Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

DRAFT
REGULATORY
GUIDE

# Environmental Monitoring Program at Class I Nuclear Facilities and Uranium Mines and Mills

G–224

Issued for public comment

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# REGULATORY DOCUMENTS

The legal framework within which the Canadian Nuclear Safety Commission (CNSC) operates includes the *Nuclear Safety and Control Act*, its Regulations and other legal instruments such as licences, certificates and orders. The legal framework is supported by regulatory documents issued by the CNSC, the main classes of which are:

**Regulatory Policy (P):** a document that describes the philosophy, principles or fundamental factors that underlie the CNSC's approach to its regulatory mission. It provides direction to CNSC staff and information to stakeholders.

**Regulatory Standard (S):** a document that describes CNSC requirements. It imposes obligations on the regulated party, once it is referenced in a licence or other legally enforceable instrument.

**Regulatory Guide (G):** a document that indicates acceptable ways of meeting CNSC requirements, as expressed in the Act, Regulations, regulatory standard or other legally-enforceable instrument. It provides guidance to licensees and other stakeholders.

**Regulatory Notice (N):** a document that provides licensees and other stakeholders with information about significant matters that warrant timely action.

# DRAFT REGULATORY GUIDE

## Environmental Monitoring Program at Class I Nuclear Facilities and Uranium Mines and Mills

## G–224

**Month/Year of Publication**

**About this Document**

This draft Regulatory Guide describes how applicants for licences in respect of Class I nuclear facilities and uranium mines and mills can develop the environmental monitoring program required by the regulations.

Comments

The CNSC invites interested persons to assist in the further development of this draft regulatory document by commenting in writing on its content and potential usefulness. Please respond by October 15, 2004. Direct your comments to the postal or e-mail address provided below, referencing file 1-8-8-224.

The CNSC will take the comments received on this draft into account when developing it further. These comments will be subject to the provisions of the federal *Access to Information Act*.

**Document availability**

This document can be viewed on the CNSC Internet web site at www.nuclearsafety.gc.ca. To order a printed copy in English or French, please contact:

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DRAFT REGULATORY GUIDE

**G–224**

# ENVIRONMENTAL MONITORING PROGRAM AT CLASS I NUCLEAR FACILITIES AND URANIUM MINES AND MILLS

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# ENVIRONMENTAL MONITORING PROGRAM AT CLASS I NUCLEAR FACILITIES AND URANIUM MINES AND MILLS

## 1.0 PURPOSE

The purpose of this Regulatory Guide is to help applicants for licences in respect of Class I nuclear facilities and uranium mines and mills, other than licences to abandon, develop environmental monitoring programs (EMP) in accordance with the *Nuclear Safety and Control Act* (“*NSC Act*,” “*Act*”) and regulations.

## 2.0 SCOPE

The document describes how applicants for licences in respect of Class I nuclear facilities and uranium mines and mills can develop the environmental monitoring program required by the regulations.

## 3.0 RELEVANT LEGISLATION

The following legislation is relevant to the proposed Regulatory Guide:

Paragraph 3(h) of the *Class I Nuclear Facilities Regulations*, which stipulates that an application for a CNSC licence, other than a licence to abandon, shall contain, in addition to other information, “the proposed... environmental monitoring program;” and

Paragraph 3(c)(vi) of the *Uranium Mines and Mills Regulations*, which stipulates that an application for a licence in respect of a uranium mine or mill, other than a licence to abandon, shall contain, in addition to other information, “the proposed … environmental monitoring program.”

## 4.0 TERMINOLOGY

The Glossary at the end of the document defines the special terms used in this regulatory guide.

## 5.0 ENVIRONMENTAL MONITORING PROGRAM

An EMP is an integrated and documented set of activities implemented to sample, measure and analyze the following items:

1. Hazardous and/or nuclear substances (herein referred to as “substances”), and
2. Physical and biological parameters in the environment.

The EMP demonstrates that adequate measures have been taken to protect the environment and to keep radiation doses to members of the public as low as reasonably achievable (ALARA), social and economic factors taken into account.

The environment is defined as the components of the Earth, including (a) land, water and air, including all layers of the atmosphere; (b) all organic and inorganic matter and living organisms and; (c) the interacting natural systems that include those components referred to in (a) and (b).

The EMP is based on facility characteristics, environmental characteristics, and the anticipated environmental effects. An EMP is designed to be appropriate to the nature and scale of the licensed activity.

The EMP shall contain five separate elements, as described in the documents listed below:

1. Design Document;
2. Staff Qualifications and Training Document;
3. Quality Assurance and Quality Control (QA/QC) Document for Field and Laboratory Activities;
4. Sampling and Analytical Procedures Document; and
5. Audit and Review Process Document.

Sections 5.2 to 5.6 describe the requirements of each document in further detail.

The EMP should instill confidence that mitigation measures are effective, and that health and environmental effects will remain acceptably low. An EMP should consist of either Pathways Contaminant Monitoring (PCM) or PCM in combination with Biological Effects Monitoring (BEM). PCM confirms that pathways model predictions are accurate and conservative for the fate and transport of substances, and human/non-human biota exposures. BEM confirms that the magnitude and extent of the predicted effects to non-human biota remain at acceptable levels.

