's environmental protection program(s) or control measure(s). Exceeding a licensed release 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 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.

limitation *(limitation)*
With respect to environmental protection, a radiation protection principle that specifies the value of a quantity used in certain activities or circumstances that must not be exceeded, such as the public dose limit.

major modification *(modification majeure)*
A modification that requires a change to the licensing basis (that is, a licence amendment) 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)

maximum predicted design release characteristics *(caractéristiques des rejets nominaux maximaux prévus)*
In accordance with the *Class I Nuclear Facilities Regulations* and the *Uranium Mines and Mills Regulations*, the proposed location of the points of release, the proposed maximum quantities~~,~~ and concentrations~~ and volumes plus operational margin) that are~~, and the anticipated~~, following~~ 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.

mixing zone *(zone de dilution)*
An area where an effluent discharge undergoes initial dilution and is extended to cover the secondary mixing in the ambient water body. A mixing zone is an allocated impact zone where water quality criteria can be exceeded so long as acutely toxic conditions are prevented. At the end of this zone, which determines the volume of water allotted for effluent dilution, the specified water quality criteria must be respected. The allocation of a mixing zone rests on the principle that a small zone of degradation can exist without harming the sustainability of the ecosystem as a whole.

normal operation *(exploitation normale)*
The operation of a nuclear facility within specified operational limits and conditions, including (where applicable) start-up, power operation, shutting down, shutdown, maintenance, testing and refuelling. In nuclear reactors, normal operation is a plant state.
Note: Normal operations for any nuclear facility are those associated with the approved licensed activities. This includes the normal operation of any treatment system(s) during refurbishment or decommissioning, as defined by the approved licensed activities, and the specified operational limits and conditions documented within the facility's licensing basis.

optimization *(optimisation)*
With respect to environmental protection, the process of determining what level of protection and safety makes exposures and the probability and magnitude of potential exposures as low as reasonably achievable, economic and social factors being taken into account.

planned exposure *(exposition prévue)*
The situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure due to a source.

- Since provision for protection and safety can be made before embarking on the activity concerned, associated exposures and their probabilities of occurrence can be restricted from the outset.
- The primary means of controlling exposure in planned exposure situations is by good design of installations, equipment and operating procedures. In planned exposure situations, a certain level of exposure is expected to occur.

point of impingement (POI) *(point d'impact)*
The nearest point where air contamination emitted by a source impinges on a building or beyond the property line; any point on the ground or on a receptor, such as nearby buildings, at which the highest concentration of a contaminant caused by the aggregate emission of that contaminant from a facility or activity is expected to occur. ~~**Note:** For a facility, the point of impingement occurs outside the facility's property boundaries.~~

regulatory public dose limit *(limite de dose réglementaire au public)*
The prescribed limit for the general public, as specified in the *Radiation Protection Regulations*. This limit is 1 milliSievert (mSv) per calendar year, and it protects the public from radiation resulting from the normal operation of a nuclear facility or activity regulated under the *Nuclear Safety and Control Act*.

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.
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6. CSA Group, CSA N288.7, *Groundwater protection programs at Class I nuclear facilities and uranium mines and mills.*
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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.
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11. CNSC, REGDOC-2.6.3, *Aging Management*, Ottawa, Canada, 2014.
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14. CNSC, REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants*, Ottawa, Canada, 2016.
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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.
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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, 2nd Edition, 2007 (translation, 2008).
26. CNSC, REGDOC-2.2.2, *Personnel Training*, Ottawa, Canada, 2016.
27. CNSC, REGDOC-3.6, *Glossary of CNSC Terminology*, Ottawa, Canada, 2018.

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).
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- 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:

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1.2 Class IB facilities
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1.4 Class II facilities
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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
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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.

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2. R. Liam Mooney (Cameco), J. Colin Braithwaite (Orano). Letter to P. Elder (CNSC). “Feedback on Residual Issues with REGDOC-2.9.2, *Controlling Releases to the Environment*” 7 Dec 2023.
3. International Atomic Energy Agency (IAEA) Integrated Regulatory Review Service (IRRS) to Canada IAEA0NS-IRRS-2019/05, Ottawa, Canada https://www.iaea.org/sites/default/files/documents/review-missions/irrs_canada_2019_final_report.pdf
4. International Atomic Energy Agency (IAEA). (2014). General Safety Requirements Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards. https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf