Procedures for the Use of Risk Assessment under Part XV.1 of the *Environmental Protection Act*

DRAFT v.2.12

July 2020

Prepared by:

Ministry of the Environment, Conservation and Parks

Technical Assessment and Standards Development Branch

Toronto, Ontario, Canada

**PREFACE**

Property owners who wish to convert brownfield properties (e.g. industrial or commercial properties) to more sensitive uses such as community centres, schools, or housing, must first have a record of site condition (RSC) filed on the Ministry of Environment, Conservation and Parks (the Ministry) Environmental Site Registry to ensure that the property meets certain requirements. An RSC documents the environmental state of the property, provides the owner with certain limited liability protections, and must be prepared in accordance with the *Environmental Protection* *Act* and Ontario Regulation 153/04. In cases where there is no change in property use, or the change in property use is not to a more sensitive use, note that the property owner still has the option of submitting an RSC for filing, even though this may not be required under the *Environmental Protection Act*.

To support brownfield redevelopment, the Ministry has developed generic site condition standards for soil, groundwater, and sediment for use under Ontario Regulation 153/04. These generic site condition standards provide protection against the potential for adverse effects to human health, ecological health, and the natural environment at typical brownfield sites and are provided in a series of Tables included in the Ministry document entitled “Soil, Ground Water and Sediment Standards for Use under Part XV.1 of the Environmental Protection Act”, dated April 15, 2011. They provide applicable site condition standards for a given property based on a series of factors, including the intended property use, soil texture, groundwater use (potable or non-potable), and several other soil and/or property characteristics. In general, these standards are developed using a risk-based approach, but background soil concentrations and analytical detection limits were also considered in developing these generic site condition standards. Details on how these standards were developed, including a more detailed description of environmental fate and transport modelling, human and ecological receptors, and specific exposure scenarios, are documented in the Ministry’s “Rationale for the Development of Soil and Ground Water Standards for Use at Contaminated Sites in Ontario”, dated April 15, 2011.

When submitting an RSC for filing, the proponent must show that their site will be able to meet the applicable generic site condition standards, or propose property-specific standards developed through a risk assessment. The risk assessment must be accepted by the Ministry before these property specific standards can be used to support submission of an RSC for filing. In some cases, the proponent may choose to remediate the site to meet either the generic site condition standards or the property specific standards (developed as part of a risk assessment) and/or employ risk management measures to manage unacceptable risks.

This document, the Procedures for the Use of Risk Assessment under Part XV.1 of the *Environmental Protection Act* (Procedures document) describes the legislative and regulatory requirements for conducting and submitting risk assessment reports under the *Environmental Protection* *Act* and Ontario Regulation 153/04. This Procedures document also contains plain language guidance for risk assessment practitioners (e.g. consultants, qualified persons) on how to conduct risk assessment work and prepare risk assessment reports.

It should be noted that the description of the legislative and regulatory requirements given in this Procedures document is for convenience only. A copy of the relevant legislation and regulations should be obtained and reviewed to determine the exact requirements, refer to Ontario’s [e-Laws website](https://www.ontario.ca/laws) (URL: https://www.ontario.ca/laws).

This Procedures document may be updated from time to time.

Table of Contents

[**PREFACE** ii](#_Toc41905636)

[**List of Commonly Used Terms and Abbreviations** viii](#_Toc41905637)

[Section 1. Initiating the Risk Assessment 1](#_Toc41905638)

[1.1. Introduction 1](#_Toc41905639)

[1.2. Background to Risk Assessment 2](#_Toc41905640)

[1.3. Purpose of Risk Assessment Under the Regulation 3](#_Toc41905641)

[1.4. Role and Responsibilities of the Risk Assessment Qualified Person 4](#_Toc41905642)

[1.4.1. Insurance and Conflict of Interest 4](#_Toc41905643)

[1.4.2. Mandatory Certifications 4](#_Toc41905644)

[1.4.3. Formation of Risk Assessment Team 5](#_Toc41905645)

[1.5. Preparation for Conducting a Risk Assessment 6](#_Toc41905646)

[1.6. Development of Standards: A Tiered Approach 7](#_Toc41905647)

[Section 2. Pre-Submission Form and Public Communication 9](#_Toc41905648)

[2.1. PSF Overview 9](#_Toc41905649)

[2.2. PSF Requirements 10](#_Toc41905650)

[2.2.1. Property Ownership and Location 10](#_Toc41905651)

[2.2.2. Risk Assessment Approach 11](#_Toc41905652)

[2.2.3. Conceptual Site Model 11](#_Toc41905653)

[2.2.4. Phase Two Conceptual Site Model 11](#_Toc41905654)

[2.2.5. Human Health and Ecological Conceptual Site Models 13](#_Toc41905655)

[2.2.6. Drawings and Figures – Additional Guidance 14](#_Toc41905656)

[2.2.7. Other Attached Documents – Additional Guidance 14](#_Toc41905657)

[2.3. Self-Declaring Qualifications in PSF 15](#_Toc41905658)

[2.4. Change in Circumstance 15](#_Toc41905659)

[2.5. Public Communication 16](#_Toc41905660)

[Section 3. Preparation Of An RA Report 19](#_Toc41905661)

[3.1. General RA Report Requirements 19](#_Toc41905662)

[3.2. Summary of Recommendations and Findings 20](#_Toc41905663)

[3.3. Conclusions and Recommendations 21](#_Toc41905664)

[3.3.1. Recommending Property Specific Standards 23](#_Toc41905665)

[3.3.2. Proposing Excessively High Property Specific Standards 24](#_Toc41905666)

[3.3.3. Proposing Multiple Sets of Property Specific Standards 25](#_Toc41905667)

[3.3.4. Non-Standard Delineation 25](#_Toc41905668)

[3.3.5. Assessment of Off-Site Risk 25](#_Toc41905669)

[3.3.6. Special Considerations for Groundwater Standards 26](#_Toc41905670)

[3.4. Appendices to RA Report 26](#_Toc41905671)

[Section 4. Property Information, Site Plan and Geological Interpretation 29](#_Toc41905672)

[4.1. Property Information 31](#_Toc41905673)

[4.2. Site Plan and Hydrogeological Interpretation of RA Property 31](#_Toc41905674)

[4.2.1. Conceptual Site Model – Additional Guidance 32](#_Toc41905675)

[4.3. Contaminants of Concern 32](#_Toc41905676)

[4.3.1. Screening for Contaminants of Concern – Additional Guidance 34](#_Toc41905677)

[4.3.2. Summary of Sampling Program 36](#_Toc41905678)

[4.3.3. Data Quality Assessment 36](#_Toc41905679)

[4.3.4. Site Investigation and Currency of Property Data 37](#_Toc41905680)

[Section 5. General Guidance for Conducting Risk Assessments 39](#_Toc41905681)

[5.1. Principal Elements of Risk Assessment (HHRA and ERA) 39](#_Toc41905682)

[5.2. Risk Assessment Objectives 39](#_Toc41905683)

[5.3. Screening Process for Quantitative Risk Assessment 40](#_Toc41905684)

[5.3.1. Using Ministry Component Values 41](#_Toc41905685)

[5.3.2. COCs with No Site Condition Standards 43](#_Toc41905686)

[5.4. Contaminant Fate and Transport Modelling 43](#_Toc41905687)

[Section 6. Human Health Risk Assessment 45](#_Toc41905688)

[6.1. Problem Formulation 45](#_Toc41905689)

[6.1.1. Human Health Conceptual Site Model 46](#_Toc41905690)

[6.1.2. Risk Assessment Objectives 47](#_Toc41905691)

[6.1.3. Discussion of Data Quality 48](#_Toc41905692)

[6.2. Exposure Assessment 48](#_Toc41905693)

[6.2.1. Receptor Characteristics 49](#_Toc41905694)

[6.2.2. Pathway Analysis 50](#_Toc41905695)

[6.2.3. Exposure Estimates 52](#_Toc41905696)

[6.2.4. Site-Specific Deviations from Generic Exposure Parameters 54](#_Toc41905697)

[6.2.5. Selecting Exposure Point Concentrations for Soil and Groundwater 55](#_Toc41905698)

[6.3. Toxicity Assessment 56](#_Toc41905699)

[6.3.1. Hazard Assessment 57](#_Toc41905700)

[6.3.2. Dose-Response Assessment 57](#_Toc41905701)

[6.4. Risk Characterization 59](#_Toc41905702)

[6.4.1. Quantitative Interpretation of Health Risks 61](#_Toc41905703)

[6.4.2. Qualitative Interpretation of Health Risk 66](#_Toc41905704)

[6.4.3. Special Considerations 67](#_Toc41905705)

[6.4.4. Interpretation of Off-Site Health Risks 67](#_Toc41905706)

[6.4.5. Discussion of Uncertainty 68](#_Toc41905707)

[Section 7. Ecological Risk Assessment 70](#_Toc41905708)

[7.1. Levels of Assessment 70](#_Toc41905709)

[7.2. Problem Formulation 71](#_Toc41905710)

[7.2.1. Ecological Conceptual Site Model 73](#_Toc41905711)

[7.2.2. Risk Assessment Objectives 75](#_Toc41905712)

[7.2.3. Discussion of Data Quality 76](#_Toc41905713)

[7.3. Receptor Characterization 76](#_Toc41905714)

[7.4. Exposure Assessment 78](#_Toc41905715)

[7.4.1. Pathway Analysis 79](#_Toc41905716)

[7.4.2. Exposure Estimates 80](#_Toc41905717)

[7.5. Hazard Assessment 82](#_Toc41905718)

[7.6. Risk Characterization 85](#_Toc41905719)

[7.6.1. Quantitative Interpretation of Ecological Risk 86](#_Toc41905720)

[7.6.2. Qualitative Interpretation of Ecological Risk 87](#_Toc41905721)

[7.6.3. Special Considerations 89](#_Toc41905722)

[7.6.4. Interpretation of Off-Site Ecological Risks 90](#_Toc41905723)

[7.6.5. Discussion of Uncertainty 91](#_Toc41905724)

[Section 8. Risk Management Plan 92](#_Toc41905725)

[8.1. Risk Management Performance Objectives 94](#_Toc41905726)

[8.2. Risk Management Measures and Ongoing Monitoring 95](#_Toc41905727)

[8.3. Additional Guidance 96](#_Toc41905728)

[8.4. Financial Assurance 97](#_Toc41905729)

[8.5. Certificate of Property Use 97](#_Toc41905730)

[Section 9. Alternative Risk Assessment Procedures 98](#_Toc41905731)

[9.1. Limited Scope Risk Assessment 98](#_Toc41905732)

[9.1.1. Modified Generic Risk Assessment 98](#_Toc41905733)

[9.1.2. Risk Assessment Based on a Community Assessment Report 99](#_Toc41905734)

[9.2. Estimation of Natural Local Background Concentration Risk Assessment 100](#_Toc41905735)

[9.3. New Science Risk Assessment 102](#_Toc41905736)

[9.3.1. No Applicable Site Condition Standard for a COC 102](#_Toc41905737)

[9.3.2. Use of Proprietary Computer Models 103](#_Toc41905738)

[9.3.3. Use of Probabilistic Models 105](#_Toc41905739)

[9.4. Wider Area of Abatement Risk Assessment 105](#_Toc41905740)

[Section 10. Risk Assessment Submission and Review Process 107](#_Toc41905741)

[10.1. Summary of Risk Assessment Process 107](#_Toc41905742)

[10.2. Ministry Review and Decision Making 108](#_Toc41905743)

[10.2.1. Notice of Circumstance 109](#_Toc41905744)

[10.2.2. Decision to “Accept” or “Not Accept” the Risk Assessment 109](#_Toc41905745)

[10.3. Additional Considerations 109](#_Toc41905746)

[Section 11. Resources and References for Risk Assessment 111](#_Toc41905747)

[11.1. Ministry Guidance and Resources 111](#_Toc41905748)

[11.2. Useful References for Human Health Risk Assessment 112](#_Toc41905749)

[11.3. Useful References for Conducting Ecological Risk Assessments 116](#_Toc41905750)

[Appendix A – Lawyer’s Letter Template 119](#_Toc41905751)

[Appendix B – Procedure to Register a Certificate of Requirement 121](#_Toc41905752)

**List of Commonly Used Terms and Abbreviations**

**Approved model:** A spreadsheet-based model that was used by the Ministry to develop the generic site condition standards and that can be used by a QPRA to develop property specific standards by modifying physical site characteristics, certain pathways and opting into risk management measures developed by the Ministry. Defined in section 1 (Definitions) of Schedule C of Ontario Regulation 153/04.

**Certificate of property use (CPU):** A CPU is a legal instrument that the Director can issue to the owner of any property for which a risk assessment has been conducted that includes risk management measures. A CPU can require that certain actions be taken to prevent, eliminate or ameliorate any adverse effect that was identified in the risk assessment, and can require that the owner refrain from using the property in specified ways or from constructing specified buildings (refer to section 168.6 of the EPA). The CPU must be issued to the property owner before an RSC can be filed if risk management measures are required for an RA property.

**Component value:** A numerical value developed by the Ministry to provide a human or ecological receptor or group of receptors protection from a contaminant via a specific exposure pathway. The Ministry’s “Rationale for the Development of Soil and Ground Water Standards for Use at Contaminated Sites in Ontario”, dated April 15, 2011, includes the generic component values used in the development of the 2011 generic site condition standards. The Ministry’s approved model includes the most up-to-date generic component values and also allows for the derivation of site-specific component values.

**Contaminants of concern (COCs):** Contaminants present in, on or under a property that exceed their applicable site condition standards, or contaminants present in, on or under a property for which there is no applicable site condition standard and the contaminant is associated with a potentially contaminating activity. Defined in section 1 (Definitions) of Ontario Regulation 153/04.

**Ecological conceptual site model:** A diagram with explanatory text that provides information for all contaminants of concern that exceed the applicable site condition standard including (i) the release mechanisms, (ii) contaminant transport pathway, (iii) the ecological receptors, (iv) receptor exposure points, and (v) routes of exposure and explains how the environmental characterization information from the phase two ESA (including the phase two conceptual site model) was incorporated and relied upon in the preparation of the risk assessment.

**Ecological receptor:** A non-human organism identified as potentially experiencing adverse impacts from exposure to a contaminant, either directly through contact or indirectly through food chain transfer.

**Ecological risk assessment (ERA):** A component of a risk assessment that characterizes the nature and magnitude of risks to the environment from exposure to contaminants of concern.

**Environmental Registry of Ontario (ERO):** A public registry under the *Environmental Bill of Rights, 1993* where certain CPUs are posted for public comment.

**Environmental site assessment (ESA):** An environmental investigation that characterizes the environmental condition of a property. Can include a phase one ESA and phase two ESA under Ontario Regulation 153/04.

**Environmental Site Registry:** A public registry under the *Environmental Protection Act* where RSCs are filed.

**Human health conceptual site model:** A diagram with explanatory text that provides information for all contaminants of concern that exceed their applicable site condition standard including (i) the release mechanisms, (ii) contaminant transport pathway, (iii) the human receptors, (iv) receptor exposure points, and (v) routes of exposure and explains how the environmental characterization information from the phase two ESA (including the phase two conceptual site model) was incorporated and was relied upon in the preparation of the risk assessment.

**Human health risk assessment (HHRA):** A component of a risk assessment that characterizes the nature and magnitude of risks to human health from exposure to contaminants of concern.