## 5.1 Risk-Based Approach to an Environmental Monitoring Program

The need for and the scope of an EMP depend on the level of risk posed by the facility's anticipated release of substances into the environment. Facilities are classified into low-, medium- or high-risk categories based on anticipated releases of substances and their environmental effects.

### 5.1.1 Low-Risk Facilities

Licensed facilities with no measurable releases of substances into the environment are classified as low-risk and therefore do not need an EMP. Licensees may demonstrate that their provisions are adequate to protect the environment and the health of persons through other means (e.g., effluent monitoring, modelling).

Licensed facilities with detectable releases of substances to the environment and that meet all of the conditions described below, also fall into the low-risk category and are exempt from developing an EMP:

1. Levels of substances are demonstrated to be below known effect levels (including safety margins) (e.g., CCME *Water Quality Guidelines* [2] for the *Protection of Freshwater Aquatic Life,* and sediment *Probable Effect Levels and Toxic Effect Levels*).
2. Substances released by a facility are not environmentally persistent or predicted to bioaccumulate or biomagnify.

3. Levels of substances in the environment are demonstrated to be indistinguishable from the natural background.

### 5.1.2 Medium-Risk Facilities

Medium-risk facilities release substances to the environment and fail to meet all of the conditions defined for classification as low-risk. However, the releases from these facilities are unlikely to affect human health or non-human biota, as determined by a risk assessment. An EMP consisting of PCM should be implemented for medium-risk facilities.

### 5.1.3 High-Risk Facilities

High-risk facilities release substances to the environment that are at levels or under conditions that may adversely affect non-human biota, as determined by a risk assessment. An EMP consisting of both PCM and BEM should be implemented for high-risk facilities.

## 5.2 Document on Design of Environmental Monitoring Program

### 5.2.1 Objectives of an Environmental Monitoring Program

The key objectives of the overall EMP are to

1. obtain data that demonstrate that controls effectively prevent unreasonable risks to public health and the environment; and
2. confirm that the facility’s anticipated environmental effects and radiation doses to members of the public remain below the levels documented in the licence application.

#### 5.2.1.1 Objectives of Pathways Contaminant Monitoring

The scope (extent and frequency) of PCM is commensurate with the risk and is designed to meet the following objectives:

1. Estimate actual or potential exposures to members of the public and non-human biota from measured substances in the environment;
2. Assess levels, detect changes and evaluate long-term trends in substance behaviour in the environment;
3. Assess performance on exposures against any applicable regulatory limits, standards, guidelines, operating limits (e.g., administrative limits and action levels), performance indicators, or other accepted criteria and objectives;
4. Obtain knowledge of the correlation between substance releases and observed levels in the environment to improve the basis for future predictions and the estimation of levels that might arise should emergency or unplanned releases and spills occur;
5. Verify environmental transfer models by validation of model parameters and assumptions used in the calculation of exposures of human and non-human biota to substances released to the environment;

6. Check sub-critical pathways by determining the fate of released substances; and
7. Identify unconsidered pathways and modes of exposure or changes in the relative importance of known pathways in the risk assessment.

#### 5.2.1.2 Objectives of Biological Effects Monitoring

The primary objective of BEM is to detect biological effects that indicate population or community level impacts for non-human biota. BEM measures the biological characteristics of organisms that may be adversely affected by released substances. These characteristics may be measured in individual organisms (e.g., gonad weight), populations (e.g., number of organisms, age structure) or communities (e.g., species composition). If the magnitude, spatial or temporal extent of the measured effect exceeds those anticipated, then the cause and effect relationship is investigated.

### 5.2.2 Designing an EMP

An effective EMP design helps meet the objectives of an EMP. The design requires supportive information on the facility characteristics, environmental characteristics, anticipated environmental effects, and anticipated radiation doses to members of the public.

#### 5.2.2.1 Environmental Characteristics

Environmental characteristics describe the abiotic and biotic features of a facility's site and surrounding environment. Documentation of these regional and local environmental characteristics is important for three reasons:

1. To establish the current state of the environment (i.e., substances that occur naturally and from anthropogenic activities);
2. To document the environmental factors that will influence the fate and transport (e.g., transformation/degradation, volatilization, sorption) of any substance that may be released from the facility and, therefore, potentially affect the exposure levels to non-human biota and humans; and
3. To document non-human biota, sensitive habitats, and humans potentially exposed to substances that may be released from the facility.

The factors influencing fate and transport range from regional environmental influences (e.g., climate and meteorology) to local environmental influences (e.g., site specific pH, redox potential, organic composition and particle size). These factors help to identify the abiotic components of the environment likely to contain or accumulate substances in measurable quantities that may require monitoring.

Characterization of the biotic components of the environment serves as the starting point for identifying the habitats or non-human biota that should be considered when monitoring for potential biological effects. Selected biotic components should be representative of the environment that the licensee, members of the public, the scientific community, and the federal government consider important (e.g., environmentally sensitive habitats, rare or endangered species, ecologically key species, commercial species).

Information on land use patterns by members of the public around the facility is needed to define the characteristics of the critical group or groups (e.g., location of farms in urban, rural, and industrial areas; well-water use; and unusual dietary patterns). Information on the dietary patterns and traditional activities may be needed to define the characteristics of special critical groups (e.g., First Nations).

