# NEW CSA GUIDELINE FOR THE EXEMPTION OR CLEARANCE FROM REGULATORY CONTROL OF MATERIALS THAT CONTAIN, OR POTENTIALLY CONTAIN, NUCLEAR SUBSTANCES

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## ABSTRACT

The Canadian Standards Association (CSA) guideline N292.5, *Guideline for the exemption or clearance from regulatory control of materials that contain, or potentially contain, nuclear substances* [1], was recently developed to address a need for guidance on approaches for clearance of materials from facilities licensed by the Canadian Nuclear Safety Commission (CNSC) consistent with Canadian and international recommendations. This guideline is also applicable to determining if an activity associated with materials that contain nuclear substances is exempt from requiring a CNSC licence. The guideline summarizes the regulatory requirements associated with the exemption and clearance of materials and provides a graded approach to designing a survey based on the risk of residual contamination being present.

## 1. INTRODUCTION

The Canadian Standards Association (CSA) guideline N292.5, *Guideline for the exemption or clearance from regulatory control of materials that contain, or potentially contain, nuclear substances* [1], was issued in July 2011 to provide guidance on developing and implementing procedures for clearance of materials from facilities licensed by the CNSC. The guideline is consistent with Canadian and international recommendations and provides a graded approach to designing and implementing surveys for clearance of materials. The guideline is also applicable to determining if an activity associated with materials that contain nuclear substances is exempt from requiring a CNSC licence.

The purpose of the guideline is to promote a standardized approach to applying clearance and exemption criteria by:

- summarizing the CNSC regulatory requirements associated with the concepts of clearance and exemption as defined by the International Atomic Energy Agency (IAEA);
- clarifying the source and use of conditional and unconditional clearance levels and exemption quantities;
- providing a summary of a structured approach that can be used to plan and execute surveys for demonstrating compliance with clearance and exemption criteria; and
- identifying where additional detailed guidance is available.

The scope of the guideline includes solids targeted for re-use, recycling or disposal including materials, equipment, building structures (*in situ*), building materials from demolition activities,

lands (*in situ*), and excavated soils. The applicability to non-effluent liquids associated with licensed activities is also addressed.

The scope of the document does not include following items:

- application of the concept of exclusion as defined by the IAEA;
- activities excluded in the *Nuclear Safety and Control Act*, and regulations made under that Act, or requirements associated with Canada's Department of National Defence;
- naturally occurring radioactive material (NORM) and technologically enhanced NORM (TENORM), other than NORM and TENORM that is or has been associated with the development, production or use of nuclear energy, which are addressed by Health Canada;
- radioactive effluents from CNSC-licensed nuclear facilities which are addressed in CSA N288.5; and
- medical patient waste.

The guideline is primarily intended for use by CNSC licensed facilities but also addresses exemption for use by unlicensed facilities and may also be a useful reference for unlicensed facilities that receive or are involved with the lifecycle of cleared material (e.g. organizations involved in the transfer, import, export, management, storage, recycle, reuse, disposal, etc. of cleared material).

## 2. DOCUMENT HISTORY

In 2004, the CNSC issued draft S-307, *Requirements for the Disposal of Nuclear Substances* [2], for public consultation. Draft S-307 included proposed clearance criteria as well as some guidance on how to apply the criteria.

As a result of the industry review, the CNSC placed S-307 on hold and focused on a project that had already been initiated, the revision and update to the Nuclear Substances and Radiation Devices Regulations (NSRDR) (SOR/2000-207) [3]. The revision to these regulations incorporated some of the clearance criteria proposed in S-307. In 2008, the CNSC completed the revision which included the following changes.

- Adoption of the activity concentration values recommended in the IAEA Safety Guide No. RS-G-1.7, *Application of the Concepts of Exclusion, Exemption and Clearance* (2004) [4], as generic unconditional clearance levels for bulk materials.
- Adoption of the Exemption Quantities recommended in IAEA Safety Series No. 115, *International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources* (BSS) (1996) [5], as generic criteria for both exemption and clearance of moderate quantities of materials.
- Inclusion of requirements for the development and use of conditional clearance levels for specific disposition paths.

Subsequent to the revision to the NSRDR, the CNSC approached the CSA about developing a document to provide guidance on applying the requirements in the NSRDR as a replacement to the draft S-307. In 2008, the CSA technical committee on radioactive waste management

(N292) formed a sub-committee to develop a guideline that included representatives from the following organizations:

- AMEC NSS
- Atomic Energy of Canada Ltd
- Bruce Power
- Cameco Corporation
- Canadian Nuclear Safety Commission
- CSA Standards
- MONSERCO/EnergySolutions Canada
- Hydro-Quebec
- MDS Nordion
- NB Power Nuclear Corporation
- Ontario Power Generation Inc
- SENES Consultants Limited
- University Health Network

## 3. DOCUMENT STRATEGY

The approach provided in the guideline is based on the Data Quality Objective (DQO) process. The DQO process is a flexible planning tool that can be applied in a graded manner depending on the complexity of the situation. The process provides a basis for developing monitoring strategies and procedures that balance decision uncertainty with available resources in a manner that is satisfactory to both the CNSC and the licensee. Within the context of clearance surveys, this is accomplished by:

- defining the scope, complexity, and hazards associated with the survey;
- identifying the decisions to be made based on measurement data;
- specifying the quality requirements for the decisions and measurement data; and
- developing a defensible survey plan acceptable to all stakeholders.