**Modified generic risk assessment (MGRA):** A risk assessment that makes use of the approved model and is completed in accordance with subsection 7 (3) of Schedule C of Ontario Regulation 153/04. Also referred to as Tier 2 risk assessment.

**Natural environment:** The air, land and water, or any combination or part thereof, of the Province of Ontario, as defined in the EPA.

**On-site:** On the RA property.

**Off-site:** Off the RA property.

**Phase one ESA:** A phase one ESA is conducted “to determine the likelihood that one or more contaminants have affected all or part of the property” (refer to Definitions in Part XV.1 of the EPA). The specific requirements for carrying out a phase one ESA are set out in Part VII and Schedule D of Ontario Regulation 153/04. Phase one ESAs include identifying any past or present uses or activities that may have resulted in contaminants on the property and identifying any areas on, in or under the property where contaminants are potentially present.

**Phase two conceptual site model:** Describes the environmental condition of a property by summarizing the presence, location and concentration of any contaminants of concern in soil, groundwater and/or sediment as determined by the phase two ESA.

**Phase two ESA:** A phase two ESA is conducted “to determine the location and concentration of one or more contaminants in the natural environment” (refer to “Definitions” in Part XV.1 of the EPA). The specific requirements for carrying out a phase two ESA are set out in Part VIII and Schedule E of Ontario Regulation 153/04. Phase two ESAs include a physical site investigation (e.g. undertaking sampling and analysis of soil, groundwater and/or sediment) to determine the presence, location, and concentration of any contaminants of concern.

**Pre-submission form (PSF):** A Ministry form that includes a description of the RA property and property ownership, lists the contaminants of concern, potential receptors; transport and exposure pathways described in the conceptual site model and provides a proposal for proceeding with the risk assessment. The PSF must contain the information specified in subsections 3 (5) to 3 (11) of Schedule C of Ontario Regulation 153/04, and any other information required by the Director.

**Property specific standard (PSS):** A soil, groundwater or sediment standard specified in a risk assessment which has been conducted according to Ontario Regulation 153/04 and accepted by the Director under Section 168.5 of the EPA.

**Qualified person (QP):** A qualified person for environmental site assessment or risk assessment, as defined in either section 5 or 6 of Ontario Regulation 153/04.

**QPESA :** A qualified person who is responsible for conducting or supervising the environmental site assessment for the purposes of section 168.1 of the EPA as set out in section 5 of Ontario Regulation 153/04.

**QPRA :** A qualified person who is responsible for conducting or supervising the risk assessment for the purposes of section 168.1 of the EPA as set out in section 6 of Ontario Regulation 153/04.

**Record of site condition (RSC):** An RSC is a document which summarizes the environmental condition of a property as determined by a QP by conducting a phase one ESA, a phase two ESA (if required) and confirmatory sampling (if remediation has been undertaken). Under Part XV.1 of the *Environmental Protection Act*, an RSC must be submitted and filed in the Registry if a property owner wishes to change the use of a property in certain ways and/or obtain protection from potential future environmental orders for the property as specified in Part XV.1.

**Remediation:** Action taken to reduce the concentration of contaminants on, in or under a property.

**Risk assessment property (RA property):** A property that is the subject of a risk assessment. Defined in section 1 (Definitions) of Ontario Regulation 153/04.

**Risk assessment report (RA report):** Written risk assessment report that includes a description of the assessments of risk, following the conduct of an HHRA and ERA, as described section 3 of Schedule C of Ontario Regulation 153/04. RA report mandatory requirements are specified in section 4 of Schedule C of Ontario Regulation 153/04.

**Risk management measure:** Measure on the RA property that is designed to prevent, eliminate or ameliorate any adverse effects on or off the RA property. Risk management measures form part of the risk assessment’s risk management plan, and are intended to control or reduce the level of risk estimated by the risk assessment.

**Site condition standards (SCS):** Site condition standards as defined in Ontario Regulation 153/04 and included in the document “Soil, Ground Water and Sediment Standards for Use Under Part XV.1 of the Environmental Protection Act” published by the Ministry and dated April 15, 2011. Also referred to as generic standards.

**Valued ecosystem components (VECs):** Specific ecological receptors (e.g. individual organism, species, population, community, specific habitat) that have been determined to be of ecological importance at the RA property considering the current and proposed land use.

# Initiating the Risk Assessment

## Introduction

This Procedures document contains plain language guidance on how to conduct risk assessment work and prepare a risk assessment report (RA report) for submission to the Ministry of the Environment, Conservation and Parks (the Ministry) under section 168.5 of the *Environmental Protection Act* (EPA) and Schedule C of Ontario Regulation 153/04 (the Regulation). The Regulation governs the preparation of a risk assessment in Ontario for chemical contaminants in soil, groundwater and sediment to support the submission of a record of site condition (RSC) for a property. RA reports must comply with the mandatory requirements specified in Schedule C (including Table 1 of Schedule C). In this document, references to the Regulation and the EPA, including portions reproduced exactly from Schedule C, are provided to identify the mandatory requirements for all RA reports and also to identify the characteristics of risk assessments that may use alternate procedures and be subject to alternate review timelines. However, it is important that property owners and qualified persons (QPs) consult the actual legislation and regulations, as amended, and seek the advice of a lawyer as appropriate.

Where this document refers to mandatory requirements for RA reports, as set out in the Regulation, these actions are signified by the word “must”. Failure to meet these mandatory requirements means that the risk assessment will be considered by the Ministry to be incomplete and not in accordance with the Regulation. Where the guidance document indicates that something “should” be done, this should be interpreted as an expression of what the Ministry considers to be a best practice. Additional updates on best practices may also be provided from time to time by the Ministry (e.g. on the Ministry’s brownfields website or through email updates). If the best practice is not undertaken, it is advisable that the reasons why the best practice was not followed be documented in the RA report. In deciding whether to accept a risk assessment under section 168.5 of the EPA, one of the factors the Director might consider is whether, and to what extent, best practices have been followed.

Note that this Procedures document does not provide a comprehensive description of all possible risk assessment approaches that may be required for every potential contaminant situation or site condition. Since site conditions differ at each property and decisions may have to be made that are unique to existing circumstances, some risk assessment options are provided. However in all cases, sound scientific judgment should be exercised throughout the risk assessment.

Additional resources for conducting human health and ecological risk assessments should be considered when site contamination or site conditions indicate additional assessment is required or for guidance on specific assessment techniques. For example, this Procedures document does not provide details for biological or hydrogeological monitoring, or epidemiological studies. It is specific to contaminated sites in a brownfields scenario and does not address all activities required for the design of community-based or area-wide risk assessment studies.

This Procedures document is intended for use by experienced risk assessment practitioners, in conjunction with best professional judgment and current science. Additional information sources are provided at the end of this Procedures document for reference purposes.

Note that this Procedures document was first published by the Ministry in 2005, to accompany the then newly enacted Regulation (which came into force on October 1, 2004). The Regulation has since been amended several times, most notably in July 2011 (updated ESA phase one and two requirements, updated generic site condition standards, release of the approved model) and December 2019; this Procedures document has been updated to account for these amendments.

## Background to Risk Assessment

Risk, in the context of environmental risk assessment, is a measure of the probability that a hazard will cause harm to an individual, population or the natural environment under defined conditions of exposure to a contaminant. Risk assessment is the scientific process used to describe and estimate the likelihood of adverse health effects resulting from exposure of both human and ecological receptors to environmental contaminant(s). “Receptors” are used to describe who or what is exposed to contaminant(s) and can include people, organisms, populations, and/or the natural environment.

Human health risk assessment (HHRA) is the evaluation of the risk of adverse health effects, and the accompanying uncertainties, to people as a result of exposure to contaminant(s) at a given property. Similarly, ecological risk assessment (ERA) is a process that evaluates the risk that adverse ecological effects may occur, or are occurring, as a result of exposure to contaminant(s). Both assessments take into consideration that many contaminants may be present simultaneously in several media such as soil, groundwater, sediment but also food, air, surface water, dust and/or consumer products, and that these contaminants reach receptors through multiple exposure pathways. An exposure pathway is the physical course or route a contaminant takes from its source to a receptor evaluated in the risk assessment.

Since property-specific characteristics are incorporated into a risk assessment for a contaminated site, there can be numerical differences between the Ministry’s published generic site condition standards and the property specific standards developed through risk assessment. While these property specific standards may be different (usually numerically higher) than the generic standards, they are still expected to provide the same level of protection to human health and the environment as the generic standards. The main difference is that the generic standards are designed to be applicable for most brownfield properties across the Province while property specific standards are based on a specific property and can incorporate site-specific input parameters into the risk assessment. In addition, some of the conservative assumptions utilized in the setting of the generic site condition standards may not be required for a specific brownfield property and site-specific information can be used instead.

Risk assessment can often lead to recommendations to utilize risk management measures in order to provide protection to human health and the environment. In these situations, risk management measures must be maintained to achieve the same level of protection as the generic standards. Risk management is a process which is distinct and separate from other components of risk assessment, by which measures to control or reduce the level of risk estimated by the risk assessment are developed and implemented. Risk management integrates the results from the other components of risk assessment with information about technical resources, socio-economic factors and control options in order to reach decisions about the best way to manage a property to protect human health and the environment. It is important that the HHRA and ERA components of risk assessment are clearly separated from the risk management component so that risk managers have scientifically based risk estimates upon which to base risk management decisions.

## Purpose of Risk Assessment Under the Regulation

For the purpose of this Procedures document, risk assessment is a process for estimating the likelihood of adverse effects that could arise from the presence of contaminants of concern (COCs) and exposure pathways to human and ecological receptors at a contaminated property. As such, information derived from conducting a risk assessment is used to determine the standard for each COC that may be applied when submitting an RSC for filing in respect of a property under section 168.4 of the EPA. The standards proposed in a risk assessment are referred to as a property specific standard. The risk assessment process can also help risk managers evaluate and compare the effectiveness of remediation and risk management alternatives for a specific property.

Risk assessment principles have been utilized in the generic process which the Ministry used to develop the site condition standards. The site condition standards are applicable at most situations encountered at contaminated sites but may not always be appropriate for situations where property-specific considerations deviate substantially from the conditions assumed in the Ministry generic process used to develop the site condition standards.

If a risk assessment approach is considered as an alternative to using the site condition standards in order to account for property specific considerations, the property owner should be advised of the recommendations in this Procedures document and the potential limitations associated with the risk assessment approach. Based on the level of effort required to assess risk for COCs on some properties, it may be preferable to remediate the property to the applicable site condition standards or first complete additional remediation (e.g. remove hotspots) prior to undertaking the risk assessment.

The following sections of the Regulation should be referred to when considering what approach might be taken to the risk assessment:

* Section 44 (Risk assessment form)
* Section 2 of Schedule C (Components of a risk assessment)
* Section 6 of Schedule C (Alternative risk assessment procedures)

In the initiation stages of a risk assessment, reference should be made to the following sections of the Regulation:

* Section 3 of Schedule C (Mandatory requirements of a pre-submission form)
* Table 1 of Schedule C (Report Section 2. Risk Assessment Team and Report Section 8. Public Communication Plan)

Additional guidance on meeting the requirements of these sections is provided in this document.

For a more general overview of the risk assessment and RSC processes, please refer to the Ministry’s guidance document “Records of Site Condition - A Guide on Site Assessment, the Cleanup of Brownfield Sites and the Filing of Records of Site Condition”, dated xx 2020.

## Role and Responsibilities of the Risk Assessment Qualified Person

A risk assessment must be conducted by a qualified risk assessment team under the supervision of a qualified person for risk assessment (QPRA). The qualifications of a QPRA are specified in the Regulation:

* Section 6 of the Regulation (Qualified persons, risk assessment)

The QPRA’s role should include communicating the risk assessment process and the complex nature of risk assessments to the property owner. This includes helping plan realistic project timelines and goals. The QPRA can also serve as the owner’s point of contact when communicating with the Ministry on risk assessment related matters.

As part of the process of submitting a pre-submission form (PSF), the QPRA will need to self-declare that they have the qualifications set out in the Regulation; a resume, post-secondary education transcripts and work references will also need to be provided at that time. Once these qualifications have been submitted to the Ministry, they do not need to be provided again in subsequent PSF and risk assessment submissions. Additional details regarding the PSF submission process and requirements are included in subsequent sections of this Procedures document.

A resume for the QPRA and each team technical lead must also be provided in an Appendix to the RA report. Mandatory appendices to the RA report are discussed in subsequent sections of this document.

### Insurance and Conflict of Interest

The Regulation specifies requirements related to conflict of interest and insurance for all QPs (QPRA and QPESA):

* Section 6.1 of the Regulation (Qualified persons, conflict of interest)
* Section 7 of the Regulation (Qualified persons, insurance)

### Mandatory Certifications

When submitting a risk assessment to the Ministry, the QPRA must make the certified statements verbatim as set out in the Regulation:

* Section 5 of Schedule C of the Regulation (Mandatory certifications)

The QPRA will need to carefully consider site-specific conditions before determining whether to include the final certification statement listed in Schedule C, Subsection 5(3) regarding potential for off-site migration.

### Formation of Risk Assessment Team

In addition, the QPRA must identify the technical leads for the risk assessment team and demonstrate that the team possesses all required/relevant disciplines to complete the risk assessment. If a technical lead for a specific discipline is absent from the risk assessment team, the QPRA must explain why that particular discipline is not required for the completion of the risk assessment. The minimum requirements for the risk assessment team are provided in Table 1 of Schedule C of the Regulation, and reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 2. Risk Assessment Team Membership | not applicable | not applicable | 1. State the expertise required to complete this risk assessment and design of any risk management measures specified in Report Section 7 (Risk Management Plan) and justify the omission of areas of expertise normally associated with the completion of a risk assessment.  2. Identify each team member with the expertise necessary to complete the risk assessment and state how their qualifications relate to the given role and expertise required for this risk assessment. |

Risk assessment team technical leads should be identified in the PSF and the RA report for each of:

* Human health risk assessment
* Ecological risk assessment
* Hydrogeology/Geoscience
* Engineering (if risk management is required)

Ideally, the QPESA who prepared or oversaw the preparation of the phase one and two ESA reports (and/or who will be responsible for submitting the RSC for filing) will be included in the risk assessment team.

The following areas of expertise are normally associated with completion of a risk assessment. A particular risk assessment team should generally cover all areas of academic expertise listed below, but may vary depending on the site being assessed. Several areas of expertise may be covered by a single team member, and team members’ expertise may overlap, however all areas should be covered by the team as a whole.

Educational qualifications for individual risk assessment team technical leads should include a specialized post-secondary education equivalent to a four-year degree level in one or more of the following areas:

* Human and/or mammalian toxicology
* Ecotoxicology (aquatic and terrestrial)
* Geology/geoscience/hydrogeology
* Soil science/soil chemistry
* Environmental science
* Environmental chemistry
* Analytical chemistry
* Engineering

One or more team members also should have work experience in one or more of the following:

* Contaminated land assessment
* Environmental sampling, including soil sampling design and methodology
* Groundwater sampling design and methodology
* Surface water and sediment sampling design and methodology
* Biota assessment, including sampling and conducting toxicity tests/bioassays
* Interpretation of analytical data and QA/QC procedures
* Assessment of contaminant exposure pathways and risk
* Contaminant fate and transport in the environment
* Exposure assessment
* Data evaluation/statistical analysis
* Toxicity evaluation (including hazard and dose-response assessment)
* Risk evaluation
* Remediation technologies

## Preparation for Conducting a Risk Assessment

Risk assessment, in the context of Part XV.1 of the EPA, is used to establish property specific standards and may include risk management measures. A risk assessment is built upon the results of a phase one ESA and the extensive sampling, analytical work, hydrogeology and other elements of property characterization done in a phase two ESA. The phase one and phase two ESAs must be conducted in accordance with the requirements of the Regulation. Any analytical results to be relied upon in the risk assessment must meet the requirements of section 47 of the Regulation.