The licensee may obtain information on environmental characteristics using a variety of sources. Some examples of where this information may be obtained include the following documents:

1. A description of the environmental baseline characteristics of the site, effects assessments, or both completed to meet Canadian Nuclear Safety Commission (CNSC) licence application requirements;

2. Environmental assessments conducted through the *Canadian Environmental Assessment Act*;

3. Environmental impact statements conducted through Environmental Assessment Review Guidelines Order;

4. Land use surveys conducted by licensees or governments (municipal, provincial, or federal);

5. Maps identifying eco-zones or eco-regions; or

6. The list from the Committee on the Status of Endangered Wildlife in Canada (COSEWIC) on Canadian species at risk.

#### 5.2.2.2 Facility Characteristics

Facility characteristics include facility-specific structures, processes, substances, and waste sources that may influence the environment. Information on the releases should include

1. points of entry to the environment;
2. maximum quantities and concentrations; and
3. volume and flow rate into the environment, including physical, chemical and radiological characteristics. [18] [19]

#### 5.2.2.3 Anticipated Environmental Effects and Radiation Doses to Members of the Public

Licensees can obtain information on the anticipated environmental effects and radiation doses to members of the public from environmental assessments completed for the facility. These may include one or more of the following documents:

1. Environmental assessments conducted through the *Canadian Environmental Assessment Act*;
2. Environmental impact statements conducted through the Environmental Assessment Review Guidelines Order;

3. Ecological risk assessments;
4. Human health risk assessments;
5. Facility safety reports; and
6. Derived release limit assessments.

Information extracted from these assessments supports the identification of major substance pathways, predictions of substance levels in various environmental media, and the predictions of potential effects on humans and non-human biota. The following elements from the risk assessment provide the data necessary to design the EMP:

1. Environmental effects and radiation doses to members of the public predicted for the facility;
2. Significant substances and their exposure pathways for humans and non-human biota;
3. The sensitive sampling component (e.g., air, water, soil, sediment, biota) in significant pathways;
4. Appropriate sampling endpoint representing the sensitive component; and
5. Appropriate sampling locations (e.g., near-field, far-field, reference or control) for monitoring temporal and spatial patterns in substance levels.

#### 5.2.2.4 Designing Pathways Contaminant Monitoring

PCM component is designed for humans and non-human biota. The selection of components for field monitoring within a pathway is based on substance characteristics; the environment; and the critical group, non-human biota, or both. PCM should include components expected to accumulate substances over time. In complex pathways, the most sensitive components should be monitored because of their influence on the anticipated effects or proximity to any pathway linking directly to the critical group or non-human biota (e.g., milk for exposure to infants from substances released to the atmosphere, or sediments for exposure to benthic invertebrates from substances released to the surface water). In some cases, the key components consist of organisms consumed by humans or non-human biota.

As a minimum, the design should consist of a near-field study area and a reference study area. High-risk facilities may need a more complex PCM capable of defining the spatial extent of an effect. The near-field study area represents sampling locations where the highest substance levels are predicted to occur. This includes locations where critical groups or non-human biota can reasonably expect to receive the highest exposure to substances. Sampling locations of multiple components within a pathway may be unfeasible or impractical. Conservatively placing sampling locations to permit estimates of maximum exposure may solve this problem. Reference study areas are important for facilities that release substances that are present in the environment as a result of natural processes or other anthropogenic activities. This puts into context the relative contribution of facility releases.

PCM design should identify the appropriate sampling frequencies. Information related to the items listed below determines sampling frequency.

1. Release patterns from the facility (e.g., continuous, intermittent or batch release);
2. Seasonality within abiotic environmental components (e.g., influences of natural seasonal flow conditions on water concentrations or activities);
3. Predicted rate of change within a sampling component. For example, air or water concentrations, and/or activities may fluctuate over short time intervals, whereas detectable changes in soil or sediment levels may only occur over several years;
4. Impact of sampling on the component itself (e.g., frequent sampling of biota may have a greater impact on the population than the actual releases);
5. Collecting biota (e.g., garden vegetables at normal harvest time so that the sample is representative of critical group or non-human biota exposures); and
6. Level of risk associated with the pathway being monitored.

#### 5.2.2.5 Designing Biological Effects Monitoring

Facilities in the high-risk category need an EMP with both PCM and BEM component. The risk assessment will determine the need for and scope of BEM. BEM may focus on biota exposed to substances via aquatic pathways (e.g., fish, benthic invertebrate), terrestrial pathways (e.g., grouse, shrews, voles, terrestrial plants and invertebrates), or both (e.g., ducks, moose and muskrat).

BEM monitors the characteristics of organisms at the individual, population or community level to assess the effects of chronic exposure to single or multiple substances. The risk assessment predictions form the basis for designing BEM and interpreting its results such that environmental effects that exceed those accepted during licensing can be identified. This allows adequate response time for confirmation and development of any necessary mitigation measures (control or preventive).

As a result of the federal *Fisheries Act*, Canada has a relatively long tradition of aquatic BEM. Guidance on the design of aquatic BEMs has been developed for the pulp and paper [3] and the metal mining [4] industries. The recommended components for BEM are based on detecting population level (using both direct measurements and individual-based indices of reproductive and somatic health) and community level effects for selected biota. Although these documents address the design of BEMs for the aquatic environment, the underlying principles apply to the design of terrestrial BEMs. Other sources (i.e., texts on statistical study design, biostatistics) should be consulted to develop the statistical study design for both terrestrial and aquatic systems.

