Draft CSA Standard on Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills

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Abstract

The Canadian Standards Association (CSA) is preparing a draft Standard on environmental risk assessments (ERAs) at Class I nuclear facilities and uranium mines and mills (CSA N288.6). It is being prepared by a technical subcommittee of the CSA N288 Technical Committee, including experts from across the nuclear industry, government and regulatory authorities, and environmental service providers, among others. It addresses the design, implementation, and management of environmental risk assessment programs, and is intended to standardize practice across the industry. This paper outlines the scope of the draft Standard and highlights key features. It is under development and subject to change.

1. Introduction

1.1 CSA

CSA Standards is a not-for-profit membership-based association serving business, industry, government and consumers in Canada, and the global marketplace. CSA develops standards designed to enhance public safety and health, advance the quality of life, help to preserve the environment, and facilitate trade. CSA standards are voluntary documents; only when a standard has been referenced by federal, local, state, provincial or municipal government, or by a regulatory authority, is compliance with the standard mandatory.

The objective of CSA Standards' nuclear program is to help promote a safe and reliable nuclear power industry in Canada and to exert a positive influence on the international nuclear power industry. While focusing on nuclear power plants, the program also encompasses other types of nuclear facilities such as uranium mines & mills and other class I nuclear facilities.

1.2 The CSA Process

CSA Standards are developed through a process accredited by the Standards Council of Canada. Volunteers represent a "balanced matrix" committee, which seeks to balance vested interests and viewpoints among various stakeholders, with no single group dominating. The committee develops the details of the Standard by a consensus process, which includes the principles of inclusive participation, and implies substantial agreement among committee members, rather than a simple majority of votes. Although CSA administers the process and applies rules to promote fairness in achieving consensus, it does not independently test, evaluate, or verify the content of its Standards.

The process includes a formal public review of the draft Standard where any interested party can comment. All comments and suggestions received are considered, the Standard is revised as appropriate, and the committee resolution on each issue is recorded. Certain issues may be placed in a "parking lot" to be considered again during subsequent reviews of the Standard.

1.3 Key Drivers for this Project:

There is currently no Canadian standard for environmental risk assessment (both human health risk and ecological risk) at nuclear facilities.

Both CSA N288.4-10 on Environmental Monitoring and CSA N288.5-11 on Effluent Monitoring refer to carrying out an "environmental risk assessment" as a necessary prerequisite for establishing an appropriate risk-based monitoring system.

A new standard is needed to give practical guidance in terms of carrying out an environmental risk assessment to:

- meet legal and business requirements,
- incorporate current best practices and technologies used internationally, and
- provide consistency across Canadian nuclear facilities

Future new build projects will benefit from having clear, consistent guidance for nuclear facilities across Canada.

1.4 Structure of the CSA N288 Technical Committee

The CSA N288 Technical Committee (TC) is comprised of members representing many points of view relating to environmental management. The TC members are responsible for the review and approval of the technical content of the Standard.

At least two and no more than four voting members must come from each of the following five interest categories:

- Owner/ Operator/ Producer
- Government and/or Regulatory Authority
- Supplier/ Fabricator/ Contractor;
- Service Industry; and
- General Interest.

An organization may have no more than one vote on the TC. In addition to individuals who represent the General Interest category, the following organizations are represented on the TC by way of voting and non-voting (associate) members:

- AECL Nuclear Laboratories
- AMEC NSS
- AREVA Resources Canada Inc.
- Bruce Power
- Cameco Corporation
- Health Canada
- Hydro-Quebec
- International Safety Research
- Kinectrics Inc.
- NB Power

- Candesco Corporation
- Canadian Nuclear Safety Commission
- Candu Owners Group Inc.
- EcoMetrix Incorporated
- Golder Associates Limited
- Ontario Ministry of Environment
- Ontario Power Generation
- Saskatchewan Ministry of Environment
- SENES Consultants Limited
- TRIUMF

1.5 Scope and Structure of the Draft CSA N288.6 Standard

The draft CSA N288.6 Standard outlines general concepts in environmental risk assessment (ERA) and defines bounds for the scope of an ERA for Class I nuclear facilities and uranium mines and mills. The scope includes human health risk assessment (HHRA) and ecological risk assessment (EcoRA). General methodology is provided for design and implementation of HHRA and EcoRA. An evaluation of uncertainty in the assessment is required and guidance on this is provided. The types of recommendations that might emerge from the ERA to guide environmental monitoring, or risk management or remediation, are briefly noted. General requirements for quality assurance and quality control (QA/QC) on the ERA process are identified, and requirements for periodic review of the ERA are outlined.