To clarify, the Ministry is fully supportive of the use of novel and innovative techniques to investigate environmental contamination, identify contaminant sources and extent of contamination, and develop a conceptual site model in a cost effective and timely manner. Analytical results which are critical to support the assumptions in the risk assessment, however, must be confirmed using methods which comply with section 47 of the Regulation. As an example, field-portable analytical devices such as photoionization detectors, portable gas chromatographs and x-ray fluorescence detectors can be effective tools to identify appropriate locations for collection of samples to be analyzed in compliance with the Regulation and can be relied upon as supporting evidence in the risk assessment. Similarly, data from older site assessments which do not comply with the Regulation can be used to identify where further assessment and/or confirmatory analysis is required. Both compliant analysis and background supporting studies should be summarized in the RA report.

The core of the risk assessment is a risk evaluation based upon proper site characterization, toxicology of COCs, and an assessment of how ecological and human receptors are exposed to these contaminants, as described in this Procedures document.

The site characterization work described in the phase one ESA and phase two ESA reports should be complete before initiating the risk assessment process. Once the ESA work has been completed, a PSF can be prepared for submission to the Ministry. The PSF is an opportunity for pre-consultation with the Ministry; PSF requirements and general considerations are provided in Section 2 of this Procedures document.

## Development of Standards: A Tiered Approach

The Ministry has taken a tiered approach to the standards setting process under the Regulation, which can be described as follows:

* Tier 1: generic site condition standards (i.e. Tables 1 to 9). These generic site condition standards provide protection against the potential for adverse effects to human health, ecological health, and the natural environment at typical brownfield sites and are provided in a series of Tables included in the Ministry document entitled “Soil, Ground Water and Sediment Standards for Use under Part XV.1 of the Environmental Protection Act”, dated April 15, 2011. They provide applicable site condition standards for a given property based on a series of factors, including the intended property use, soil texture, ground water use (potable or non-potable), and several other soil and/or property characteristics. In general, these standards are developed using a risk-based approach, but background soil concentrations and analytical detection limits were also considered in developing these generic site condition standards. Details on how these standards were developed, including a more detailed description of environmental fate and transport modelling, human and ecological receptors, and specific exposure scenarios, is documented in the Ministry’s “Rationale for the Development of Soil and Ground Water Standards for Use at Contaminated Sites in Ontario”, dated April 15, 2011.
* Tier 2: property specific standards developed as part of a risk assessment, by only using the Ministry’s approved model. The approved model uses the same risk-based approach (including modelling and exposure assumptions) as Tier 1; however, for Tier 2, the QPRA can modify some parameters to better reflect property specific conditions. For this reason, Tier 2 is formally known as modified generic risk assessment (MGRA) in the Regulation. Tier 2 also allows for the incorporation of a limited set of predefined risk management measures. The approved model was first released in April 2011 and updated in November 2016. The approved model may be updated by the Ministry from time to time to reflect advances in science; only the latest version of the model may be used.
* Tier 3: property specific standards developed as part of risk assessment, by using a wide range of risk assessment models and tools. Tier 3 risk assessments are typically conducted for more complex sites and often require additional oversight and management to ensure contaminants that remain at the property do not result in any unacceptable risks to human health or the environment based on the proposed future use(s) of the property.

Much of the information provided in this Procedures document will apply to both Tier 2 and Tier 3 risk assessment approaches, as both approaches share several commonalities (e.g. must be prepared by QPRA, submission of PSF, identification of COCs, proposing property specific standards, etc.). However, in this document, greater emphasis has been placed on Tier 3 risk assessments (e.g. standard risk assessment, alternative risk assessment procedures, reporting requirements for human health and ecological sections).

For more information on the use of the Ministry’s approved model, its limitations and how to submit a Tier 2 risk assessment, please refer to the document titled “MGRA User Guide: A Guide to Using the “Approved Model” (November 2016) When Submitting a Modified Generic Risk Assessment (MGRA)”, PIBS#8450e.

# Pre-Submission Form and Public Communication

## PSF Overview

As the first stage of conducting a risk assessment, a PSF must be completed and submitted to the Ministry.

The PSF must include property characterization and receptor characterization information. The QPRA should develop the PSF with a team of experts who possess the knowledge and experience required to address all exposure pathways and receptors of potential concern.

For Tier 3 risk assessments, the PSF must be submitted to the Ministry prior to submission of the risk assessment. In these cases, the PSF provides an important opportunity to pre-consult with the Ministry regarding the risk assessment approach and general scope as described in both narrative and visual forms (conceptual site model), developed in consideration of site-specific conditions. For Tier 3 risk assessments, the Ministry will prepare a letter of response that indicates the review timeline required for the risk assessment approach, as well as comments concerning the conceptual site model and scope of the risk assessment.

For Tier 2 risk assessments, the PSF is included with the risk assessment submission; the Ministry will review and provide comment on the PSF and risk assessment at the same time.

The QPRA must prepare the PSF for the property owner, based on results of the completed phase one ESA and phase two ESA, and any other investigations that may have been conducted. The purpose of the PSF is to:

* Identify the RA property and ownership;
* Identify the risk assessment team technical leads and self-declaration of the QPRA;
* Confirm that a phase one ESA and phase two ESA have been conducted as prescribed by the Regulation;
* Provide the proposed scope of the risk assessment including a conceptual site model and hazard identification of the RA property by:
* Describing the RA property setting, contaminant sources, COCs, transport pathways, exposure pathways (including the results of any screening level assessment, if performed), and human and ecological receptors,
* Including a summary of key data that supports the conceptual model,
* Proposing the collection of additional data, if required, and
* Proposing an approach for proceeding with the risk assessment that will determine the timeline for risk assessment review.

The PSF process is intended to improve the overall quality of risk assessment submissions by providing the Ministry with the conceptual site model, an overview of the approach to the risk assessment and the risk assessment team at an early stage. The outcome of this preliminary consultation is not binding on the RA property owner or the Ministry, as the understanding of site conditions may develop and/or change during the course of the risk assessment. For this reason, the Ministry comment on the PSF does not in any way indicate acceptance of the final risk assessment approach or other conclusions or acceptance of the risk assessment by the Director pursuant to section 168.5 of the EPA.

## PSF Requirements

The PSF that is approved is available at the Ministry’s brownfields website and may be updated from time to time. The QPRA should refer to the following section regarding requirements for the preparation and submission of a PSF:

* Section 3 of Schedule C

The Regulation specifies that the PSF must include the information listed in subsections 3 (5) to 3 (11) of Schedule C (e.g. property ownership and location information, the type of risk assessment approach, and conceptual site models), as well as any other information required by the Director (i.e. required by the Director through the PSF).

### Property Ownership and Location

Requirements regarding property ownership and location information are listed in:

* Subsection 3 (5) of Schedule C

The Regulation states that the PSF must include details concerning the owners of the RA property, the owner responsible for the submission of the risk assessment and any other current owner and for the RA property, a lawyer’s letter providing a legal description of the RA property and a list of its owners and a description of the nature of their interest, and any municipal address, assessment roll number and property identification number (PIN), that has been prepared by a lawyer after reviewing a current plan of survey and all other necessary documents. Note that the current plan of survey must be submitted with the PSF.

In listing the owners of the property and describing the nature of their interest, the lawyer’s letter should indicate which owner(s) are registered owner(s) and which owner(s) are beneficial owner(s), if applicable. In addition, the lawyer’s letter should attach and refer to the following:

* the plan of survey;
* the parcel registers/PIN abstracts for the RA property;
* the transfer instrument(s) whereby the property owner(s) acquired the RA property;
* documents regarding the owners of the property; and
* other necessary documents.

Please refer to Appendix A for a suggested template for the lawyer’s letter.

Note that in most cases, the phase two ESA property, RA property and RSC property all have the same vertical boundaries, and are owned by a single entity throughout the risk assessment process. In cases where the phase two ESA, RA and RSC properties do not have the same vertical boundaries (e.g. multiple RSCs will be sought for the RA property), or in cases where property ownership is more complex (e.g. multiple owners of the RA property), this must be clearly identified in the PSF and thoroughly explained in the lawyer’s letter. As these circumstances may limit the possible approaches taken in the risk assessment and ultimately the ability to have RSC(s) filed in the Environmental Site Registry, additional consultation with the Ministry may be required in some cases.

In addition to the above, note that in cases where there is more than one owner of the RA property, each owner must be identified in the appropriate section of the PSF and must sign the PSF.

### Risk Assessment Approach

The Ministry’s risk assessment program identifies two main risk assessment approaches: Tier 2 and Tier 3. Schedule C of the Regulation provides additional details regarding the different types of risk assessment (e.g. standard risk assessment, limited scope risk assessment (which includes MGRA/Tier 2), estimation of natural local background concentration risk assessment, wider area of abatement risk assessment) conducted under the Regulation. At the PSF stage, the QPRA must identify the proposed risk assessment approach; this requirement is specified in:

* Subsections 3 (6) of Schedule C

The different types of risk assessment approaches are discussed in further detail in Section 9 of this Procedures document.

### Conceptual Site Model

Explanatory notes should be provided to the extent necessary for the reader to understand the hazards, transport and exposure pathways, receptors and key site data on which the risk assessment approach is based, and including the rationale for why receptors will or will not be exposed to the contaminated media, with and without risk management, and the type of risk management which is contemplated.

Clearly describing the proposed conceptual site model in the PSF is key to obtaining useful Ministry comment. The complete requirements of the Regulation with respect to the PSF and attached drawings are specified in section 3 of Schedule C.

The conceptual site model can be broken down into the following parts:

* Phase two conceptual site model;
* Human health conceptual site model; and
* Ecological conceptual site model.

The different parts of the conceptual site model are further discussed below.

### Phase Two Conceptual Site Model

The purpose of the phase two conceptual site model is to summarize the information on site characterization based on results of the completed phase one ESA and phase two ESA, and any other investigations that may have been conducted. At the PSF stage, the requirements for the phase two conceptual site model are specified in:

* Subsections 3 (8)(a) to (a.4) of Schedule C

These requirements mirror the phase two ESA reporting requirements for the phase two conceptual site model specified in Schedule E of the Regulation:

* Table 1 of Schedule E (Section 6. Review and Evaluation)

For this reason, providing the phase two conceptual site model, extracted directly from the phase two ESA report, is recommend at the PSF stage.

Specifically, the phase two conceptual site model provided with the PSF is expected to include the following information:

* Potentially contaminating activities (PCAs).
* Areas of potential environmental concern (APECs).
* Subsurface structures and utilities that may affect contaminant distribution.
* Stratigraphy from ground surface to the deepest aquifer or aquitard investigated.
* Hydrogeological characteristics (including aquifers, aquitards and lateral and vertical hydraulic gradients).
* Depth to bedrock and water table(s).
* Areas where soil has been brought from another property and placed on, in, or under the RA property.
* Locations of existing and proposed buildings and other structures (if known).
* Identification of the applicable generic site condition standards.
* Identification of all COCs in soil, groundwater and sediment.
* Lateral and vertical distribution (i.e. delineation) of all COCs. Delineation must extend to the next “clean” sampling location (i.e. next sampling location that meets the applicable generic standard), also refer to section 7(3)(c) of Schedule E of the Regulation.

In certain circumstances, the Regulation allows QPs to conduct non-standards delineation (NSD) as part of the phase two ESA, when using a risk assessment approach. NSD provides a limited ability to vary from the delineation requirements set out in clause 7 (4) (c) of Schedule E when a QP provides a rationale that shows that an RA property is appropriately characterized and additional efforts to delineate are unlikely to contribute meaningful and significant information about the distribution and extent of contaminants at the property. Specifically, this relief is limited to the vertical and lateral investigation to the point where COCs in soil or groundwater meet the applicable site condition standard. Refer to provisions of the Regulation, including the following, regarding NSD:

* Subsections 3 (8) (d) of Schedule C
* Section 7.1 of Schedule E (Non-standard delineation)

Note that the NSD approach is intended for Tier 3 risk assessments; QPs should contact the Ministry’s local District Office if they are considering this approach for their site. The local District Office can provide support to help QPs understand Ministry expectations related to NSD.

Based on the information included in the phase two conceptual site model, a complete list of COCs present in soil, groundwater and sediment at the RA property must be included with the PSF. The PSF must include a contaminant inventory, which includes all analytical results for all parameters that were analyzed in soil, groundwater and sediment as part of the phase two ESA; this information should be presented in tabular format to demonstrate proper COC screening.

Finally, it is important that the QPRA confer with the QPESA to ensure that the site characterization work meets the requirements of the Regulation, will be appropriate to support the risk assessment (including any property specific standards that will be developed as part of the risk assessment) and will also support the eventual submission and filing of an RSC in the Environmental Site Registry.

### Human Health and Ecological Conceptual Site Models

Separate human health and ecological conceptual site models must be provided as diagrams; the requirements for these are listed in:

* Subsections 3 (8) (b) and (c) and subsection 3 (9) of Schedule C

As a starting point, the QPRA should review the Ministry’s generic conceptual model used in the development of the generic site condition standards, which is included in the Ministry’s 2011 Rationale document (refer to Section 1.3 and Figure 1.1 of the Rationale document).

The human health and ecological conceptual site models must include all potential receptors, including sensitive receptors (e.g. children, pregnant woman, species at risk, etc.) that are located both on and off the RA property.

It is recommended that the human health and ecological conceptual site models differentiate between the following exposure pathways:

* Major exposure pathways that are complete (which will likely be assessed in a quantitative manner);
* Minor/negligible exposure pathways that are complete (which could be addressed using a qualitative approach);
* Pathways that are not present or incomplete, based on the intrinsic physical/chemical properties of the contaminant (e.g. volatility) and the natural geology/hydrology of the site;

Both the human health and ecological conceptual site models must also first be shown without any risk management measures, and then with any existing (or proposed) risk management measures, if applicable. For the conceptual site models that show risk management measures, pathways that are considered incomplete based on the presence of a risk management measure (e.g. barrier or restriction, whether current and/or designed as part of the proposed land use and which relies on human intervention) must be clearly identified. This approach will allow for these risk management measures to be accounted for in the risk assessment and carried forward to the risk management plan, if necessary, to ensure that they are put in place and communicated to future site owners/users.

### Drawings and Figures – Additional Guidance

The PSF is comprised of a completed form and attached drawings and figures. Drawings that support and elaborate on the content of the form are to include a scale site plan, one or more cross-sections of the property and other line drawings, including pictures, line art, flow diagrams, text and tabulated data at the discretion of the proponent and QP. Note that any information that is already included as part of the phase two conceptual site model does not need to be duplicated here.