Environment Canada's most recent version of the *Metal Mining Guidance Document for Aquatic Environmental Effects Monitoring* [4] describes the minimum design needs for uranium mines and mills to meet the requirements of the *Metal Mining Effluent Regulations* under the *Fisheries Act*. However, licensees of Class I nuclear facilities, and of uranium mines and mills should note that the minimum requirements outlined in the Environment Canada guidance document [4] are designed specifically to meet the needs of the *Fisheries Act* and may be insufficient to fulfill the CNSC's broader environmental protection mandate under the *NSC Act*. Environment Canada's guidance [4] can also be used for the design of a basic BEM for Class I nuclear facilities.

BEM measures performance indicators related to biological effects in selected non-human biota that are deemed most suitable for monitoring the effect or effects predicted in the risk assessment. BEM study areas should incorporate the study areas used in PCM. Co-occurring data on concentrations of substances and biological effects may be needed to help determine any cause and effect relationship.

Monitoring occurs over an extended period of time to allow for the identification and measurement of the anticipated effects. Therefore, this BEM is performed on a cyclical basis (i.e., the frequency of cycles is determined on a site-specific basis) according to the nature of anticipated effects and its predicted time of occurrence. A three- to five-year cycle is recommended as the initial starting point. Justification for increasing or decreasing the cycle frequency can be based on the results of two or more consecutive cycles. The program design enables detection of a specified level of effect or change in the performance indicator relative to a reference condition.

## 5.3 Document on Staff Qualifications and Training

### 5.3.1 Training Program

A training program based on a systematic approach to training (SAT) ensures that workers (i.e., staff and contractors) are adequately trained and qualified to perform EMP activities, and that they remain trained and qualified as changes in work practices occur. The EMP training program depends on the complexity of the EMP activity, the employees' educational background, demonstrated level of competence and previous work experience.

The SAT framework is based on the identification of the knowledge and skills required to perform a job. The SAT should result in training programs tailored to the needs of each category of workers involved in the EMP. This ensures that no knowledge or skill required by a job will be omitted and that the program will be the appropriate length for the needs of the job. SAT-based programs help prevent the loss of motivation to learn. A SAT normally consists of five phases:

1. Analysis;
2. Design;
3. Development;
4. Implementation; and
5. Evaluation.

#### 5.3.1.1 Analysis

The analysis phase identifies training needs and competencies required for a particular job. A training needs analysis determines where a need exists for training and the type of training necessary to ensure that workers adequately perform EMP activities. A training needs analysis includes the following components:

1. An organization analysis;
2. A task analysis; and
3. A person analysis.

The organization analysis examines the environment in which the worker will be performing the work, and the activities and resources of the organization. Information from this analysis is used to develop training that harmonizes with the activities of the organization. A task analysis determines the skills, knowledge, and attitudes necessary to successfully perform the tasks associated with a job. Finally, the person analysis determines the gap between what the worker needs to know to do the job and what the worker actually knows. This gap indicates the training required.

#### 5.3.1.2 Design

The design phase involves the conversion of the training requirement and the associated, identified competencies to training objectives. These objectives form the basis of the training program.

#### 5.3.1.3 Development

The development phase comprises the preparation of training materials to meet the training objectives. The objectives of the training program and the type of information that needs to be conveyed determine the type of training delivery methods.

#### 5.3.1.4 Implementation

The implementation phase involves training using the prepared training materials. Trainees are assessed for their mastery of the training objectives.

#### 5.3.1.5 Evaluation

The evaluation phase comprises the evaluation of the training program and trainees to determine whether the training has been successful in meeting the initial goals/objectives. Suitable feedback mechanisms from the evaluation phase relating to all phases of the SAT process are integral in the continuous improvement of the training program.

Maintenance of appropriate knowledge and skills plays a significant role in ensuring that workers involved in the EMP remain trained and qualified. Refresher or continuing training needs should be examined using a systematic approach.

### 5.3.2 Personnel Qualifications, Training and Assessment

Only qualified workers can carry out EMP activities. Therefore, the qualification and training requirements for each worker performing any EMP activity should be defined. Qualification refers to specific training needs for EMP activities, and to the review of applicable and relevant education/experience. A job description includes, as a minimum, the following information:

1. Position title;

2. Minimum qualifications (e.g., education, experience and training) for the position;
3. Responsibilities;
4. Reporting relationships; and
5. Any supervisory responsibilities.

A documented process or mechanism to obtain and evaluate worker qualifications provides formal assurance that a worker has been found competent to perform a specified EMP activity, either through education, experience or successful completion of the training specific to the EMP activity. A list of all EMP activities for which a worker has been assessed as competent, including the basis on which the competency was judged, forms an integral portion of this documented process.

Once a worker has been assessed as competent, continuous and documented evaluations should be performed to provide formal assurance that the worker remains competent to perform EMP activities, and that he or she has been adequately trained. These evaluations can be done through work supervision by experienced staff, provision of known samples submitted as unknowns for evaluating performance in analytical procedures, provision of sample blanks for evaluating performance in sampling procedures, or sign-offs on work performed. Such periodic evaluations will help identify ongoing training needs, and assess the need to develop and maintain the expertise of existing staff.