The draft Standard does not provide guidance on making risk management or remediation decisions. Such decisions are considered to be the responsibility of the risk manager, not the risk assessor. However, it is recognized that findings about risk coming out of the ERA will inform risk management decisions.

The overall structure of the draft Standard is as follows:

- Introduction – Clause 0
- Scope – Clause 1
- Reference Publications – Clause 2
- Definitions and Abbreviations – Clause 3
- Environmental Risk Assessment Objectives – Clause 4
- Environmental Risk Assessment Framework, Tiers and Timelines – Clause 5
- Human Health Risk Assessments – Clause 6
- Ecological Risk Assessments – Clause 7
- Evaluation of Uncertainty – Clause 8
- Risk-based Recommendations – Clause 9
- Quality Assurance and Quality Control – Clause 10
- Periodic Review of the ERA – Clause 11

Annexes to the draft Standard provide informative material, including a suggested table of contents for ERA reports, examples of materials that summarize or illustrate the conceptual model for a site, and example dose and risk calculations.

1.6 Scope of an ERA for a Nuclear Facility

The objective of an ERA at a facility is to evaluate risks to relevant receptors (human and ecological) resulting from exposures to contaminants and physical stressors that are related to the site and its activities.

Human receptors will usually be off-site (members of the public) since on-site workers are typically assessed under a facility's Radiation Protection Program and Health and Safety Program. Any on-site workers not addressed in these programs can be included in the ERA.

Ecological receptors are representative plants and animals and may be either off-site or on-site at locations where exposure to contaminants or physical stressors of concern will occur.

Contaminants of potential concern (COPC) include both radioactive and non-radioactive substances. The latter may be toxic, corrosive or otherwise deleterious. Physical stressors may include, for example, heat from a thermal plume, noise or cooling water withdrawal. Contaminants may arise from facility releases to the environment, and exposure levels may be determined through measurement or modelling. Releases to be considered are routine emissions, including those from reasonably foreseeable upset events. The intent is to represent normal operations, excluding the rare but high level exposures potentially associated with spills and accidents.

2. General ERA Concepts

2.1 ERA Relationship to Monitoring and Environmental Assessment

The ERA utilizes monitoring data, and serves to focus environmental and effluent monitoring programs on areas or contaminants of potential concern. The CSA Standards on environmental and effluent monitoring programs (CSA N288.4 and N288.5) recognize this mutual relationship.

The ERA can be part of a larger environmental assessment (EA) report, or any other document that contains the required information. An ERA is often triggered during an EA process.

2.2 ERA Components and Tiers of Assessment

The structure of an ERA, whether HHRA or EcoRA, includes four main components: problem formulation, exposure assessment, toxicity or effects assessment, and risk characterization. The draft CSA N288.6 Standard follows this structural framework. A parallel structure is used for the HHRA and the EcoRA sections.

The problem formulation defines the issues to be addressed in the ERA, based on review of contaminant and physical stressors, receptors and exposure locations at the site. The issues are summarized in a conceptual site model (CSM) which is a blueprint for the further assessment.

Different issues may progress at their own pace through three tiers of assessment, using increasingly complex assessment approaches. Table 1 outlines the new content that may be brought in as an issue progresses through these tiers, from a screening level, to preliminary quantitative assessment (PQRA) to detailed quantitative assessment (DQRA). The screening level serves to identify issues (receptors

and stressors) that require quantitative assessment. The PQRA uses simple conservative approaches and may overestimate risk. The DQRA uses additional methods, if needed, to refine the assessment and resolve the risk issue.

Figure 1 illustrates the review/update cycle and ERA progression in complexity. The ERA should be reviewed every 5 years or sooner if triggered by a major change at the site. A full or partial update of the ERA may then be completed, if needed to ensure that the ERA is current. Issues can drop out through time as they are resolved. Similarly, new issues can arise, usually associated with some facility change, or perhaps a change in science. The ERA essentially becomes a living document.

At any point in time, the ERA may have different issues addressed at different levels of complexity, depending on the type of data available. For example, at a PQRA level, we may use upper bound exposure estimates compared to benchmark values. Later, at a DQRA level, we may have refined exposure estimates, or field studies of toxicity, or ecological field surveys to support a more definitive conclusion about whether effects are likely occurring. Both levels of complexity can be included in one ERA report.