The goal of the drawings is to provide a three dimensional illustration (site area and depth) of the subsurface hydrogeological conditions, contaminant source(s), extent of contamination, transport pathways, receptors and routes of exposure which, together, comprise a preliminary conceptual site model. The soil layers and groundwater units identified on the PSF should be clearly identified in the drawings and figures. Combined with the information provided in the PSF, the drawings and figures are intended to convey to the Ministry the risk assessment team’s current understanding of the types and location of hazards, potential exposure pathways and barriers to pathways, and the type and location of potential receptors consistent with the proposed land use. Sufficient site information data should be provided to determine if there is adequate knowledge of the site on which to base a risk assessment consistent with the illustrated conceptual site model and the planned risk assessment approach.

It is suggested that a location map showing the property in context to the local neighbourhood and adjacent land uses be included.

The proponent should include with the PSF any additional supporting information which they believe provides additional information to support the proposed risk assessment as well as any plans for the collection of additional information.

In developing and illustrating a conceptual site model, the QP should consider whether:

* Site and local knowledge are sufficient to support the geological and hydrogeological interpretation. For example;
* are all contaminant sources identified?
* have contaminant plumes been adequately delineated and characterized for the purpose of the risk assessment?
* Sampled media and sample locations address all potential transport pathways; and
* The models to be used;
* are suited to the conceptual site model, and
* will have adequate site data to support assumptions.

Based on Ministry feedback, the conceptual site model presented in the PSF may still need to be modified, updated or refined further prior to the submission of the risk assessment.

### Other Attached Documents – Additional Guidance

The proponent may attach other documents which they believe support the risk assessment approach, including any documentation which supports deviation from best practice, reliance on updated science (e.g. new TRVs) or plans for additional data collection (e.g. sampling, site-specific toxicity testing), if any are contemplated at the time of PSF submission.

The proponent may also include in the PSF any toxicological information relating to potential adverse human health effects and surrogate ecological test species, if these have been considered at the time of submitting the PSF, on which the proponent wishes to seek Ministry comment. For example, if at the time of preparing the PSF, the risk assessment team has selected surrogate species which they intend to represent the site valued ecological components (VECs), they may provide by way of a table the VECs selected for the site (a subset of the species present on the site) and the species selected from the literature to be used for determining the toxicity reference value (e.g. whether dog or rat toxicity data will be used as a surrogate for the red fox).

If a public communication plan has been developed at the time of the PSF submission, this may also be attached, for Ministry comment.

Proponents are also strongly encouraged to include an appendix (in text and or tabular form) that describes the planned risk assessment approach. This can include a list of COCs, an overview of how the QPRA intends to perform the human health and ecological risk assessments (i.e. receptor pathways, secondary screening processes, etc.), and any other pertinent information. Providing this information can provide reviewers with the opportunity to provide useful feedback to improve the overall quality of the risk assessment.

The phase one and phase two ESA reports (and any other reports deemed to be relevant by the QP) may also be attached, for reference. Although ESA reports are not reviewed as part of the PSF review process, these documents can help further inform the PSF, when necessary.

Borehole logs, certificates of analysis, chain of custody information, grain size analysis results and pH sampling results should also be provided with the PSF. Note that the Ministry may request that additional ESA information be provided at the risk assessment stage on a case by case basis.

## Self-Declaring Qualifications in PSF

If the QPRA has not previously self-declared their qualifications to the Ministry, the PSF will have attached the resume, work references and post-secondary transcripts (originals, in an institution-sealed envelope) that support the QPRA declaration. While attached to the PSF submission, the QPRA qualifications should be bound separately from the rest of the PSF material and provided to the Ministry as a single copy, so that it can easily be separated from the rest of the submission and handled in a manner which respects the privacy of the QPRA. If a QPRA has previously self-declared, they are not required to attach supporting documentation to subsequent PSFs.

## Change in Circumstance

If, at any time after submitting the PSF (and any time before a decision is made on the risk assessment), there is a change in ownership of the RA property or change in QPRA, the property owner shall give notice to the Director of the change in circumstance, as per the Regulation:

* Subsection 3 (13) of Schedule C

Note that failure to provide this information to the Ministry in timely way may cause delays in Ministry’s review of the risk assessment.

## Public Communication

The RA property owner is encouraged to prepare a public communication plan, which includes both the general public and the local municipality when choosing the risk assessment approach. This Procedures document uses the term “public communication” to include both consultation and notification.

There are two situations when public communication or notification is required in the conduct of an RA:

1. Notification of the risk assessment approach to the municipality is required where the QPRA intends to prepare a risk assessment that assumes groundwater under the RA property does not or will not serve as a raw water supply for a drinking water system (as defined in the Safe Drinking Water Act, 2002) and non-potable standards are to be developed. Refer to subsection 4 (5) of Schedule C of the Regulation. Note that in cases where the municipality objects to the non-potable groundwater assumption, the Ministry may also request that the RA property owner provide copies of the PSF and all subsequent risk assessment submissions to the municipality, for their consideration.
2. The RA property owner is required to provide broader public communication in situations where the Ministry District Office has indicated by way of comment on the PSF, that the site is located in a wider area of abatement. Refer to subsection 10 (2) of Schedule C of the Regulation.

The property owner is encouraged to undertake public communication if there is a likelihood of contaminant migration off the RA property and in relation to any property for which risk management is being proposed to help control or limit contaminant migration off the RA property. Where public communication is undertaken, a summary of any public input must be provided to the Ministry.

Minimum requirements for reporting on public communication as part of the risk assessment are provided in Schedule C, Table 1 of the Regulation, and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 8. Public Communication Plan (if applicable) | (a) Public Communication Plan | (i) Optional Communication Plans | If the owner has implemented a plan to consult the public as part of the development of the risk assessment, provide,  (a) a description of the plan, including any opportunities given to the public to comment on the proposed risk assessment;  (b) a summary of the comments received during the consultation; and  (c) a description of how the public comments were considered as part of the risk assessment process. |
| 8. Public Communication Plan (if applicable) | (a) Public Communication Plan | (ii) Required Communication Plans For RA Properties in Wider Area of Abatement | If the risk assessment has been identified by the Ministry as relating to a property located within a wider area of abatement under section 10, the risk assessment shall include,  (a) a description of the public communication plan required by clause 10 (2) (b) including any opportunities given to the public to comment on the proposed risk assessment;  (b) a summary of the comments received during consultation under the plan;  (c) a description of how the public comments were considered as part of the risk assessment process; and  (d) a copy of all the written comments received from the Ministry under clause 10 (2) (a). |

If public communication is planned, the Ministry recommends that whenever possible, the RA property owner include the public communication plan in the PSF. This communication plan should, as a minimum provide for:

* Notification of the owners of neighbouring properties that a risk assessment will be undertaken, and
* Provision for input to the risk assessment process by the local community.

Any written input offered by the community should be recorded and attached to the submitted RA report as an Appendix.

The specific conditions and situation at each RA property should always be considered in determining the methods and the extent of public communication required, and the appropriate response to community input. Ideally, public concerns should be addressed throughout the risk assessment process.

The property owner should consider the goals listed below when designing and implementing a public communication plan:

* Providing an explanation of the process to be followed including the inter-relationship of the phase one ESA, phase two ESA, risk assessment work and remediation of the RA property, the steps to be followed at each phase, the proposed timing and the opportunities for public input;
* Providing a forum for receiving public input and information on potential contamination at the RA property;
* Providing initial and ongoing information to the public as needed, on the nature and extent of RA property contamination and the activities proposed for risk assessment and including any risk management requirements (the Ministry recommends that at least 30 days’ notice of property activity be provided to affected stakeholders);
* Allowing public input on plans for addressing risk, including the basis for the property specific standards developed through risk assessment and ongoing management and monitoring, if warranted; and
* Allowing the public to provide input on the risk associated with the parts of the proposed remediation activities, such as soil excavation, treatment and/or transportation, which may generate dust or have impacts on other exposure pathways that may affect workers or local residents.

Examples of methods which can be considered for inclusion in a communication plan are:

* Posting a notice on the RA property;
* Advertising in the local newspapers or community bulletins;
* Delivering flyers or newsletters door to door;
* Using dedicated telephone lines to provide or receive information;
* Using a dedicated website to provide or receive information;
* Placing material in local libraries, community centres or establishing a temporary local office;
* Holding public meetings, information sessions or an open house;
* Establishing a public liaison committee; and/or
* Any other method of consultation or notification that, in the opinion of the QPRA, is adequate.

# Preparation Of An RA Report

RA reports must meet the requirements of Schedule C of the Regulation. The risk assessment process must include both human health and ecological risk assessments in a single report. Under the Regulation, the RA report must include the following sections:

Section 1 - Summary of Recommendations and Findings

Section 2 - Risk Assessment Team Membership

Section 3 - Property Information, Site Plan and Geological Interpretation

Section 4 - Human Health Risk Assessment (HHRA)

Section 5 - Ecological Risk Assessment (ERA)

Section 6 - Conclusions and Recommendations

Section 7 - Risk Management Plan (if applicable)

Section 8 - Public Communication Plan (if applicable)

Appendices – including Mandatory Certifications and phase two conceptual site model

The RA report must include the headings, sub-headings and minimum requirements as stated in Table 1, Schedule C of the Regulation. Other headings, sub-headings or other information considered relevant may also be included in the RA report. A standard RA report format is intended to improve consistency in risk assessment submissions and reduce the time required for the Ministry to complete reviews.

For Tier 2 risk assessments, the QPRA must use the Ministry’s reporting template, which is embedded within the approved model. However, note that the use of this reporting template is not appropriate for other risk assessments (e.g. Tier 3 risk assessments).

## General RA Report Requirements

The following provisions of Schedule C of the Regulation are especially important for the preparation of RA reports, as they set out mandatory requirements:

* Section 4 of Schedule C (Mandatory Requirements For Risk Assessment Reports)
* Section 5 of Schedule C (Mandatory certifications)
* Table 1 of Schedule C (Mandatory Requirements For Risk Assessment Reports)

Guidance on the RA Report Sections “Risk Assessment Team” and “Public Communication” as specified in Table 1 of Schedule C has been provided in Sections 1 and 2 of this Procedures document, for reference at an early stage in the risk assessment process.

Guidance on reporting the risk assessment outcome and meeting the requirements of the “Summary and Recommendations” and “Conclusions and Recommendations” Report Sections in Table 1 of Schedule C, as well as “Appendices” as specified in section 4 of Schedule C, is provided in this section of the Procedures document.

Guidance on how to report on the geological setting and COCs to meet the requirements of “Property Information, Site Plan and Geological Interpretation”, is provided in Section 4 of this Procedures document.

General guidance on conducting risk assessment is presented in Section 5 of this Procedures document. Detailed guidance on conducting HHRAs and ERAs and presenting the results in accordance with the Regulation are provided in Sections 6 and 7 of this Procedures document, respectively.

Additional report sections which may be required are “Risk Management Plan” and “Public Communication Plan”. Guidance on preparing these sections is provided in Sections 8 and Section 2.5 of this Procedures document, respectively.

## Summary of Recommendations and Findings

As set out in the Regulation, Section 1 of the RA report must provide a summary including the findings of the HHRA and ERA. This section will form the basis of information to be available in the Environmental Site Registry in support of filing an RSC. The information will also assist processing of the risk assessment review. Any deviations from information which was provided previously to the Ministry in the PSF must be identified (including changes in ownership and changes in the RA property boundaries). Property specific standards, risk assessment assumptions, and risk management requirements are also stated in this section. The minimum requirements for the Summary and Recommendations Section are provided in Table 1 Report Section 1 “Summary and Recommendations” in Schedule C, and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 1. Summary of Recommendations and Findings | (a) Risk Assessment Objectives and Approach | not applicable | 1. Summarize the risk assessment objectives, including those specified in Report Section 4 (Human Health Risk Assessment (HHRA)) and Report Section 5 (Ecological Risk Assessment (ERA)).  2. Summarize the type or types of risk assessment approaches taken to meet the objectives. |
| 1. Summary of Recommendations and Findings | (b) Deviations from Pre-submission Form | not applicable | Describe in detail any deviations from the information provided in the pre-submission form including,  (a) any changes to the conceptual site model that was submitted as part of the form;  (b) whether there has been a change in the type of risk assessment approach identified in the form; and  (c) whether another computer model was used other than the model specified in the form. |
| 1. Summary of Recommendations and Findings | (c) Risk Assessment Standards | not applicable | State the proposed standard specified in the risk assessment for each contaminant of concern. |
| 1. Summary of Recommendations and Findings | (d) Risk Assessment Assumptions | not applicable | State the assumptions used in determining each standard specified in the risk assessment, including property use assumptions. |
| 1. Summary of Recommendations and Findings | (e) Risk Management Requirements | not applicable | State the risk management measures and on-going monitoring, maintenance and contingency plan requirements, if applicable. |

The standards specified in the risk assessment (i.e. property specific standards), risk assessment assumptions and risk management measures should be listed in table form. Risk assessment assumptions should highlight key assumptions which place limits on the outcome of the risk assessment, i.e. the assumptions made in the risk assessment which are critical to the acceptability of these standards (e.g. sensitive model parameters, risk management measures, property use assumptions).

Report Section 2 requires information on the Risk Assessment Team. For guidance on how to complete this section, refer to Section 1.4.3 of this Procedures document. Guidance on how to complete Report Sections 3 through 5 is provided in Sections 4 to 7 in this Procedures document.

## Conclusions and Recommendations

Conduct of the risk assessment will include separate assessments for HHRA and ERA based on a single geological interpretation of the site and conceptual site model. Guidance for conducting and reporting on those assessments follow in Sections 4, 5, 6 and 7 of this Procedures document. The conclusions and recommendations of the RA report must therefore summarize and consolidate the findings of the HHRA and ERA and propose the property specific standards to be used for submitting an RSC for filing. Minimum requirements for conclusions and recommendations (Section 6) of the RA report are provided in Table 1 of Schedule C of the Regulation, and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 6. Conclusions and Recommendations | not applicable | (i) Recommended Standards | 1. A standard must be specific in the risk assessment for each contaminant of concern. The specified standard shall be, at a minimum, the more stringent of the human health standard and the ecological standard being proposed for the RA property.  2. In the case of an estimation of natural local background concentration risk assessment, the specified standard shall be the local background concentration soil standard proposed under subsection 8 (1) of this Schedule.  3. State critical assumptions on which the standards specified in the risk assessment rely, having regard to the discussion of uncertainty under Heading (d) (Risk Characterization) in Report Section 4 (Human Health Risk Assessment (HHRA)) and under Heading (e) (Risk Characterization) in Report Section 5 (Ecological Risk Assessment (ERA)).  4. If the phase two environmental site assessment that was relied upon in the preparation of the risk assessment has been prepared using a non-standard delineation conducted in accordance with section 7.1 of Schedule E,  i. state that the phase two environmental site assessment was prepared using a non-standard delineation,  ii. state the contaminants of concern and media to which non-standard delineation was applied, and  iii. provide a discussion of the implications that the application of the non-standard delineation to the stated contaminants of concern and media may have on the conclusions reached in the risk assessment report. |
| 6. Conclusions and Recommendations | not applicable | (ii) Special Considerations for Ground Water Standards | If a standard being proposed in the risk assessment for ground water in or under the RA property is greater than 50% of the solubility limit, demonstrate the risk of free product formation and propose any risk management measures necessary in order to mitigate the formation of free product. |

### Recommending Property Specific Standards

It is not sufficient for the RA report to demonstrate that risk to human health and the environment is acceptable or negligible. Schedule C of the Regulation requires that the risk assessment specify a property specific standard (i.e. numerical value) for each COC identified in soil, groundwater and sediment. COCs are identified as part of the phase two ESA and must again be highlighted in Report Section 3 of the RA report. Proposing a property specific standard is necessary because a QPESA, when submitting an RSC for filing, is required to enter the maximum concentration of every COC at the RA property. The Environmental Site Registry requires a standard for each COC for comparison purposes and the maximum COC concentration present at the RA property cannot exceed the property specific standard.