Worker competency can be objectively determined through the use of established and documented performance criteria. Performance criteria should be defined and communicated to the persons who will be doing the work. Workers should also be advised that they will be assessed against these criteria and be informed of the consequences of failing to meet the performance criteria. Any worker non-compliance should be reported and handled expeditiously, in a formal manner.

### 5.3.3 Maintenance of Training Records

A process describing the maintenance of records that documents the education, training, and technical experience of workers is essential. Personnel records may include details of academic and professional qualifications, work experience, the successful completion of all necessary training, when the training was received (as it may be necessary to retrain workers over an extended period of time), as well as an assessment indicating that a worker has been found competent for specified tasks in the EMP.

## 5.4 Document on Quality Assurance and Quality Control for Field and Laboratory Activities

The site QA program provides the managed process under which the EMP QA/QC program functions. However, some elements are specific to the EMP program; the following sections provide guidance on these elements.

A QA/QC document, approved by senior management, uniquely reflects the details of all field and laboratory activities. A QA/QC plan will generate quality data using standardized and accepted sampling and analytical techniques; be sensitive to sampling and analytical error; be sensitive to sample contamination, extreme values due to natural conditions, or both; provide complete documentation and defensibility of all data; expedite data evaluation and acceptance, and document and record every step of the process leading to the final data report. The QA/QC plan is scaled to the scope of the EMP.

The QA/QC Document for Field and Laboratory Activities should contain the processes and procedures to support and implement an EMP. Licensees may use the following references to develop a field and laboratory QA/QC Plan. Although they are predominantly laboratory-specific, the underlying general principles and concepts of the following documents can be applied to a field setting (further guidance can be found in Environment Canada's *Metal Mining Guidance Document for Aquatic Environmental Effects Monitoring* [4]):

1. ASTM. *Standard Guide for Establishing a Quality Assurance Program for Analytical Chemistry Laboratories within the Nuclear Industry*. C 1009-96. [5]
2. ISO/IEC 17025 (*General Requirements for the Competence of Testing and Calibration Laboratories*). [6]

### 5.4.1 Roles and Responsibilities

A staff position should be delegated the appropriate responsibility, authority and resources for the QA/QC plan and supporting documents. Responsibilities may include overseeing the audit and review process specific to the QA/QC plan and the sampling/analytical procedures for the field and laboratory. The designated staff member should also have access to the highest level of management at which decisions are taken on the QA/QC plan. This staff member should be independent, but have working knowledge of the daily EMP operations.

The responsibilities, authorities and inter-relationships of all EMP staff should be described. All EMP staff should have authority commensurate with their responsibilities and have resources to adequately perform EMP activities. Arrangements should be made for assigning responsibilities in the absence of a staff member.

### 5.4.2 Equipment Maintenance

The document should describe the physical and administrative controls used to manage equipment failure, both field and laboratory. The document should also describe a process for ensuring the availability of appropriate and adequate instrumentation (including reference materials) for performing calibrations and tests properly.

### 5.4.3 Non-conformance

Non-conformance includes

1. failure of procedures, sampling and analytical methods, and internal quality controls;
2. audits and review findings;

3. failure of data management processes; and
4. exceeding performance targets and action levels;

The non-conformance process should be objective, structured, systematic, and comprehensive. This ensures that licensee non-conformance investigators will proceed through data gathering, analysis, evaluation, recommendation, and follow-up phases using appropriate techniques and mechanisms. Recommended practices include the identification, evaluation, resolution, and recording of the non-conformance. Non-conformances are often identified during the normal performance of work through audits and reviews or surveillance activities, such as inspections. Once a non-conformance is identified, a technical evaluation should be undertaken and include a determination of the root cause, identifying the actions required for correction (including actions that will minimize the recurrence) and a determination of the validity of any analyses that may have been affected. Once the root cause has been identified, emphasis should be placed on those actions that will minimize the probability of subsequent failures. A staff member is typically designated to determine corrective action and to establish schedules for resolution or final disposition, as well as to verify the implementation and effectiveness of the corrective actions. Assigned actions and schedules should be recorded, reported, and communicated to the responsible management and technical personnel. All aspects of the non-conformance process should be documented and recorded.

### 5.4.4 Performance Verification

Conclusions resulting from an EMP may have important operational consequences. Data can be used for this purpose only if the degree of their reliability is known and documented. A systematic quality control plan should be in place for continually checking the accuracy and precision of the results for all methods.

Precision is tested through duplication of analysis. Accuracy is evaluated through analysis by different laboratories, analysts and methods. Attempts should be made to verify that no systematic error has been introduced into the results of analytical procedures because of differences in techniques among analysts, or because of differences in performances among supposedly equivalent instruments. Analyses of selected samples are usually repeated using different analysts or different instruments and the results compared to ensure that variations are within the expected range. In addition, where possible, measurements can be made or samples analyzed using more than one technique to ensure that the technique used routinely gives results that are consistent with results from other approved techniques. In practice, accuracy may also be evaluated through the use of standard reference materials or by participation in analytical inter-comparisons.