Screening level risk assessment (SLRA) — Tier 1	Preliminary quantitative risk assessment (PQRA) — Tier 2	Detailed quantitative risk assessment (DQRA) — Tier 3
Problem formulation • characterize the site • compare screening levels to screening criteria • select contaminants and physical stressors • select receptors and exposure pathways • define assessment and measurement endpoints (EcoRA) • develop conceptual model • problem formulation checklist (HHRA)		
	Exposure assessment • estimate exposure/dose for receptors at relevant locations for each contaminant of potential concern (COPC) or physical stressor Toxicity/effects assessment • select TRVs/benchmarks for each receptor and COPC or physical stressor (if possible) Risk characterization • calculate HQs for each COPC or physical stressor (if possible) at relevant locations • calculate cancer risk for non-radiological carcinogens for human receptors (HHRA)	
		• Refine exposure assessment and risk characterization as needed to reduce uncertainty (additional site data might be necessary) • Consider any other lines of evidence (e.g., epidemiology and field studies of toxicity or of population/community effects) • Provide recommendations for further uncertainty reduction, effects monitoring, or risk management if applicable

Note: *Only issues (receptors or stressors) that remain of concern at the end of each assessment tier need to be considered further in the next assessment tier.*

Table 1 Outline of new content as an ERA progresses through tiers of assessment
(taken from CSA N288.6 currently under development)