A recommended tabular format for summarizing the proposed property specific standards in the RA report is provided in the example below.

**Table Title**: Proposed Property Specific Standards for RA property

| ***Environmental Media*** | ***Contaminant Of Concern*** | ***Maximum Measured Concentration*** | ***Applicable Site Condition Standard1*** | ***Proposed Property Specific Standard*** | ***Dominant Exposure Pathway(s)*** | ***Risk Management Requirement(s)*** | ***Potential for Off-site Exceedance of SCS*** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Soil (full depth) | lead | 2215 µg/g | 120 µg/g | 2300 µg/g | Incidental ingestion | Surface cover, PPE | No |
| Groundwater | lead | 40 µg/L | 25 µg/L | 40 µg/L | Aquatic biota off-site | No | Yes |

**1Table footnote**: Table 3 in the document “Soil, Ground Water and Sediment Standards for Use Under Part XV.1 of the Environmental Protection Act”, dated April 15, 2011, for I/C/C use and coarse textured soil.

Special considerations may apply if the risk assessment determines that existing contaminant concentrations on, in or under the property present acceptable or negligible risk. The QPRA can propose either the maximum site concentration (measured or estimated) as the property specific standard, or the concentration below which adverse effects would not occur (effects-based or risk-based standard), as predicted by the risk assessment. In either case the concentration proposed as the standard must be evaluated explicitly in the risk assessment, as the QPESA will be required to certify in the RSC that in their opinion, there is no evidence of any contaminants in, on or under the RSC property that would interfere with the proposed use of the property.

### Proposing Excessively High Property Specific Standards

For the purpose of clear communication to public stakeholders through the Environmental Site Registry, the Ministry expects that the proposed standard will not exceed a reasonable upper estimate of the actual concentrations remaining on, in or under the property at the time the standards are to be used to submit an RSC for filing. The Ministry also expects that the proposed property specific standard will respect public expectations regarding aesthetics (taste, odour, visibility) and be physically possible (i.e. not be greater than 100%, that is, pure chemical compound). These principles are important for fostering public and commercial confidence in the risk assessment process.

For clarity in the risk assessment review process, it is the Ministry’s preference that the standard specified in a risk assessment be no greater than an estimate (e.g. based on measured sample variance) of the maximum concentration existing on, in or under the property at the time of undertaking the risk assessment. For example, in Tier 2 risk assessments, the approved model does not allow the property specific standard to exceed the maximum measured concentration plus 20%; this same approach can also be adopted in Tier 3 risk assessments.

If a standard specified in a risk assessment exceeds the maximum concentration on, in or under the property by a significant amount, the property owner should be aware that the risk management measures required in conjunction with that standard may be more onerous than what is required for the actual contamination present. Risk management measures are required in conjunction with the property specific standard, not the phase two ESA data, and must apply to the entire property area to which the property specific standard (and the RSC) applies. They must be sufficient to manage risk to all receptors (human and ecological) due to contamination of all portions of the property at the concentration proposed as the standard.

In some cases, risk management measures may be allocated to a portion of the property only where site characterization clearly demonstrates that the rest of the property meets some other approved standard such as the applicable site condition standards published by the Ministry – however further consultation with the Ministry’s local District Office is recommended if considering this approach, as its appropriateness will depend on the circumstances of each case. Also refer to Section 8 (Risk Management Plan) of this Procedures document for additional details. Thorough site characterization therefore should be considered as a more efficient and effective approach to managing site uncertainty than the use of risk management alone.

### Proposing Multiple Sets of Property Specific Standards

A single Tier 3 risk assessment may propose more than one set of property specific standards to support submitting more than one RSC for filing. In such a case, each RSC property must be clearly identified in the risk assessment and defined in the legal description and plan of survey. The requirements of the Regulation must be met for each RSC property.

The RA report will need to include the following information, in a clear and straightforward manner, for each RSC property:

* Phase two conceptual site model (Appendices),
* COC screening and inventory (Report Section 3),
* Human health risk assessment (Report Section 4),
* Ecological risk assessment (Report Section 5),
* Set of property specific standards (Report Section 6),
* Risk management plan, if applicable (Report Section 7), and
* Mandatory certifications (Appendices).

In addition, note that at the time of RSC submission, only one standard can be selected by the QPESA per contaminant and environmental medium for use in the RSC.

Due to the added complexity, this approach is not expected to be useful or provide much benefit for the vast majority of Tier 3 risk assessments. For this reason, further consultation with the Ministry (ideally at the PSF stage, or sooner) is strongly recommended if this of approach is being considered by the QPRA and property owner; its appropriateness will depend on the circumstances of each case.

### Non-Standard Delineation

In cases where the phase two ESA was prepared using non-standard delineation, Section 6 of the RA report must include a statement to this effect, specify the COCs to which non-standard delineation was applied and discuss the implications this may have on the conclusions of the risk assessment (including the setting of property specific standards and the proposed risk management measures, if any).

### Assessment of Off-Site Risk

Under the Regulation, property specific standards can only be proposed for the RA property. However, the potential effects of a property specific standard on neighbouring off-site properties must be considered as part of the risk assessment and review process. Any expectation that a proposed property specific standard will result in an exceedance of the appropriate full depth site condition standards on a neighbouring property must be assessed and explicitly reported.

As part of the mandatory certifications included in the RA report Appendices, the QPRA must certify whether meeting the property specific standards will result in an exceedance of the appropriate full depth site condition standards at the closest off-site receptor (human or ecological). For a given COC, the Ministry’s response to the potential for any off-site exceedance of the soil and/or groundwater site condition standard will be determined on a case-by-case basis by the Ministry District Office, which will prioritize any action that may be warranted on a specific property, considering the potential human health and ecological risk level, social and economic impacts. RA properties with known or suspected contamination migration issues are strongly encouraged to contact the Ministry’s local District Office as soon as possible in the risk assessment process, to avoid delays in the risk assessment review process.

### Special Considerations for Groundwater Standards

In the development of generic site condition standards for groundwater and the approved model, the Ministry included decision rules to protect against the possible formation of free phase product in soil and groundwater. For soil, the numerical value of the standard cannot exceed its free phase threshold concentration (which is applicable to petroleum hydrocarbons). For groundwater, the numerical value of the standard cannot exceed 50% of its solubility concentration.

In a risk assessment, if the groundwater concentration for a given chemical parameter exceeds the 50% solubility limit, then additional risk management may be required, based on a demonstration of the risk of free product formation and the need for mitigation. This requirement is included in Table 1 of Schedule C. In addition, it is recommended that when proposing property specific standards for petroleum hydrocarbons in soil, a comparison to the free phase threshold concentration also be included and discussed in Report Section 6.

Free product on a site should be removed to the extent technologically practicable. Standards specified in a risk assessment should not result in the formation of free petroleum hydrocarbon product. Standards specified for potable groundwater use should not result in a sheen, taste or odour due to petroleum hydrocarbon contamination. Consistent with the approach in place through the 1996 Guideline for Use at Contaminated Site in Ontario, the issuance of a certificate of property use and registration on title through a certificate of requirement will generally be required where risk management is necessary to control potential for free product. QPs should contact the Ministry’s local District Office in cases where free product (or the risk of free product formation) is expected to remain at an RA property.

If no groundwater standards are proposed that exceed the 50% solubility limit and no other special considerations apply, the QPRA should indicate that no special considerations apply to the groundwater.

## Appendices to RA Report

Additional documents which must be supplied as Appendices to all RA reports are identified in the Regulation:

* Subsection 4 (6) of Schedule C (Mandatory requirements for risk assessment reports)
* Section 5 of Schedule C (Mandatory certifications)

A list of documents that must be attached as appendices to the RA report is provided below. The QPRA is directed to the Regulation regarding the required content of these documents:

* Mandatory Certifications set out in section 5 of Schedule C.
* PSF, Ministry response and how Ministry concerns, if any, were addressed.
* Resumes for the QPRA and team technical leads. Contact information for work references (employers, colleagues, clients) who can support experience claims of the QPRA should also be provided.
* List of documents relied upon in the preparation of the RA report.
* A summary of the phase one ESA and phase two ESA reports, including,

1. justification for the sampling program used in undertaking the phase two ESA,
2. a summary of quality assurance and quality controls used for the sampling program and analysis of the samples,
3. an assessment of whether the sampling program is sufficient for the purposes of the risk assessment and if not, a description of what further site investigations were conducted to support the risk assessment, and
4. a rationale for and description of any hydrogeological and geological interpretations which differ from assumptions on which the Soil, Ground Water and Sediment Standards are based.

* The appendix to the phase two ESA report that reports on requirements in a phase two ESA in support of an MGRA (i.e. Table 4 of Schedule E). This requirement is specific to Tier 2 risk assessments only, however for Tier 3 risk assessments which rely in part on the Ministry’s approved model (e.g. for updated component values, site-specific component values, soil vapour screening levels, etc.), this information should also be provided.
* The portion of the review and evaluation section of the phase two ESA report headed “phase two conceptual site model”. The phase two conceptual site model should be extracted directly from the phase two ESA report.
* A copy of any reports documenting further site investigations conducted for risk assessment purposes (if applicable).
* A copy of the written notice of intention to conduct a risk assessment that assumes non-potable groundwater condition addressed to the municipality in which the RA property is located, together with a copy of any response from the municipality (if non-potable groundwater use was assumed).
* An engineering or hydrogeological report recommending the design of engineering and/or hydrogeological controls, including detailed plans and specifications (if applicable).
* Note that if there was any change in the RA property ownership and/or change in the RA property boundaries since the submission of the PSF, then an updated legal description (including plan of survey) will need to be included in a separate appendix to the RA report.

Other information may be provided as Appendices to the RA report at the discretion of the QPRA.

# Property Information, Site Plan and Geological Interpretation

The HHRA and ERA rely on a common description of the property, its geological and hydrogeological setting and contamination status. This information is collected and reported through phase one and phase two ESAs. A summary of this information, along with the phase two conceptual site model, which supports the approach and assumptions of the human health and ecological risk assessments must be provided with the RA report. Much of this information would have been provided with the PSF to support the preliminary conceptual site model. The information provided with the RA report would confirm or finalize the conceptual site model for use in the HHRA and ERA.

The third section of the RA report must provide a summary and analysis of information from the phase one and phase two ESA, including property information, a site plan and pertinent geological information. The minimum requirements for Section 3 of the RA report are provided in Table 1 Report Section 3 “Property Information, Site Plan and Geological Interpretation” of the Regulation, Schedule C, and reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 3. Property Information, Site Plan and Geological Interpretation | (a) Property Information | not applicable | 1. State the property location and ownership.  2. Describe the general physical characteristics of the property including size of the property and size of contaminated area.  3. Provide sufficient detail on the property to support the conceptual site model used in the preparation of the risk assessment report, including,  (a) a summary of past and current use of property;  (b) a summary of past and current use of any relevant property that is adjacent to the property;  (c) a description of off-site sources of contaminants of concern and off-site receptors; and  (d) an indication of the proposed use of property. |
| 3. Property Information, Site Plan and Geological Interpretation | (b) Site Plan and Hydrogeological Interpretation of RA Property | not applicable | 1. Provide the site plans, cross-sections and a hydrogeological interpretation of the RA property that satisfies the requirements of clauses 3 (8) (a), (b) and (c) and that was relied upon in the preparation of the risk assessment and all documentation used to support this interpretation.  2. If a non-standard delineation was conducted in accordance with section 7.1 of Schedule E as part of preparing the phase two environmental site assessment report, a narrative description of how the non-standard delineation satisfies the requirements in that section. |
| 3. Property Information, Site Plan and Geological Interpretation | (c) Contaminants of Concern | not applicable | 1. List all of the contaminants of concern.  2. The contaminants of concern must include the following:  i. Any contaminants detected on, in or under the RA property that exceed the applicable site condition standards.  ii. Any contaminants detected on, in or under the RA property and for which no applicable site condition standard is prescribed under Part IX (Site Condition Standards and Risk Assessment) of the regulation. |
| 3. Property Information, Site Plan and Geological Interpretation | (c) Contaminants of Concern | (i) Sampling Programs | 1. With reference to the sampling programs summarized in the appendices to the risk assessment report, describe how the program is adequate for the risk assessment objectives and approach specified in Report Section 1 (Summary of Recommendations and Findings).  2. In the case of an estimation of natural local background concentration risk assessment, specify the methods that were used to estimate the local background concentrations in soil, including details of,  (a) any sampling programs undertaken in accordance with subsections 8 (4) to (8);  (b) any existing geological data, as described in subsection 8 (9) that were used to estimate the natural local background concentrations in place of sampling data. |

## Property Information

The property description must provide basic information on the RA property, including location, ownership, a summary of past and current use of the property and a summary of past and current use of all other relevant adjacent properties. If there has been a change in ownership and/or changes in the RA property boundaries since the submission of the PSF, then updated legal description (including a plan of survey) must be included in an appendix to the RA report. In addition, in cases where there is a change in ownership, updated property owner information and confirmation that the owner has signed on to the risk assessment (e.g. by providing updated sections of the PSF) must be included. For additional questions or direction regarding changes in ownership and/or RA property boundaries, QPs should contact the Ministry directly.

The proposed property use that will be used when submitting the RSC should also be identified; note that the possible property uses are defined in the Regulation.

## Site Plan and Hydrogeological Interpretation of RA Property

It is the risk assessment team’s responsibility to utilize the results of the phase one and phase two ESAs, and any additional investigations required, to determine the hydrogeological setting, and the anticipated contaminant behavior in that setting and to articulate a conceptual site model of contaminant distribution for the property. Sufficient detail must be provided to demonstrate that the site has been adequately characterized and that the site and regional geology, hydrogeology and natural and contaminant geochemistry, are adequately understood to support the development of a conceptual site model and to support the risk assessment and any risk management plan proposed. The risk assessment team must be able to provide a description of routes of potential contaminant transport in the context of property specific characteristics.

Note that much of the information required under this heading (and subheadings) should already be included in the phase two conceptual site model, which was previously provided with the PSF and which now must be included with the RA report, as a separate, stand-alone appendix. In most cases, including a short summary of the required information, along with a reference to where this information is located within the phase two conceptual site model, will be sufficient to meet the requirements. Note that additional information (narrative, summary, figures, etc.) may be required for more complex sites or for sites where additional information not included in the phase two conceptual site model is being relied upon.

The requirements for the phase two conceptual site model, including non-standard delineation, were previously covered in Section 2.2 of this Procedures document, for the PSF.