The quality control plan normally varies with the nature and number of analyses to be performed. In standard practice, typically 1 out of every 10 samples is designated a QC sample. QC samples include blanks (laboratory/field or trip blanks), replicates, reference materials, control samples and spikes. Field QC samples (e.g., trip or field blanks) test for contamination during sample collection and field preparation. Laboratory QC samples (e.g., spikes or controls) test whether the performance of analytical methods is in control. Examples of other QC practices include inter-laboratory, intra-laboratory comparisons, or both. Intra-laboratory comparisons involve routine analysis of replicate samples. These may be replicates of monitoring samples, reference samples or both. Blank and spiked samples can be submitted as unknowns to provide a basis for estimating the accuracy of the sampling and analytical methods. Laboratory blanks are analyzed to detect and measure sample contamination, and to provide information on the adequacy of background subtraction. Inter-laboratory comparisons involve the analysis of environmental samples from one or more independent laboratories. If results fall outside the specified control limits, an investigation is carried out to identify the cause and the appropriate corrective actions.

A process should be established to verify that staff and contractors correctly follow procedures. All work done within the EMP should be documented to ensure that it can be verified. To ensure that work is conducted satisfactorily, checks should be made through either work supervision, provision of known samples submitted as unknowns for evaluating performance in analytical procedures, provision of travel or trip blanks for evaluating performance in sampling procedures, sign-offs on work performed, etc.

### 5.4.5 Development of Sampling and Analytical Procedures

A process should be established for developing, validating, authorizing, controlling, implementing, documenting, maintaining and revising (at a specified frequency) sampling and analytical procedures. The process should consider the procedures, responsibilities and authorities for drafting, revising, approving and issuing documents, and the procedures needed for performing work within the EMP. The process should also consider preventing the use of obsolete and superceded documents.

Rules should be developed to identify documents, changes to documents, document distribution, and the registration of copies issued. The control information on all documents includes a unique identifier, revision number and history, date of issue, and name of the person authorizing issuance of the document to clarify the identity of the controlled documents at all times.

A formal process for writing procedures helps to promote well-written, complete and correct procedures. Before writing the procedures, a format should be established to provide consistency across a series of procedures and completeness within each procedure. The format may include purpose, scope, applicability, a revision sheet, and responsibilities for ensuring that procedures are being applied as intended, references, and technical instructions. Technical instructions may include a description of equipment and materials required, safety precautions, tolerances, step-by-step instructions for doing the work, calculations, expected results, and so on.

Writers should have competent writing skills and knowledge of the subject matter involved. Writers should ensure that procedures are clear and concise to avoid user confusion and misunderstanding.

The review process may consist of several different types of reviews. For example, an editorial review by one or more staff, other than the writer, may assess the procedures for conformity to format, consistency of terms, abbreviations, and clarity. A technical review by one or more staff, other than the writer, may evaluate the procedures for technical accuracy. Technically competent persons, having no direct responsibility for the procedures, would normally conduct this evaluation. Such a peer review could extend outside the laboratory to provide a more independent evaluation of technical adequacy.

Management should approve each procedure to certify that procedures were prepared as prescribed by established practices. Management approval signifies that management has accepted the responsibility for the adequacy of the procedures. Changes in procedures should be controlled to avoid changes that would cause errors. All controlled copies of a procedure should be updated when a change (whether minor or major) is made and approved. Changes to procedures should be reviewed and approved by the same staff that performed the original reviews and approvals.

### 5.4.6 Recordkeeping

A process for recordkeeping describes how to maintain complete historical files of all documentation within the EMP, with at least one copy of all current and superceded documents on file. Retention periods should be specified for all documents and data associated with the EMP, typically for the life of the facility (i.e., until a Licence to Abandon is sought). A complete master list of all procedures within the EMP with current issue dates and identities of the copyholders should also be maintained.

## 5.5 Document on Sampling and Analytical Procedures

### 5.5.1 Sampling/Analytical Methods

Sampling and analytical procedures should be representative, well referenced, and reproducible. For example, a field measurement or collected sample should be representative of the parameter or material to be analyzed as most vary with location and time. Therefore, the details of sampling and sample handling should be considered to avoid jeopardizing the sampling effort through the careless omission of a needed safeguard. Every effort should be made during field sampling, measurement, and analysis to record all aspects of the procedure that could reasonably be expected to affect its outcome. Original observations should be entered into bound notebooks or appropriate work sheets. Unbound sheets of paper should be avoided as they can easily be lost or mislaid. Mistakes should never be erased or deleted but noted by striking through the error, entering the correct value alongside, and initialling the change.

A system for uniquely identifying the samples should be established to avoid confusion regarding the identity of the sample at any time. Procedures should be developed for handling, packaging, and shipping to avoid deterioration or damage to samples, including instructions for samples that require storage under specific environmental, security or hazard conditions. Upon receipt at the laboratory, the condition of the sample, including any abnormalities or departures from procedures, should be recorded. If doubt exists about the sample’s suitability for analysis, or if it fails to conform as expected to the description provided, it should be flagged for investigation.

### 5.5.2 Verification of Equipment Performance

A staff member should be responsible for the traceability of reference materials.