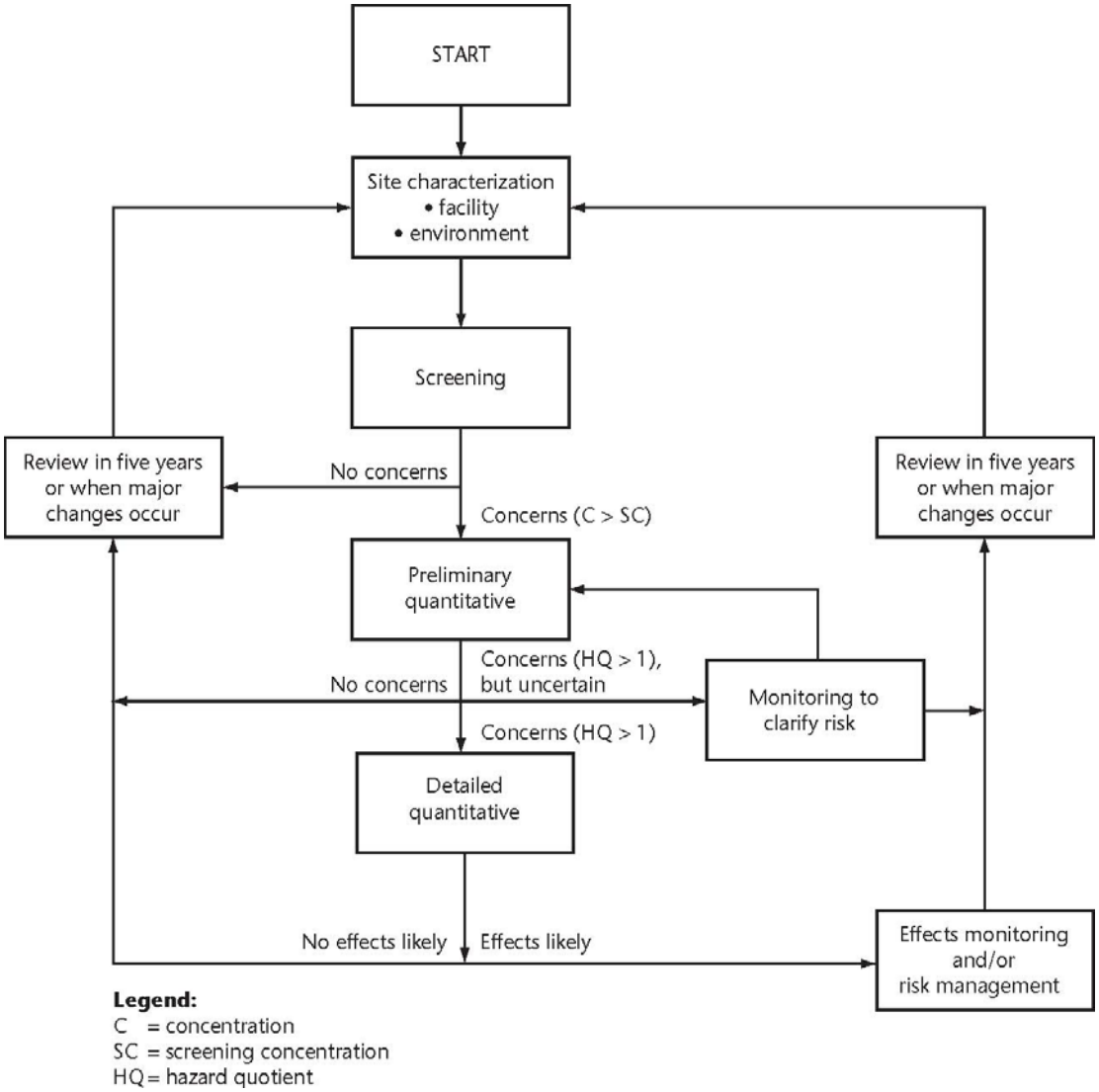

Figure 1 ERA progression through tiers of assessment
(taken from CSA N288.6 currently under development)

3. Strategy and Key Sources for ERA Guidance

A wide variety of guidance is available from government and other agencies on either HHRA or EcoRA. Risk assessment approaches differ based on their human or ecological focus, and they also differ in some aspects between agencies simply based on the preferences of their different authors. In preparing the draft Standard, an attempt was made to follow best practice, as judged by the N288 TC, based on well documented rationale, and considering the needs of Canadian nuclear facilities. An effort was made to standardize approaches among facilities by offering specific guidance on issues where there has been a wide range of practice, and by suggesting a hierarchy of preferred sources for parameter values important to the assessment. The use of site-specific parameter values, if available, is encouraged. However, it is recognized that parameter values from literature sources will be needed.

The HHRA guidance generally follows Health Canada, but refers to CSA N288.1-08 for many aspects of radiological exposure assessment. Guidance from the U.S. EPA, the Ontario MOE, and the Canadian Council of Ministers of the Environment (CCME) was also utilized in development of the draft Standard.

The EcoRA guidance draws from a number of agencies, particularly the CCME, the Ontario MOE, the U.S. EPA, the U.S. DOE, the Electric Power Research Institute (EPRI), the International Commission on Radiological Protection (ICRP), the International Atomic Energy Agency (IAEA), the United Nations Scientific Committee on the Effects of Radiation (UNSCEAR), the Oak Ridge National Laboratory, and the European Commission.

4. Highlights of the HHRA Guidance

4.1 Problem Formulation

The draft Standard provides guidance on problem formulation. The goal of problem formulation is to identify the contaminants, pathways, receptors, and their relationships that influence human health risk, and to focus the assessment on those that are relevant. It can include considerations from public consultation, stakeholder concerns, and regulatory input. Problem formulation also defines the objectives, scope and complexity of the risk assessment. Problem formulation involves site characterization, selection and characterization of receptors, selection of chemicals radiological and other stressors, selection of exposure pathways, and development of a human health conceptual model.

4.2 Exposure Assessment

The draft Standard provides guidance on exposure assessment. Exposure assessment uses information related to contaminants, physical stressors, receptor characteristics, behaviour, and activity patterns in order to quantify exposure. For radiological assessments, exposure assessment identifies the radiation dose (whole body or specific tissue). For non-radiological chemical assessments, exposure assessment identifies the amount of a chemical that is taken into the body (though exposure assessment can be based on air concentrations specifically for inhalation pathways).

4.3 Toxicity Assessment

The draft Standard provides guidance on toxicity assessment. Toxicity assessment involves an investigation of the effects caused by a stressor on a receptor and includes a description of the magnitude, significance and characteristics of those effects. Both radiological contaminants of potential concern (COPCs) and chemical COPCs are included in the toxicity assessment. Guidance is provided for both threshold and non-threshold acting chemicals.

4.4 Risk Characterization

The draft Standard provides guidance on risk characterization. In broad terms, risk characterization involves estimating and discussing the risk posed to receptors resulting from exposure to contaminants

and physical stressors in the environment by integrating the results of the exposure assessment and toxicity assessment.

For radiological COPCs, the estimated total dose for each receptor is compared directly to relevant dose limits. If the total dose received by a receptor is less than the applicable regulatory dose limit, the dose is not regarded as likely to be associated with meaningful health effects. An important concept recognized in the standard is "keep the amount of exposure to radon progeny and the effective dose and equivalent dose received by and committed to persons as low as reasonably achievable (ALARA), social and economic factors being taken into account" as required by the Radiation Protection Regulations. Dose limits, set by regulation, provide a boundary to protect people against unacceptable risks. However, achieving doses below the dose limits is not sufficient if actions can be taken at a reasonable cost to further reduce the dose. Optimization is therefore an essential part of the system of dose limitation. Optimization is generally the responsibility of the risk manager, not the risk assessor.