The guideline also incorporates the four phases of the data life cycle as they apply to planning and implementing clearance surveys. The data life cycle includes a:

- planning phase;
- implementation phase;
- assessment phase; and
- decision-making phase.

The DQO process is primarily associated with the planning phase where the data quality objectives (DQOs) are defined and the survey design is developed and documented. Data quality requirements are defined according to the type of survey being designed, the risk of making a decision error based on the data collected, and the consequences of making such an error.

The guideline is intended as a summary of how the DQO process can be applied to designing and implementing clearance surveys in a manner that will be acceptable to the CNSC. The document is laid out in the following structure:

- Scope – Clause 1
- References and definitions – Clauses 2 - 3
- Regulatory requirements – Clause 4
- Summary of clearance process – Clause 5
- Process details – Clauses 6 - 12
- QA considerations – Clause 13
- Interpretation of NSRDR requirements – Annex 1
- Summary of the DQO process – Annex 2
- Example scenario – Annex 3

The following references were the primary guidance used to develop the guideline.

- NUREG-1575, *Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)*
- NUREG-1575 Supplement 1, *Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME)*
- NUREG-1640, *Radiological Assessments for Clearance of Materials from Nuclear Facilities*
- EPA QA/G-4, *Guidance on Systematic Planning Using the Data Quality Objectives Process*
- UK Exemption and Clearance Code of Practice, *Clearance and Exemption Principles, Processes and Practices for Use by the Nuclear Industry*
- Draft IAEA document, *Monitoring for Compliance with Exemption and Clearance Values*

The guideline incorporates the statistical concept of hypothesis testing as a means of assessing two assertions regarding the actual level of radioactivity present in the material being monitored (e.g., above or below the clearance levels). It also adopts the material classification and survey class concepts provided in MARSSIM [6] and MARSAME [7] to provide a basis for developing a graded approach to determining the degree of effort required to assess the radiological status of a material.

The concepts and parameters associated with the statistical decision making process, as applied in the guideline, are summarized in Table 1.

**Table 1. Inputs into the statistical decision making process.**

| Source | Parameter/concept | Description |
|---|---|---|
| Regulatory requirement (*NSRDR or Licence*) | Exemption quantity | Prescribed for moderate quantities of material (radionuclide specific in Bq/g and total Bq) |
| | Unconditional clearance level | Prescribed for bulk quantities of material (radionuclide specific in Bq/g) |
| | Conditional clearance level | Developed for a specified disposition path based on potential dose to the public |
| Regulatory requirement (*Licence* or as agreed to by the CNSC) | Surface contamination limit | Prescribed for surface contaminated materials in the licence or in a supporting document accepted by the CNSC (may be radionuclide, or radiation specific in $Bq/cm^2$) |
| User-defined requirement | Action level | Criteria for deciding between alternative actions - developed by user based on the regulatory requirements, radionuclides that may be present, and type of measurements to be taken |
| Input into statistical decision making | Decision rule | Process used for deciding between alternative actions based on measurement data - developed by user to comply with regulatory requirements |
| | Decision errors | |
| Operational guideline | Discrimination limit | Developed by the user based on the expected average radioactivity level - the ratio of the difference between the action level and discrimination limit to the expected measurement variance determines the survey effort required |

## 4. REGULATORY ISSUES

The generic clearance criteria provided in the NSRDR only apply to materials where the radioactive nuclear substance(s) are uniformly distributed within the material. The NSRDR does not provide any default criteria for surface contaminated materials which are normally addressed in individual licences issued by the CNSC or in supporting documentation prepared by the licensee that has been accepted by the CNSC. In some cases, the CNSC may also define

volumetric clearance criteria in a licence which is only applicable to the licensee's activities and therefore considered 'conditional clearance criteria'.

There are two key areas of confusion when interpreting the requirements of the NSRDR. These are:

- how the concepts of 'exemption' and 'clearance', as defined in IAEA RS-G-1.7, relate to the criteria for 'exemptions from licence requirement' defined in Sections 5 and 5.1 of the NSRDR; and
- the application of exemption quantities as the default unconditional clearance criteria for moderate quantities of materials (i.e., less than 1000 kg of material per year per nuclear facility).

The NSRDR does not define or clarify the concepts of 'exemption' or 'clearance' when stating the conditions under which an activity can be conducted "without a licence" in sections 5 and 5.1. In general, the exemption process is used to determine if a licence is required initially for an activity and the clearance process is used to determine if a material can be released or removed from a licensed activity. The NSRDR term 'exemptions from licence requirements' applies to both of these concepts. Typically, the clearance process is used to release materials for recycling, reuse, or disposal that are considered suspect until proven otherwise because of the radiological controls associated with operation of a licensed facility. The guideline provides an interpretation of how these concepts apply to the NSRDR requirements and criteria.