An independent body that can provide traceability to national or international standards of measurement usually calibrates reference materials. Normally, the independent body provides a certificate of calibration to the laboratory to confirm traceability. The laboratory can use the appropriate calibration standards, calibration procedures and calibration frequencies, and keep a record of the traceability of the standardizations to ensure the optimal quality of measurements. Reference materials should be used for calibration only and for no other purpose. The laboratory should demonstrate that sufficient reference materials are available to calibrate the relevant items of equipment over their intended range of use. Full records should be kept of the identity and source of the reference material. Precautions are taken to match the matrices of the reference materials with those encountered in the sample and effects of non-matching matrices are determined.

A designated staff member normally oversees the calibration and maintenance of field and laboratory equipment. All calibration procedures, especially those performed in-house, should be documented and include acceptance criteria and corrective action if equipment performance falls outside the criteria. Each calibration procedure written for a method or instrument should specify the standards to use, instructions necessary for obtaining reliable calibration data, data treatment, and the frequency of calibration required.

Calibrations should be conducted at a specified frequency or as recommended by the manufacturer. A schedule of preventive maintenance is needed to ensure that field and laboratory equipment function efficiently and properly. A record of instrument performance is maintained and any modifications made to the instrument, whether permanently or for a specific project, are documented. The calibration status of each item of equipment, including reference materials, should be identified. Equipment should be subjected to in-service checks between calibrations and verifications. Maintenance procedures should include a provision to remove from service any equipment that has been subjected to overloading or mishandling, provided suspect results, or shown to be defective. Such instruments should remain out of service, clearly identified, and stored until they have been repaired and shown, by calibration, verification, or testing, to work satisfactorily.

### 5.5.3 Data Management

Procedures for data management include

1. protecting the integrity and security of data;
2. describing criteria for recognizing data outliers/abnormalities;
3. statistical methodology and criteria;
4. the documentation and verification that all computer software and programs are adequate for use before initial routine use and after each program modification;
5. operation of software programs;
6. reporting computer-generated results; and
7. data validation.

Data integrity and security includes data entry, capture, storage, transmission and processing; retention of original data and calculations; and prevention of unauthorized access to and amendment of data. Some equipment has, as an integral part of its operation, a significant computer function. In this case, the data generated by the software should be demonstrated to be equivalent to manually generated data. If a data management system is created or used to integrate, collate, and check data, checks should be in place to handle computer operations that may include organization and management functions. These functions would identify knowledgeable staff, required equipment, and software.

Data validation includes checks for determining the accuracy of calculations, conversions and data transfer; for transcription errors, omissions and mistakes; and for determining consistency with expected validation values. Data validation can vary from simple, manual calibration and control-charting practices to computer software programs. Ideally, a staff member, other than the person performing the calculations or handling the data, should verify the work. Consideration should be given to include instructions for reporting significant digits based on the capability of the measurement method. Consideration should also be given to include instructions on identifying and treating outliers. The upper and lower limits for the acceptance of data should be established. Tolerances for all critical parameters and procedural steps made during an analysis should be specified and uncertainties provided for all reported results. The meaning of the uncertainty value should be clearly defined.

## 5.6 Document on Audit and Review

The facility QA program provides the managed process under which the EMP audit and review process functions. However, the following sections provide guidance on elements that are specific to the EMP program.

### 5.6.1 Audit and Review Process

A staff position should be designated with the appropriate authority, resources, and responsibility for the audit and review process and its associated documents to ensure that the process is conducted appropriately and consistently. The designated staff member will establish a planned schedule for audits and reviews of the EMP for the five-year cycle. The audit is performed by a person or persons who have no direct responsibility for the work and operations of the EMP element being audited or reviewed, but who have good working knowledge of its operations.

The methodology, scope, criteria and corrective action describe the extent and boundaries of the audit and review. A flexible audit and review enables changes in emphasis based on information gathered during the audit and review, and permits effective use of resources (i.e., issues should be probed where warranted, regardless of the scope of the audit). Audits and reviews include matters arising from previous audits and reviews, reports from external audits, and future plans and estimates for new work, staff, or equipment.

The suitability and effectiveness of each EMP element is judged against changing legislation, expectations of the licensee and and of the CNSC, changes in the licensed activity, advances in science and technology, lessons learned from environmental incidents, reporting and communication.

A licensee should conduct its own internal audits regardless of any external or third-party audits conducted.

### 5.6.2 Audit and Review Results

Audits and reviews identify deficiencies and assess the severity/consequence of the deficiencies against the proper function of the EMP. Corrective action is needed whenever evidence arises that the EMP has failed to function properly or as effectively as it should. Often, corrective action arises on two levels:

1. To correct an immediate failure, such as exceeding performance targets; and
2. To investigate the root cause of a failure, such as failure of staff to perform procedures.

Once a corrective action is identified, a staff member should be designated to implement the corrective action, establish a schedule for its resolution or final disposition, and verify the effectiveness of the corrective action. Effective corrective actions should be undertaken within a reasonable and agreed-upon time frame.

### 5.6.3 Audit and Review Records

All aspects of the audit and review process should be documented and recorded, including procedures, results, the disposition of corrective actions, and verification of effectiveness of corrective actions.

# 6.0 ENVIRONMENTAL MONITORING PROGRAM REPORTING

## 6.1 Annual Reporting

The Annual Environmental Report should summarize the results of the EMP. The annual report should also document activities or events influencing the EMP, including the QA/QC plan.