For non-radiological COPCs, receptor exposures or doses are used to estimate risk. Risk estimation involves the calculation of Hazard Quotients (HQs) for threshold acting contaminants and cancer risk quotients (incremental lifetime cancer risk – [ILCR]) for non-threshold acting contaminants. The resulting hazard and/or risk values are then compared to selected criteria.

When all pathways of exposure and background sources are considered, if the HQ is below a value of 1.0, no potential exists for an adverse effect for the selected receptor. However, when an assessment considers select media, and there are potential pathways of exposure from other sources (e.g., natural background levels in water, food, air, etc.), the calculated HQ is compared to a more conservative value of 0.2 per medium. This is consistent with the approach taken by OMOE in the development of soil standards [2] and is referred to by Health Canada [1].

For non-threshold acting chemicals, exposures should not exceed an ILCR value of 10^{-6} per medium. For example, risk due to exposure to soil through the combined pathways of oral ingestion and dermal contact should not exceed 10^{-6}. If an individual COPC produces a systemic effect in which more than one pathway results in the same endpoint at the same target site, the sum of risk levels for those pathways should be no greater than 10^{-5} [1]. This applies whether or not the pathways arise from the same medium. Both systemic and local effects may be assessed and considered separately, subject to the availability of toxicity data from a credible agency. By definition, an incremental lifetime cancer risk is additional to background risk. For most COPCs, the calculation of risk due to background exposure is not required as part of risk assessments; however, background exposure should be considered for contaminants, which are above the 10^{-6} risk level [3].

The draft Standard also addresses cases where it is necessary to calculate the risk and/or hazard for exposure to mixtures of chemical contaminants. The term "multi-stressor" is used to describe such situations where a receptor is simultaneously exposed to a number of chemicals near a level of concern (i.e., multi-stressor effects). The resulting effects originate from one or more chemicals as well as their influence on one another.

5. Highlights of the EcoRA Guidance

5.1 Problem Formulation

The draft Standard provides guidance on site characterization, receptor selection and characterization, assessment and measurement endpoints, selection of COPCs and physical stressors, selection of exposure pathways, and development of an ecological conceptual model. The latter summarizes the other elements, providing a blueprint for the subsequent assessment.

Ecological receptors and locations are chosen to represent the main exposure pathways, feeding habitats and habitats on the site. Protection of the selected species should provide reasonable assurance that all species are protected. A receptor is not necessarily a particular species but may be defined at a higher taxonomic or community level, such as soil invertebrate or aquatic plant.

Selection of COPCs involves comparing upper bound concentrations on the site (measured or predicted) to screening criteria such as environmental quality criteria or no-effect levels. The screening criteria should not be set below a reasonable upper end of background. Thermal effects and entrainment/impingement should be addressed as physical stressors at nuclear power plants.

5.2 Exposure Assessment

The draft Standard provides guidance on exposure points, temporal and spatial averaging of exposure concentrations, calculating doses as needed for some receptors and COPCs, sources of relevant parameter values, and use of modelled concentrations where measured values are not available.

At least one exposure value (EV) for each receptor should represent the highest COPC exposure likely to be received by that receptor. Critical habitat areas should be represented as exposure areas. For immobile receptors, such as plants and soil invertebrates, the maximum or upper percentile concentration for an area should be used to represent exposure. For mobile organisms, an upper confidence limit on the mean concentration for an exposure area is recommended. When using modelled concentrations, an area-weighted average of concentrations can be used.

Doses are used to represent exposure for radiological COPCs (all organisms) and non-radiological COPCs (birds and mammals only). Radiological dose calculations follow Brown et al. [4]. Dose coefficients for reference organisms are cited [5] [6]. Non-radiological dose calculations follow Sample and Suter [7]. For wildlife, ingestion pathways are considered to dominate, with a few exceptions, such as noble gases.

The uptake of COPCs into tissues is calculated using bioaccumulation factors, or intakes and transfer factors for birds and mammals. Sources these factors are cited [8], and use of site-specific factors is encouraged. Specific activity models are recommended for tritium and carbon-14.

A nominal radiation weighting factor of 2 is recommended when calculating dose from tritium, and a range of 1 to 3 should be considered in evaluation of uncertainty. A weighting factor of 10 is

recommended as a central value for the alpha component of internal dose from alpha emitting radionuclides [9].