### Conceptual Site Model – Additional Guidance

A conceptual site model is described in section 3 of Schedule C of the Regulation as comprising specified diagrams with explanatory notes (text description). The conceptual site model provides a three-dimensional (area and depth) description of site conditions that illustrates contaminant sources and distributions, release mechanisms, exposure pathways, migration routes and potential receptors. A conceptual site model must show all potential human receptors and VECs along with exposure pathways specific to the site and adjacent properties. Each relevant pathway is to be provided, including those that may be eliminated through risk management measures. The conceptual site model is expected to highlight the effects of any existing or anticipated pathway barrier on potential exposure pathways. Therefore, the conceptual site model must distinguish between the routes of exposure which would potentially exist without risk management measures and routes which are expected to exist under conditions which include risk management measures (existing or future pathway barriers).

The conceptual site model for sub-surface transport provides an organized, three dimensional picture of the hydrogeologic setting (minimum of site plan and cross section). A narrative should be provided to explain the groundwater flow and contaminant behavior, interactions with receptors, as well as consideration of the consequences of natural and human activities.

The conceptual site model must meet all the requirements specified in section 3 of Schedule C and described in Section 2.2 of this Procedures document, for the PSF. The conceptual site model presented in the RA report should be a finalized and refined version of the model presented in the PSF. Any changes to the conceptual site model which may impact the risk assessment outcome (e.g. new COC, new maximum concentration, COC being dropped, etc.) must be identified in Report Section 1 “Summary of Recommendations and Findings” under the heading “Deviations from Pre-submission Form”.

## Contaminants of Concern

Contaminants of Concern (COCs) identified for the RA property must be listed in the RA report. Note that the COC identification process is completed at the phase two ESA stage. It is however useful for the QPRA and the QPESA to work together to identify COCs at the RA property. COCs are defined as follows under the Regulation:

“contaminant of concern” means,

1. one or more contaminants found on, in or under a property at a concentration that exceeds the applicable site condition standards for the property, or
2. one or more contaminants found on, in or under a property for which no applicable site condition standard is prescribed under Part IX (Site Condition Standards and Risk Assessment) and which are associated with potentially contaminating activity;

When considering contaminants not listed in the Ministry’s generic tables of site condition standards, the following section of the Regulation must be considered:

* Section 43 of the Regulation (Applicable site condition standard: “N/A”, “N/V” or not listed)

In addition, the QPRA and the QPESA should consider the following in the COC selection process:

* Are there any characteristics of the property which may increase the likelihood for one or more contaminants to interfere with the property use beyond that considered by the Ministry in the development of the site condition standards?
* Are there any contaminants on, in, or under the property which may degrade to a more toxic product?
* If there are chemicals without Ministry site condition standards and likely not associated with any potentially contaminating activity, are they likely to interfere with property use?

Based on consultation with the QPESA, COCs may include one or more contaminants which meet the site condition standards if there is some concern on the part of either QP that they may interfere with the proposed use of the property. The latter may occur if the conceptual site model on which development of the site condition standards was based did not include site-specific features which may increase the level of risk to the proposed receptors (e.g. contaminated groundwater situated within 1 m distance from a building slab, and groundwater contaminants are volatile). The conceptual model on which development of the site condition standards was based is described in the Ministry’s Rationale document. The introduction included with the document “Soil, Ground Water and Sediment Standards for Use Under Part XV.1 of the *Environmental Protection Act*” (dated April 15, 2011) also reiterates several of the important assumptions made by the Ministry when developing the site condition standards.

Also, based on consultation with the QPESA, COCs may include contaminant degradation products or other chemicals for which there are no published site condition standards and for which there is some concern on the part of either QP that they may interfere with the proposed use of the property.

If a chemical has been measured at the property which does not have a Ministry site condition standard and is not associated with a potentially contaminating activity, the QPESA must decide if the chemical is a COC based on an understanding of geoscience. For example, natural elements of the earth’s crust that are in all likelihood not associated with potentially contaminating activity may be measured but have no Ministry site condition standards. These chemicals are generally ubiquitous in soil at non-toxic concentrations but may become limiting to site use at some concentration. The QPESA must determine within the context of the phase two ESA if the presence of a chemical without a standard is trivial or if there is potential for concern. This decision must be clearly documented in the phase two ESA, with appropriate supporting rationale and lines of evidence. If the chemical is determined to be of concern (i.e. a COC), this must be identified as such in the phase two ESA report and the chemical will need to be evaluated as part of the risk assessment and a property specific standard developed.

The QPESA should also consider the certifications that will need to be made in the RSC, which are included in Schedule A of the Regulation. The certifications made by the QPESA in the RSC are intended to confirm that there is no evidence of contaminants left on, in or under the property that will interfere with the proposed use of the site.

Where a chemical is measured and there is no site condition standard and the chemical is determined to be a COC, the risk assessment may be considered as a new science risk assessment. For additional details regarding this type of risk assessment, refer to Section 9 of this Procedures document.

The RA report must include a brief description of the sampling program, a contaminant inventory, a description of the COCs and justification for determining if contaminants measured on-site are not considered COCs. The QPRA and QPESA should also consider the following in identifying COCs:

* The hazard profile (see guidance on Toxicity Assessment, Sections 6 and 7 of this Procedures document) of each identified COC and potential degradation products, including but not limited to, adverse effects, environmental fate and transport, persistence and bioaccumulation (e.g. vinyl chloride is a known degradation product of trichloroethylene, under specific conditions); also refer to the additional guidance on COC screening, included below.
* Uncertainty that exists in terms of the completeness of the phase one ESA and/or phase two ESA and the quality of data to be relied upon in the risk assessment. A contaminant should be considered a COC if the QPRA and QPESA are not confident that the data demonstrates that a pathway is incomplete or that a Ministry generic site condition standard is not exceeded.

Some or all of these COCs may require a detailed quantitative risk assessment in order to justify a property specific standard. Others may be evaluated using a qualitative descriptive approach (non-numeric) or a qualitative screening (numeric) approach.

A risk assessment is not required for contaminants that are not detected or present at concentrations less than the detection limits identified in the “Protocol for Analytical Methods Used in the Assessment of Properties Under Part XV.1 of the Environmental Protection Act” (MOE 2011), as updated from time to time.

### Screening for Contaminants of Concern – Additional Guidance

Additional guidance regarding COC screening for specific contaminant groups is included below.

Polycyclic Aromatic Hydrocarbons (PAHs)

For PAHs, the Toxicity Equivalency Factor (TEF) approach is used to estimate the potency of individual carcinogenic PAHs relative to benzo[a]pyrene (B[a]P), which is the reference compound. Additivity is assumed in this approach; the risks of individual carcinogenic PAHs are summed to give an estimate of total risk.

If one or more carcinogenic PAHs are identified as COCs, then all carcinogenic PAHs detected at the RA property should be carried forward as COCs, for further assessment in the HHRA (where total B[a]P equivalent concentration for all carcinogenic PAHs will be calculated in the HHRA, as per the TEF approach). Note that when conducting a Tier 2 risk assessment, this may not be necessary, due to the inherent conservatism built into the approved model when dealing with this contaminant group.

Dioxins, Furans, and Dioxin-like PCBs

Mixtures of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and polychlorinated biphenyls (PCBs) compounds are aryl hydrocarbon receptor agonists that share a common mechanism of action that is consistent with an additive model. If one or more of these compounds are identified as COCs, then the QP should consider carrying forward all related compounds as COCs, for further assessment in the HHRA.

Vinyl Chloride and Parent Compounds

Vinyl chloride detected at some properties may not necessarily arise from industrial sources. The anaerobic biodegradation of chlorinated solvents such as trichloroethylene, tetrachloroethylene, 1,1-dichloroethylene, *cis-* and *trans-*1,2-dichloroethylene and 1,1,1-trichloroethane can produce vinyl chloride as a degradation product, and may contribute to the presence of vinyl chloride at these sites. Vinyl chloride is also considered to be more toxic than several of its parent compounds. The Ministry accounted for this in the development of its generic groundwater site condition standards by including a 10% rule (refer to Rationale document, Section 7 for details).

In risk assessment, a similar approach can be used, whereby 10% of the sum of the maximum measured concentrations of all parent compounds are added to the maximum measured vinyl chloride concentration on the RA property for a total vinyl chloride concentration that is representative of potential future impacts from biodegradation at the property. In cases where site-specific information is available (e.g. groundwater trend data, site-specific information regarding redox conditions in subsurface, etc.), alternate approaches to account for the potential future degradation of vinyl chloride can be proposed.

Chemical Mixtures

Some two- or three-chemical mixtures share a common mode of action and/or target tissue/organ consistent with an additive or synergistic model. Examples of binary or tertiary mixtures are the dichlorobenzene isomers (1,2-, 1,3- and 1,4-dichlorobenzene), dichloroethylene isomers (*cis-* and *trans-*1,2-dichloroethylenes), dinitrotoluene isomers (2,4- and 2,6-dinitrotoluene), and methylnapthtalene isomers (1- and 2-methylnapthalene), trichlorophenol isomers (2,4,5- and 2,4,6-trichlorophenol). The general approach for conducting a mixtures assessment for compounds with additive effects is to estimate the combined risk (non-threshold contaminants) or hazard index (threshold contaminants) for the mixture. This will also need to be carefully considered by the QP at the COC screening stage when chemical mixtures are present at the RA property. For example, the QP may wish to carry forward as COCs all contaminants in the mixture that have additive effects.

### Summary of Sampling Program

All risk assessments are dependent on the quality of information provided through the property characterization, carried out in the phase one and phase two ESAs and any other investigations, and the associated uncertainty in the supporting toxicological and exposure information. At a minimum, phase one and two ESAs must be conducted in a manner consistent with the requirements of the Regulation (including Schedules D and E, respectively). Studies relating to other media (e.g. surface water, biota, soil vapour, indoor air) may also be required to support a risk assessment. These should be conducted with consideration of the most recent Ministry guidance and best scientific practice.

The RA report must include a summary of the phase one and two sampling programs, specifically considering data quality, uncertainty and suitability of the data for use in the risk assessment, and details of any additional sampling undertaken to support the risk assessment. On a case by case basis the Ministry may request additional information or copies of phase one or two ESA reports and/or other relevant site reports that the Ministry deems necessary for review. Characterization of the RA property and COCs in the risk assessment should fully document the following:

* What investigation methods were used?
* What portions of the property or environmental media remain uncharacterized, if any?
* Can the risk assessment objective be addressed through the use of available information?
* What quality assurance/quality control procedures were used? and,
* An analysis of the sources, relative magnitude and implications of uncertainty in the data obtained.

### Data Quality Assessment

Quality assurance and control is necessary in both sample collection and sample analysis to ensure that the data utilized in a risk assessment is representative of the site conditions at the RA property. The collection and analysis of environmental data that will be relied upon when submitting the RSC for filing must be carried out in accordance with the requirements of the Regulation; the collection and analysis of other environmental data (e.g. used to support the risk assessment) should also be should be carried out in accordance with the requirements of the Regulation, where possible. The data quality objectives which the site assessment information should meet are specific to the issues addressed by the risk assessment and are to be determined by the QPRA (in consultation with the QPESA and risk assessment team) as part of the risk assessment.

The Regulation requires that the QPRA demonstrate that the data used for the HHRA and ERA is sufficient to meet the objectives of these assessments. In the risk assessment, the QPRA and risk assessment team should discuss the completeness of all data sets and indicate whether appropriate analytical methods were utilized (e.g. the methods comply with the analytical procedures described in Section 47 of the Regulation and the method detection limits were met).

The risk assessment team is expected to use standard data quality measures of representativeness and reproducibility (accuracy and precision) when evaluating the data.

The required QA/QC data quality objectives will be dependent on the sensitivity of the risk assessment outcome to uncertainty in the data. The QPRA and QPESA should exercise professional judgment in selection of appropriate techniques to obtain representative samples and achieve the risk assessment objective. The designer of the sampling program should have expertise in the design of sampling for the subject environmental medium.

It should be noted that it is the responsibility of the QPRA to ensure that all analytical results used to support critical assumptions in the risk assessment comply with section 47 of the Regulation. In addition, the QPRA should always be diligent about the quality of analytical results obtained from a laboratory. If historical investigations on an RA property included analysis of samples which may be questionable, it is expected that the QPRA and the QPESA clearly identify these analyses and obtain confirmatory sampling data that is representative of current site conditions for use in the risk assessment (and for use in the phase two ESA report, to support submission of the RSC for filing, as necessary).

### Site Investigation and Currency of Property Data

Property characterization data used in the assessment should reflect the most recent site conditions. This is to assist the QPRA in ensuring that certified statements in the RA report relate to site conditions which are still relevant at the time of signing the report.

Substantial time may elapse between an initial phase two ESA, the initiation of the risk assessment and the submission of an RA report. The risk assessment team should satisfy themselves that the concentrations of the COCs at the site and the problem formulation/hazard assessment used in the risk assessment are representative of site conditions present at the time of the risk assessment and will support the RSC submission. This may include consideration of any potential remediation that is expected to occur after the risk assessment has been initiated but before the RSC is submitted for filing (e.g. targeted soil removal).

In general, information contained in the risk assessment, including the description of site conditions, COC selection and ecotoxicity tests, should include or rely on measurements carried out within the two years prior to submission to the Ministry. Two years is proposed based on a typical period which may elapse between initiating a site assessment and submitting a risk assessment. If the phase two ESA includes older data or measurements (more than two years from risk assessment submission), the QPRA and QPESA should assess the quality and relevance of the data and possibly confirm with more recent sampling any information which may have changed, potentially impacting the risk assessment outcome. The use of older data in the risk assessment is ultimately left up to the judgment of the QPs, as two years may be sufficient or insufficient, depending on the contaminant, receptors and site circumstances. It is also important for QPs to account for temporal variability at their site and multiple sampling events over time may be needed to support the risk assessment.

Additional characterization may be undertaken, such as collection of additional property or receptor characterization data, to reduce uncertainty in the overall risk assessment so that the risk assessment results will be useful for making meaningful risk management decisions.

In addition, the QPRA and QPESA should be aware of the requirement that the phase two ESA report be current (e.g. the date the last work on all of the planning of the site investigation, conducting the site investigation and reviewing and evaluating the information gathered through the site investigation required for the phase two ESA is no later than 18 months before the commencement of the risk assessment). The Regulation includes requirements regarding currency of the phase two ESA report when commencing a risk assessment and when submitting an RSC, specifically refer to:

* Section 33.5 of the Regulation (Requirements re phase two site assessment report)

The commencement date of the risk assessment is when the PSF is submitted to the Ministry for review. It is not uncommon for the date of last work (on components of the phase one ESA or phase two ESA) to be greater than 18 months by the time a risk assessment is accepted by the Director. Before the RSC can be submitted for filing, both the phase one and phase two ESA reports must be updated. Updates to the phase one ESA and phase two ESA reports are expected to be prepared as standalone addendums that address the requirements identified in the Regulation and identified as an “update” in the list of reports used in submission of an RSC for filing in the Environmental Site Registry.

# General Guidance for Conducting Risk Assessments

Depending on the required scope of the risk assessment, the various components set out in Schedule C of the Regulation may be conducted in a qualitative or quantitative manner. However, the Regulation requires that a property specific standard be proposed for each COC identified in the RA report.

Section 5 of this Procedures document describes the risk assessment procedures common to the HHRA and ERA, while Sections 6 and 7 describe procedures specific to HHRA and ERA, respectively. Section 9 describes alternative procedures that may be used for risk assessment under certain specified conditions.