The criteria provided in the NSRDR include Exemption Quantities (EQs) in Schedule 1, Unconditional Clearance Levels (UCLs) in Schedule 2, dose limits for developing conditional clearance levels, and the requirements for addressing radionuclide mixtures. The UCLs are applicable to bulk materials (i.e., > 1000 kg/year/facility) and are typically at concentrations (Bq/g) that are two orders of magnitude lower than the EQ concentrations. The NSRDR allows the use of EQs for clearance of moderate quantities of materials (i.e., ≤ 1000 kg/year/facility) however, this is not obvious or clearly stated. The guideline provides the justification for how this is applied.

## 5. SUMMARY OF THE CLEARANCE PROCESS

The DQO process provides a structured approach to planning and executing the clearance of materials that strives to balance decision uncertainty with available resources in a manner that is acceptable to all stakeholders. The DQO approach is iterative in nature with the intent of developing an optimized approach while limiting the probability of decision errors.

Table 2 provides a brief summary of the DQO steps and how they apply to the clearance process.

**Table 2. DQO process as applied to the clearance process.**

| DQO Process | Clearance Process |
|---|---|
| State the problem | Is there radioactive contamination present in excess of clearance criteria? |
| Identify the goal of the study | Determine the radiological status of the item, material, or structure with respect to potential contaminants and the associated clearance levels. |
| Identify the information inputs | Specify the necessary information required to determine the potential contaminants, disposition options, appropriate clearance levels, and associated risk of residual contamination being present. |
| Define the boundaries of the study | Specify limits for which the survey method is valid. |
| Develop the analytical approach | Create decision rules as a basis for drawing conclusions from measurement results. |
| Specify performance or acceptance criteria | Define required detection sensitivity and limits on decision errors. |
| Develop the plan for obtaining data | Finalize survey methodology and prepare a survey design. |

The clearance process as it is presented in the guideline consists of seven steps. The following summarizes these steps within the context of the data life cycle.

### 5.1 Planning phase

Step 1: Perform an initial assessment

- Review historical information
- Identify potential contaminants (radiological and non-radiological)
- Identify risk of residual contamination
- Identify materials requiring clearance monitoring
- Assess material physical, radiological and hazardous attributes
- Propose suitable disposition methods

Step 2: Develop a decision rule

- Determine appropriate clearance criteria
- Define how measurement results are used and the parameters of interest
- Incorporate acceptable decision errors
- Identify possible actions based on the monitoring result
- Define the survey envelope
- Select provisional measurement methods
- Identify background reference materials

Step 3: Develop a monitoring strategy

- Define measurement and sampling requirements and proposed measurement methods
- Account for material segregation requirements
- Identify surrogates for hard to detect radionuclides

### 5.2 Implementation phase

Step 4: Select the measurement techniques and instrumentation

- Define health and safety considerations
- Define material preparation, handling, segregation, and transportation requirements
- Set measurement quality objectives
- Consider practicality of implementation and cost
- Finalize measurement method and instrumentation
- Set quality control requirements

Step 5: Implement the survey

- Obtain appropriate background measurements
- Execute survey and record the results
- Consider effects of environmental conditions on instrument performance

### 5.3 Assessment phase

Step 6: Interpret and report the results

- Simple scenarios may require little documentation and no additional approvals (decide as you go)
- Complex scenarios may
  - Incorporate statistical tests
  - Require significant documentation
  - Require additional approvals

- Require independent evaluation or verification

### 5.4 Decision-making phase

Step 7: Finalize the disposition method

- If clearance survey passes, disposition method used to develop the decision rule is applied (unconditional or conditional clearance)
- If clearance survey fails, an alternative disposition path is used
  - Conditional clearance if intended disposition path is unconditional clearance
  - Reuse with radiological controls
  - Decontamination and resurvey
  - Storage for radiological decay
  - Storage or disposal as radioactive waste

The guideline adopts an iterative approach that encourages revisiting inputs into the process as additional information is obtained regarding the material to be cleared, the contaminants to be measured, the measurement methods and equipment that are available, and any updates to the disposition options. The intent is to ensure an optimized approach is developed prior to survey implementation.

## 6. FUTURE PLANS

Additional annexes are planned for the next revision to the guideline that includes examples of simple and complex scenarios as well as suggested approaches for addressing issues such as acceptable measurement averaging methods. The CSA also solicits feedback from the practitioners of the guideline on areas where additional clarification and information would enhance the use of the guideline.

## 7. REFERENCES

[1] CSA N292.5, Guideline for the exemption or clearance from regulatory control of materials that contain, or potentially contain, nuclear substances (July 2011)

[2] CNSC Draft S-307, Requirements for the Disposal of Nuclear Substances

[3] CNSC, Nuclear Substances and Radiation Devices Regulations (NSRDR) (SOR/2000-207)

[4] IAEA Safety Guide No. RS-G-1.7, Application of the Concepts of Exclusion, Exemption and Clearance (2004)

[5] IAEA Safety Series No. 115, International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources (BSS) (1996)

[6] NUREG-1575, Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) (2000)

[7] NUREG-1575 Supplement 1, Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME) (2009)