5.3 Effects Assessment

The draft Standard provides guidance on radiological, toxicological and thermal benchmark values. A benchmark value (BV) provides a point of comparison for estimated exposure values (EV).

Benchmark values applicable under chronic (long-term) exposure situations are generally appropriate. Site-specific modifying factors should be considered, if relevant, for non-radiological COPCs. Radiation dose benchmarks, thermal benchmarks, and sources of chemical-specific toxicological benchmarks are cited.

5.4 Risk Characterization

The draft Standard provides guidance on risk estimation by calculating hazard quotients (HQ = EV / BV), and on incorporating other lines of evidence, such as field toxicity data or field survey data, if available.

An HQ>1 for an area indicates that a COPC is present at levels that have the potential for adverse effects. The area(s) where HQ>1 should be noted; field evidence may be useful in these areas to resolve whether there are measureable effects. If the area(s) where HQ>1 are small, only a few individuals might be potentially affected, out of an entire population, with little potential for population level effects. However, for vulnerable, threatened or endangered species, potential effects on a few individuals will be of greater concern.

Some issues, such as entrainment/impingement (E/I) at nuclear power plants, are not amenable to HQ approaches. Nevertheless, it is recommended that E/I be specifically addressed at the power plants, by quantifying organism losses, and comparing to relevant harvest statistics, if available. Definition of relevant populations is often problematic. However, the losses can at least be tracked over time, and investigative/corrective actions taken if they start to increase.

6. Evaluation of Uncertainty

For both HHRA and EcoRA, for each component of the assessment (problem formulation, exposure assessment, toxicity/effects assessment, risk characterization) the important uncertainties must be evaluated, either qualitatively or semi-quantitatively, and discussed in the ERA report. Approaches or parameters used in the assessment that will likely lead to an overestimation or underestimation of exposure, toxicity or risk should be identified, and judgements about the degree of over- or underestimation should be provided, if possible. The evaluation can aid in identifying areas where collection of additional data might help to reduce uncertainty around the conclusions of the risk assessment. Uncertainty may also be addressed through probabilistic risk assessment (PRA). General guidance on PRA is provided, and references to more comprehensive guides are cited.

7. Risk-based Recommendations

The ERA results might point to a need for more monitoring data to address new issues, or to better resolve existing environmental issues. Alternatively, the ERA might indicate that some existing monitoring activities are unnecessary. As such, if appropriate, the ERA should recommend any changes to the monitoring program that are needed to focus the program and reduce uncertainties.

The ERA results might indicate that meaningful human health or ecological effects are likely, which will trigger consideration of risk management (e.g. blocking key exposure pathways) or remediation (e.g. reducing concentrations of contaminants). While decisions about risk management or remediation are the responsibility of the risk manager, the risk assessor may make recommendations about the need for such actions, about possible conceptual approaches, and about preliminary remediation goals if remediation is recommended.

8. Quality Assurance and Quality Control

Quality assurance (QA) activities are performed to monitor, document, and control the quality of the ERA process (e.g. planning, data gathering, data management, data analysis, report preparation, and record keeping). Quality control (QC) activities specifically monitor and control discrete laboratory and field tasks. QA/QC requirements for the ERA should be specified in the planning phase, and QA/QC data should be routinely evaluated to verify that the ERA is adequately addressing environmental issues. The requirements may exist as part of a larger facility QA program or as part of a related environmental monitoring program.

9. References

[1] Health Canada, “Federal Contaminated Site Risk Assessment in Canada, Part I: Health Canada Preliminary Quantitative Risk Assessment (PQRA).” 2004.

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[4] Brown, J., Strand, P., Hosseini, A. and Borretzen, P., “Handbook for Assessment of the Exposure of Biota to Ionising Radiation from Radionuclides in the Environment. FASSET Deliverable 5.” 2003.

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[6] International Commission on Radiological Protection, “Environmental Protection: The Concept and Use of Reference Animals and Plants.” Publication 108, Annals of the ICRP, Volume 38 Nos4-6, 2008.

[7] Sample, B.E. and Suter, G.W., “Estimating Exposure of Terrestrial Wildlife to Contaminants” ES/ER/TM-125. Oak Ridge National Laboratory, Oak Ridge. 1994.

[8] International Atomic Energy Agency, “Handbook of Parameter Values for the Prediction of Radionuclide Transfer in Terrestrial and Freshwater Environments.” TRS No. 472. 2010.

[9] United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), “Sources and Effects of Ionizing Radiation. Report to the General Assembly, with Scientific Annexes. Annex E.” 2008.