## Principal Elements of Risk Assessment (HHRA and ERA)

All risk assessments must include each of the following four elements for both HHRA and ERA:

* Problem Formulation/Hazard Identification/Receptor Characterization,
* Exposure Assessment,
* Toxicity/Hazard Assessment for contaminants with complete exposure pathways, and
* Risk Characterization.

Requirements of both HHRA and ERA are described in the Regulation. Guidance for the four basic elements will be discussed in detail in subsequent sections. Depending on the objective of the risk assessment, individual elements may be conducted in a qualitative or quantitative manner.

## Risk Assessment Objectives

For each of the HHRA and the ERA, the QPRA must provide a statement of the objective of the risk assessment. The risk assessment objectives determine the most appropriate procedures to follow in undertaking the risk assessment, the necessary data quality to meet the objectives and whether uncertainty in site-specific property knowledge could prevent the risk assessment from meeting the objectives.

A statement of the objective of the risk assessment includes, but is not limited to, identifying the proposed use of the RA property, the receptors and exposure pathways to be assessed and choosing from one or several of the following approaches:

* conducting a quantitative risk assessment for the purpose of calculating property specific standards;
* conducting a qualitative risk assessment for the purpose of justifying the use of existing standard values (Ministry site condition standards, Ministry component values or standards from other jurisdictions) when developing property specific standards;
* using the standard risk assessment procedures (as described in Sections 6 and 7 of this Procedures document), and/or
* using one of the alternative risk assessment procedures (as described in Section 9 of this Procedures document). Alternative risk assessment procedures include:
* Limited scope risk assessment, including MGRA and Risk Assessment Based on a Community Assessment Report;
* Estimation of natural local background concentrations risk assessment;
* New science risk assessment; and
* Wider area of abatement risk assessment.

## Screening Process for Quantitative Risk Assessment

In a Tier 3 risk assessment, the list of COCs which potentially require a quantitative assessment may be lengthy for some properties. The QPRA may wish to reduce the number of COCs to be carried through to the detailed quantitative assessment in the HHRA and ERA. An acceptable technique for doing so is to conduct a screening assessment of the COCs at the property. A screening assessment is a preliminary tool, for use within the HHRA and ERA, with specific purposes as follows:

* To identify if, in the opinion of the QPRA, there is an insignificant likelihood of risk to human health or the natural environment; and/or
* To assist in determining the scope of the risk assessment.

For the purposes listed above, a screening assessment may be undertaken as part of the problem formulation step and may also be presented with the PSF. The results of this process are qualitative or semi-quantitative only and can be used only in contaminant selection, eliminating irrelevant routes and/or pathways of exposure or irrelevant receptors from further consideration in the risk assessment. The result of any screening assessment must be reported as a qualitative risk assessment in the RA report.

Screening assessments are usually based on a “worst case scenario”, including generic assumptions regarding site conditions, instead of verifiable property specific conditions. For example, the screening assessment should use maximum concentrations (or an estimate of maximum concentrations) and the physical/chemical characteristics of the most toxic isomer or member of a chemical group. Note that screening assessments cannot always provide a quantitative estimate of risk or back-calculate a risk-based property specific standard.

A screening assessment may include consideration of values from the Ministry or from other reputable jurisdictions, together with an assessment of the basis of that value, as part of the screening process.

If a screening process is employed, the following should be provided:

* The complete list of COCs found on, in or under the RA property, including a summary of the monitoring data and detection limit for each COC and illustration of the spatial distribution of COCs on, in or under the property (most of this information should already be included in RA report Section 3 and the phase two conceptual site model);
* The screening approach, including which COCs are to be followed through quantitative calculations in subsequent steps in the risk assessment process; specifically, toxicity/hazard assessment and exposure assessment; and
* An appropriate property specific standard recommended for all COCs found on, in or under the property, including those deemed to present no significant risk through a screening process. The recommended property specific standard must be determined from some means other than the screening method (see Sections 6 and 7 of this Procedures document). Maximum concentrations (or estimates of the maximum concentrations) found on-site can be proposed as property specific standards, as described in Section 3.3 of this Procedures document, for COCs which pose negligible risk based on the outcome of the screening assessment.

The suitability of a screening assessment approach for a particular circumstance must be explained in the risk assessment. The Ministry will consider whether a particular approach is suitable as part of the risk assessment review.

### Using Ministry Component Values

The Ministry’s generic site condition standards were developed based on a component value approach. Component values are, for the most part, risk-based values derived to be protective of a receptor (or group of receptors) from a contaminant via a specific pathway. The Ministry’s conceptual model identifies the receptors and pathways that were considered.

These component values can also be used for screening purposes within the HHRA and ERA, so long as the QPRA has previously confirmed that the Ministry’s conceptual model and component values are appropriate for use at the RA property. The most up-to-date Ministry component values are included in the Ministry’s approved model.

Some Ministry component values rely on criteria or values from other programs or jurisdictions, and these values may be updated from time to time. The Ministry will make every effort to update the approved model to account for these changes, however the QPRA will need to confirm that the component values used for screening purposes are appropriate for use at the RA property. For example, the QPRA should consider the following when using Ministry component values:

* Most GW1 component values are set to Ontario Drinking Water Quality Standards (ODWQS). Note that ODWQS are updated from time to time and the most recent standards may not be included in the approved model. The QPRA is expected to use the most recent ODWQS in the risk assessment.
* Human health and ecological component values are derived based on values or TRVs selected from other jurisdictions. The QPRA is expected to check these values to ensure that the most up-to date ones are used in the risk assessment.

In addition, there are limitations to the use of the Ministry’s component values. These are covered in detail in the Ministry’s Rationale document and some of the more relevant ones summarized here:

* Shallow Depth to Water Table: GW2 component values from the Ministry’s generic Tables 2, 3, 4, 5, 8 and 9 were developed assuming a depth to the water table of 3 mbgs. These values may not be appropriate for use at RA properties where the depth to the water table is shallow or where the bottom of the building’s foundation will be in close proximity to the water table. GW2 component values from generic Tables 6 and 7, which were derived using a default attenuation factor, would be appropriate for these scenarios.
* Impacted Soil Volume and Dimension: The generic brownfields standards were developed assuming a finite volume of impacted soil with specific dimensions (e.g. 13 m by 13 m by 2 m or approximately 340 m3). If the total impacted zone at the RA property has a volume or dimensions that are significantly greater than what was assumed, the component values that employ source depletion or groundwater transport (e.g. S-IA, S-GW1, S-GW2, S-GW3, and S-Odour) may not be appropriate for use at the RA property.
* Buildings with High Susceptibility to Soil Vapour Entry: If buildings at the RA property have characteristics that vary significantly from the generic assumptions (e.g. earthen floors, deteriorating basements, crawlspaces, etc.), this could result in a reduction in vapour attenuation between the subsurface and the building. Under such circumstances, the S-IA and S-GW2 component values may not be appropriate for use at the RA property.
* Significant Preferential Pathways: The development of generic brownfield standards assumed that preferential pathways for vapour migration were not present. Preferential pathways may be caused by shallow fractured bedrock, gas under pressure/landfill gas, and/or utility conduits that provide a direct connection to the enclosed space of the building. If preferential pathways are present at the RA property, then the S-IA and S-GW2 component values may not be protective.
* Continuous Source: If there is a continuous source of contamination, the component values which assume a depleting source (i.e. S-IA, S-GW1, S-GW2, and S-Odour) may be underestimated and may no longer be appropriate for use at the RA property.
* Acceptable pH Range (from 5.0 and 9.0 for surface soil and from 5.0 to 11.0 for subsurface soil): Highly acidic or alkaline soil can cause chemicals to behave differently from the manner assumed in the generic model. This could affect component values for leaching (S-GW1, S-GW3) and some ecological component values (which were derived from toxicity tests where soil was within a pre-defined range).
* Surface Water Condition: If there is a surface water body that could be affected as a result of chemical migration via groundwater discharging to surface water, and the surface water has a total hardness level of less than 70 mg/L (as CaCO3) and/or has pH less than 6.7, the aquatic protection values for some metals and pentachlorophenol may be nonconservative. In such cases, a site specific estimate of hardness and pH resulting from mixing of groundwater and surface water is may be needed to estimate an appropriate aquatic protection value (and resulting GW3 and S-GW3 component values) for this site.

The approved model also allows for the derivation of site-specific component values. While this approach may be appropriate in some cases, this should be completed as part of the detailed assessment and not at the screening stage (also see Section 5.4 of this Procedures document).

### COCs with No Site Condition Standards

Screening or short-listing COCs can also prove useful when dealing with COCs without site condition standards; these COCs should be included for detailed assessment unless there is enough information to support their exclusion.

When considering information to support exclusion of COCs without site condition standards, the following should be considered:

* Known or probable human carcinogens;
* Contaminants for which no human threshold has been established by a credible agency (see Section 6 of this Procedures document);
* Contaminants which are environmentally persistent (i.e. do not readily degrade and/or metabolize);
* Contaminants that are known or suspected to bioaccumulate and/or biomagnify; and/or
* Contaminants which may degrade to more toxic and/or persistent degradation products.

## Contaminant Fate and Transport Modelling

For some contaminants and exposure pathways, fate and transport modelling in the subsurface must first be completed in order to determine the exposure point concentration. The exposure point concentration can be defined as the concentration in an environmental medium (soil, water, air, sediment) to which a human or ecological receptor is presumed to be exposed. In the development of the generic site condition standards, the Ministry relied on fate and transport algorithms (which are described in the Ministry’s 2011 Rationale document and included in the approved model) to determine the following:

* Vapour intrusion of contaminants (from both soil and groundwater sources);
* Leaching of soil contaminants to groundwater (note that the leaching was not modelled for inorganics);
* Migration of contaminants in groundwater to surface water;

In general, section 7 of the Ministry’s Rationale document details the fate and transport assumptions and equations used in the approved model.

In a Tier 3 risk assessment, the Ministry’s approved model can be used to assess specific exposure pathways. However, the QPRA and risk assessment team must first confirm that the Ministry’s modelling approach and related limitations and assumptions (including all input parameters used in the model) are appropriate for use at the RA property, based on their understanding of site-specific conditions. When using site-specific input parameters in the approved model as part of the HHRA and/or ERA, the Ministry’s expectation is that the requirements of Table 4 of Schedule E are met (or equivalent rationale provided) when selecting and/or modifying input parameters.

# Human Health Risk Assessment

## Problem Formulation

The first component in the HHRA is Problem Formulation. The minimum requirements for the Problem Formulation component of HHRA are provided in Table 1 of Schedule C of the Regulation, and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 4. Human Health Risk Assessment (HHRA) | (a) Problem Formulation | (i) Human Health Conceptual Site Model | Provide a human health conceptual site model that,  (a) satisfies the requirements of clause 3 (8) (b) and is consistent with the information upon which the diagrams referred to in that clause are based;  (b) explains how the information provided under Report Section 3 (Property Information, Site Plan and Geological Interpretation) was incorporated into and is consistent with the human health conceptual site model; and  (c) was relied upon in the preparation of the risk assessment. |
| 4. Human Health Risk Assessment (HHRA) | (a) Problem Formulation | (ii) Risk Assessment Objectives | 1. State the objectives of the human health risk assessment and include an indication of,  (a) the proposed use of the RA property;  (b) the receptors and exposure pathways to be assessed by the human health risk assessment;  (c) whether a qualitative or quantitative assessment of risk or both will be used in the human health risk assessment; and  (d) the type of approach used for the human health risk assessment.  2. Demonstrate that the data used for the human health risk assessment is sufficient to meet the objectives of the assessment, having regard to,  (a) the data quality objectives specified in the reports on the sampling program summarized in the appendices to the risk assessment report; and  (b) any other relevant information the qualified person has gathered or obtained in conducting the assessment.  3. State how any uncertainty resulting from variable data, poor data quality or gaps in data in relation to the RA property affected,  (a) the setting of objectives for the human health risk assessment; and  (b) the ability to meet those objectives. |

### Human Health Conceptual Site Model

The human health conceptual site model is a physical description of the potential contamination problem to be assessed from a human exposure and health risk perspective. The human health conceptual site model must meet the requirements of the Regulation as described in:

* Section 3 (8)(b) of Schedule C
* Table 1 of Schedule C, Report Section 4. Human Health Risk Assessment

Potential receptor populations for the proposed property use must be identified along with all associated potential exposure routes and pathways. For each of the sources of COCs for the RA property, the QPRA must ensure that the conceptual site model identifies 1) the release mechanisms and transport pathways, 2) all human receptors located both on and off the RA property, as well as exposure points and routes of exposure.

The human health conceptual site model must identify potential exposure pathways for those receptors based on physical/chemical characteristics of the COCs and geological characteristics of the site as identified in the subsurface transport component of the conceptual site model (i.e. phase two conceptual site model) in Report Section 3.

The human health conceptual site model must clearly distinguish between pathways which are naturally incomplete and those which may be rendered incomplete through risk management measures.

For each applicable receptor, the risk assessment team should identify all potential on-site and off-site exposure pathways (e.g. soil ingestion) based on the characteristics and anticipated activities of that receptor and the expected mobility of the COCs under the geological conditions present at the site. For each receptor and exposure pathway, the risk assessment team should indicate further if a man-made barrier or measure to interrupt this pathway is present or anticipated.

Any exposure pathways which can be anticipated based on chemical properties and site geology should be included in the risk assessment. Elimination of these pathways from assessment will require justification in the form of pathway-specific site assessment evidence. Pathways which can be anticipated but which will be mitigated by a barrier or other measure (e.g. site restriction) must be included for the assessment of risk level. The barrier or other measure can then be identified as a risk management measure in the development of the human health standard.

### Risk Assessment Objectives

The QPRA must provide risk assessment objectives which describe the approach to studying the potential contamination problem (refer to Section 4.2 of this Procedures document) with reference to the human health conceptual site model (Section 6.1.1) and demonstrate that data used in the HHRA are sufficient to meet those objectives. It is important to state whether the risk assessment is a qualitative or quantitative assessment of risk and the type of approach used for the human health risk assessment.

Examples of HHRA Objective Statements would be;

The objective of the HHRA is to estimate the potential health risk to human receptors that result from exposure to the COCs identified in soil and groundwater at the RA property without risk management measures in place. The RA property has been designated for mixed residential and commercial land use. As such, the receptors that will be assessed include residents, indoor workers, visitors, landscape workers, construction workers, and utility workers. The exposure pathways will consist of ingestion, dermal contact, and inhalation, as detailed in the human health conceptual site model.

Risk will be assessed both quantitatively and qualitatively. Quantitative risk characterization is conducted to evaluate the non-cancer hazard and cancer risk posed by exposure to COCs for each receptor and for each identified complete exposure pathway. In some instances, risks will be assessed qualitatively based on selected exposure pathways being minimal or exposure concentrations being lower than their respective generic human health component values (included in the Ministry’s approved model). The quantitative determination of risk from exposure to each COC will be used to determine if risk management measures will be required to block specific exposure pathways. The resulting human health property specific standards will be compared to the ecological property specific standards to determine a final property specific standard for each COC.

### Discussion of Data Quality

As indicated in the table above, the Regulation requires that the QPRA demonstrate that the data used for the HHRA and described in Section 3 of the RA report is sufficient to meet the objectives of the assessment. Data quality or availability may be insufficient for a quantitative assessment, for example, and a qualitative approach may be proposed. Examples of data quality problems which may impact on the risk assessment approach include;

* Elevated detection limits (above the applicable site condition standards),
* Low analytical recovery,
* High relative standard deviation,
* Variable monitoring data, inconsistent year-to-year trend,
* Assumptions made for one or more pathway that rely on older/stale data, data based on analytical method that does not comply with section 47 of the Regulation, insufficient monitoring or no supporting data.