### 6.1.1 Results of the EMP

The results of the EMP include the measures of central tendency and associated error estimate (standard deviation). Results also include the total number of replicates and number of replicates less than the method detection limit used in the calculation of the measure of central tendency. This information should be provided in the report to allow independent verification of the conclusions, including the following:

1. Measurements of the monitored substances, and physical and biological parameters, including their statistical analyses (assess for changes through time and space);
2. Individual radiation doses calculated as doses to the critical group;
3. An assessment of the of EMP results compared with the predicted performance indicators and targets; and
4. Documentation and justification of any deviations from field sampling, analytical methods and data management procedures.

### 6.1.2 Results of QA/QC and Audits and Reviews

The summary and assessment of the field and laboratory QA/QC results should include a summary of every non-conforming event or occurrence that resulted in or could have resulted in a compromise of the stated objectives of the EMP, along with the corrective measures taken or proposed.

The summary of audit and review results and subsequent corrective action plans should include an assessment of the effectiveness of the corrective actions implemented and/or proposed.

### 6.1.3 Proposed Modifications to the EMP

The summary of any proposed modifications to the EMP should include the rationale and the process used to identify the proposed modifications and an assessment of the impact of the proposed modifications on the ability of the EMP to meet its objectives.

There should also be documentation, assessment, and review of any special studies, supplementary studies, or both that have been initiated or completed. This applies to confirmation/validation of biological effects or of studies undertaken to document cause and effect relationships, and substance behaviour in the environment.

## 6.2 Special Reporting

At least three months before implementation, the licensee should submit information to the CNSC on any proposed special study, supplementary study or both to address EMP findings. This includes the proposed QA/QC measures to follow. A specialized QA/QC component, in addition to the regular QA/QC component, may be required to meet the needs of field and laboratory activities related to studies with unique characteristics (i.e., benthic invertebrate studies, fish studies, etc.). Environment Canada’s *Metal Mining Guidance Document for Aquatic Environmental Effects Monitoring* [4] provides further guidance on this subject.

# GLOSSARY

**ALARA**
As low as reasonably achievable, social and economic factors taken into account

**BEM**
Biological Effects Monitoring

**Bioaccumulation** [13]
The net accumulation of substance in an organism to the concentration in water, based on uptake from the surrounding medium and food.

**Bioavailability** [15]
The extent to which the form of a substance occurring in media is susceptible to being taken up by an organism.

**Bioconcentration** [13]
The net accumulation of a substance in an organism to the concentration in water, based only on uptake from the surrounding medium.

**Biomagnification**
The result of the processes of bioaccumulation and bioconcentration. Biomagnification occurs when tissue concentrations of bioaccumulated substance increase as it moves upward through two or more trophic levels (e.g., a trophic includes all species in an ecosystem that obtain energy primarily from a common source, such as photosynthetic organisms in a marine habitat all obtain energy from the sun).

**Biological Effect**
Alteration of biological processes resulting from exposure to hazardous and radioactive nuclear substances. Biological processes may range from chromosome aberrations to community dynamics.

**Biological Effects Monitoring**
Monitoring characteristics of organisms, populations, and or communities that may be adversely affected by released substances.

**Biota**
All living organisms, including humans.

**CNSC**
Canadian Nuclear Safety Commission

**COSEWIC**
Committee on the Status of Endangered Wildlife in Canada

**Critical Group**
For a given radionuclide and source, a fairly homogenous group of people whose location, age, habits, diet, and so on cause them to receive doses greater than the average received by typical people in all other groups in the exposed population.

**Derived Release Limit**
The upper limit for the release of a single radionuclide from a single facility for airborne and for liquid effluents that results in an annual dose of 1 mSv to a member of the critical group.

**Effluent**
The waste stream (in particulate, gaseous, or liquid form) from a facility released into the environment.

**Environmental Effect**
Consists of

(a) any change that an activity, substance, equipment, or facility that is regulated by the CNSC may cause in the environment, including any effect of any such change: on health and socio-economic conditions; on physical and cultural heritage; on the current use of lands and resources for traditional purposes by aboriginal persons; or on any structure, site, or thing that is of historical, archaeological, paleontological, or architectural significance; and

(b) any change to any activity, substance, equipment, or facility that the environment causes, whether any such change occurs within or outside Canada.

**EMP**
Environmental Monitoring Program

**Pathways Contaminant Monitoring**
Monitoring substance levels in abiotic or biotic components in the environment.

**PCM**
Pathways Confirmation Monitoring

**Performance Indicator**
A quantifiable variable related to the actions of a proposed or licensed activity that may cause or indicate an adverse environmental effect if a certain threshold value is reached.

**Performance Target**
A limit on a performance indicator designed to prevent unreasonable risks to the environment. More than one limit may be set or considered for a performance indicator.

**Persistent** [13]
A substance that has at least one of the following characteristics:

a) In air,

i) its half-life is equal to or greater than 2 days; or

ii) it is subject to atmospheric transport from its source to a remote area.

b) In water, its half-life is equal to or greater than 182 days.

c) In sediments, its half-life is equal to or greater than 365 days.

d) In soil, its half-life is equal to or greater than 182 days.

**QA/QC**
Quality assurance and quality control

**Release**
The discharge of substances to the environment.

**Risk Assessment**
A process that evaluates the likelihood that potential effects may occur or are occurring as a result of human and non-human exposure to one or more substances.

**SAT**
Systematic Approach to Training

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