Uncertainty in the data resulting from variable or poor data quality, as well as any data gaps should be discussed in terms of the risk assessment approach used to accommodate them. The QPRA should explicitly discuss the extent to which suspect data can and will be relied upon in the risk assessment.

## Exposure Assessment

The exposure assessment provides an estimate of the daily exposures of receptors to COCs on a contaminated property for each exposure pathway described in the human health conceptual site model (Section 6.1.1 of this Procedures document). A receptor’s estimated exposure to a COC for each relevant exposure pathway is determined through an estimation of their exposure frequency and duration and medium-specific intake rate, and an assessment of the uncertainties associated with this estimation. Qualitative or quantitative exposure assessment may be undertaken according to the risk assessment objectives as described in Sections 4.3 and 6.1.2 of this Procedures document.

The HHRA exposure assessment should describe:

* All relevant on-site and off-site human receptors that could be exposed to the COC(s).
* Receptor characteristics that are clearly articulated in the RA report, and
* Potential exposure routes and pathways.

Minimum requirements for the Exposure Assessment component of the HHRA are provided in Table 1, Schedule C of the Regulation and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 4. Human Health Risk Assessment (HHRA) | (b) Exposure Assessment | (i) Receptor Characteristics | Describe in detail the characteristics of every human receptor, both on and off the RA property, identified in the human health conceptual site model. |
| 4. Human Health Risk Assessment (HHRA) | (b) Exposure Assessment | (ii) Pathway Analysis | Describe in detail every exposure pathway identified in the human health conceptual site model. Justify which exposure pathways are incomplete. |
| 4. Human Health Risk Assessment (HHRA) | (b) Exposure Assessment | (iii) Exposure Estimates | For every complete exposure pathway state,  (a) the relative frequency and duration of actual or potential exposures;  (b) the relative magnitude of exposure to the human receptors, using measured contaminant exposure concentrations or concentrations predicted through fate and transport modelling; and  (c) given the uncertainty described under Heading (a) (Problem Formulation), how does this uncertainty affect the outcomes of the exposure assessments conducted under clauses (a) and (b). |

Additional guidance is provided in the following sections of this Procedures document.

### Receptor Characteristics

The RA report should describe the characteristics of all relevant on- and off-site receptors identified in the human health conceptual site model. Receptor characteristics should be defined to include gender, age (including elderly), predisposing physiological and/or medical conditions (e.g. asthmatics, immunologically impaired, pregnant women, etc.) and other exposure variables (e.g. inhalation rate, water ingestion rate, soil ingestion rate, etc.).

The QPRA should identify receptor populations currently present at or near the RA property and those that may be present given the proposed use of the property by considering the following;

* The proposed use of the RA property, distance to the closest receptor, public accessibility and receptor activities and patterns, including but not limited to the amount of time the potentially exposed populations spend at the RA property; the proportion of time human activities occur primarily indoors or outdoors; any variations due to seasonal changes; and any property-specific population characteristics that might influence exposure frequency and/or intensity;
* Use of the groundwater for drinking or agricultural purposes under present and future conditions;
* The receptor sub-populations of potential concern: any group with increased sensitivity, (e.g. infants, asthmatics, elderly, pregnant women) either due to, for example, the behaviour, activity pattern or health status of the sub-population or to the sensitive endpoint(s) of the COC’s toxicity, including, but not limited to, schools, day-care centres, hospitals, retirement communities, nearby residential areas with children, and hunters/gatherers at or near the property;
* The uncertainty that exists in terms of the characteristics of the exposed receptors via the identified exposure pathways. This should include the uncertainty associated with the quality of supporting site-specific data, the understanding of proposed land use and knowledge of uses and likely uses of adjacent or potentially impacted sites.

Receptors should include those who may be exposed during the proposed property use while giving consideration to the property surroundings. This also includes consideration of occasional receptors, including but not limited to visitors and utility workers. Each receptor should be considered to the level of detail appropriate to meet the objectives of the HHRA (refer to Section 6.1.2 of this Procedures document).

### Pathway Analysis

In the RA report the pathway analysis must identify the exposure routes and pathways considered potentially complete or complete without risk management measures. Any exposure pathways which can be anticipated based on chemical properties and site geology should be included in the exposure assessment. Elimination of these pathways from assessment will require justification in the form of pathway-specific site assessment evidence. Pathways which can be anticipated but which will be mitigated by a barrier or other measure must still be included in the risk assessment. The barrier or other measure (e.g. site restrictions) can then be identified as a risk management measure in the development of the human health standards. The pathway analysis should include the following:

* Exposure pathways of concern according to the human health conceptual site model, including exposures via all potential media, and considering the current and/or future condition of the RA property without risk mitigation measures (refer to Section 6.1.1 of this Procedures document);
* The sources for all potential releases (past, present and future);
* The potential receiving media (e.g. indoor air, surface water, groundwater, soil, sediment, biota, etc.);
* The physical and chemical fate and transport properties of all COCs to identify the media that are receiving or may receive the property-related contaminant;
* The exposure points (i.e. where the potentially exposed population can contact the COC); and,
* The exposure routes (e.g. incidental ingestion of soil, ingestion of groundwater, ingestion of garden produce, inhalation of vapours, etc.) that may be associated with the COCs.

The following points should be considered when evaluating exposure pathways:

* Discuss the environmental fate of the contaminants including possible degradation. When sufficient laboratory and field evidence indicates that a contaminant could be degraded/biodegraded (transformed/biotransformed) to a relatively more toxic and persistent intermediate/product, the future concentration of the potential degradation product/intermediate should be estimated from the present concentration of its precursors, if possible (e.g. the anaerobic biodegradation of chlorinated aliphatics in groundwater).
* Identify direct and indirect routes (via intermediate receptors such as garden produce) and pathways of exposure for each receptor.
* Taking into account the proposed property use, plans for construction and the fate and transport of the contaminant in the environment, identify and document relevant exposure scenarios and exposure route/pathways to on-site and off-site human receptors.
* Justify the exclusion (if any) of receptors and exposure routes/pathways identified in the human health conceptual site model.

Numerous exposure pathways that were not considered in the setting of generic site condition standards should be considered on a site-specific basis, based on the nature of the COC present on the RA property, the physical characteristics of the RA property, and proposed future site uses. Some of these exposure pathways are listed below, as examples:

* Dermal contact with groundwater.
* Incidental ingestion of surface water while swimming and/or wading.
* Consumption of fish and/or wild game.
* Consumption of locally grown fruits/vegetables.
* Consumption of breast milk.
* Inhalation (e.g. of soil particulate) for receptors with high physical activity levels (e.g. athletes).

Various credible agencies can be consulted for suitable exposure parameters and general exposure equations for determining pathway-specific exposure estimates (Health Canada Contaminated Sites Program guidance documents, US EPA Risk Assessment Guidance for Superfund (RAGS), US EPA Exposure Factors Handbook, etc.).

### Exposure Estimates

In most cases, quantification of exposure estimates will be required to meet the risk assessment objectives. Quantification of a receptor’s exposure to a specific COC refers to the calculation of intake or uptake rates or delivered target dose for each exposure pathway and/or the exposure from several exposure pathways, if relevant. Quantification of the contaminant intake and uptake should be done for each potentially complete exposure pathway. Quantification should include the following information:

* Exposure concentration (concentration that is or may be present at the site over the exposure period),
* Contact rate (amount of contaminated medium contacted per unit time or event) and absorption rate, and
* Total time of exposure (estimated from exposure frequency and duration).

Reasonable maximum and/or average estimates of exposure for relevant site-specific receptors should be developed based on both current and future property use assumptions, and measured concentrations at the property.

Fate and transport models are frequently used to predict the likely current extent of contamination as well as to assess the behaviour of contaminants under potential future scenarios. Such modelling can be useful to direct sampling programs and draw conclusions regarding potential off-site migration of contaminants. When a fate/transport model is utilized in the risk assessment to predict contaminant concentrations in soil or groundwater, the predicted concentrations should be verified through field sampling wherever possible. For example, when modelling indoor air concentrations, the collection of soil vapour, sub-slab and indoor air data may also be warranted.

In some cases, quantification may also include exposure from other sources/pathways/routes not specifically associated with the RA property, such as food ingestion, water supply and ambient air (i.e. typical background exposures) if sufficient information is available.

In conducting quantitative exposure assessment, the following should be considered;

* Document the exposure models, model assumptions and characteristics of the receptors used for evaluation of exposures.
* Provide the equations and sample calculations for evaluating human exposure for the various pathways.
* Calculate exposures to the different receptors from various pathways identified for different contaminants.
* A contaminant source, for the purpose of a HHRA, is an environmental medium which can include, but is not limited to soil, groundwater, air and garden produce.
* Determine exposures for all relevant receptor life-stages, and consider composite receptors for non-threshold carcinogens.
* Consider the adult female receptor (e.g. female outdoor worker), and exposure assumptions relevant to the adult female receptor, for all COCs for which developmental effects have been identified as a critical effect.
* In the calculation of uptake, the COC concentrations should be characterized with an estimate of the average and the upper range of the data, for example using the mean and maximum or 95th percentile. The US EPA’s Superfund program has traditionally used the 95% UCL of the mean as the concentration in point estimates of reasonable maximum exposure for human health risk assessment (US EPA, 1992; 1997). It is recommended that the risk assessment team consider the US EPA’s RAGS as a starting point for the most appropriate estimate of reasonable maximum exposure (RME), and to consider other options that are available. It should be noted that any methods chosen for use in the development of an exposure point concentration will be driven by the quality and quantity of data available. See Section 6.2.5 of this Procedures document regarding the selection of exposure point concentrations for soil and groundwater.
* Consideration of background exposures other than exposure to on-site contamination (soil, air, water, etc.), if included, should also be discussed with reference to the property specific exposure.
* Analysis of the major sources of uncertainty and how they affect the exposure estimates. Uncertainty in the pathway analysis, for example, should be discussed in terms of the dependency of the exposure estimates on pathway assumptions that are unconfirmed or beyond the knowledge and control of the proponent.

If computer models are utilized, ensure the models have been validated and/or are considered acceptable based on scientific principles. These models should also be available in the public domain. Use of proprietary models may be considered only when sufficient documentation of the modelling is provided. Use of proprietary models will require additional Ministry review as provided by the Regulation (refer to section 9 of Schedule C of the Regulation). Such models (validated and/or accepted) should be provided to the Ministry and accompanied by available technical support documentation of basic principles, user instructions, etc. The documentation should include all mathematical expressions and assumptions used in the model(s). A comprehensive sensitivity analysis should also be conducted and included with the RA report.

If proprietary models and any supporting documentation are considered confidential, such material should be clearly marked confidential. In either case, review of an RA report will be facilitated by provision of any computer software being utilized for the exposure calculations. The Ministry will require evidence that such software models are provided in a manner that will not infringe any third party’s copyright. The rationale for the suitability of any chosen model to the RA property should also be documented (refer to Section 9.3.2 of this Procedures document).

If conducting probabilistic modelling, statistical distributions developed from site-specific data or obtained from published peer reviewed scientific literature applicable to the RA property should be used for input parameters associated with receptor characteristics (refer to Section 9.3.3 of this Procedures document). The statistical distributions used in probabilistic modelling may require additional time for Ministry review, as provided by the Regulation (refer to section 9 of Schedule C of the Regulation).

### Site-Specific Deviations from Generic Exposure Parameters

In specific cases, due to the intrinsic characteristics of the site, receptor behavior and exposures may be significantly different that those generically assumed by the Ministry.

Soil Ingestion Rate (SIR): The generic SIRs are recommended for site-specific HHRAs as the default value because these values offer the same level of protection as the generic soil standards. Alternately, the selection of a different SIR value should be sufficiently justified within an HHRA and will be reviewed on a case-by-case basis.

As an event-driven parameter, the SIR is dependent on human behaviour and human activity throughout the day. Therefore, the selection of a SIR should be based on: 1) site-specific conditions and, 2) site-specific receptor activity. For example, the exposure scenarios considered for the S1 receptor (in the development of the Ministry’s generic soil standards) are for residential properties. The generic SIR is intended to represent estimated ingestion of both soil and dust.

Some site-specific exposure scenarios may warrant the use of site-specific SIRs which deviate from generic assumptions if (1) exposure to soil is considerably blocked or, if (2) the expected possible behaviour(s) on the site are considerably different from the behaviour(s) considered in the key studies used for the derivation of the generic SIRs. For example, using site-specific SIRs may be appropriate under the following scenario:

* RA property that has dense vegetation cover (forested) or saturated soil (wetland, swamp) and is not easily accessible to the general population, but might have occasional site users/trespassers. Future use of the property would need to remain consistent with this assumption and further documentation of this may be required in the risk management plan (e.g. as a restriction on future use of the RA property).

Exposure Frequency and Duration: As stated above, certain exposure parameters can be modified from generic assumptions if there is sufficient justification provided to support such changes. The exposure frequency and duration of a receptor can differ from generic Ministry assumptions in an RA property under these circumstances. For example, using a site-specific exposure frequency may be appropriate under the following exposure scenario:

* For an outdoor maintenance/landscape worker, at an RA property that is very small in size, and where the proposed use will remain commercial. The QPRA may find that the use of the generic exposure frequency of 5 days per week for this type of receptor may be overly conservative for this scenario, at the RA property.

It should be noted that while the effects from exposure to threshold contaminants are directly associated with the period of time an individual spends in a contaminated site, the effects from exposure to non-threshold contaminants assume continuous lifetime exposures. A cancer risk level cannot be calculated if both the exposure concentration and the oral slope factor or inhalation unit risk are not based on continuous lifetime exposure since it is assumed that a threshold for adverse effects may not exist. Therefore, exposure durations cannot be modified for exposure calculations with non-threshold COCs by assuming that a period of “no exposure” occurred before or after an exposure period.

It should also be noted that it is reasonable to expect that residents live on their property their whole lives and, if residents move, they could move near their old residence or move to another site which may have similar contaminant concentrations. Therefore, applying shorter exposure durations than lifetime for residential properties is not considered to be appropriate under the Regulation.

### Selecting Exposure Point Concentrations for Soil and Groundwater

Because the property specific standards cannot be exceeded at the time of RSC filing (the Environmental Site Registry requires that the maximum concentration measured at the property be reported when submitting the RSC and this value cannot exceed its respective property specific standard) and risks at the property specific standard must also be characterized, the risk assessment will usually select the maximum measured concentration (or the maximum + 20%) as the exposure point concentration (EPC) in soil and groundwater. In most cases, this approach is expected to be sufficient to meet the objectives of the risk assessment.

However, in some cases, the QPRA may wish to further refine the exposure assessment by considering other scenarios (in addition to the one described above), by deriving EPCs by other means (e.g. 95th percentile, 95% UCLM).

Important considerations when evaluating the feasibility of this approach include the following:

* For each receptor where this approach is used, an exposure unit will need to be clearly defined. The exposure unit is defined in the US EPA’s RAGS (Volume 3, Part A, 2001) as: “the area throughout which a receptor moves for the duration of the exposure”. Note that under a brownfield redevelopment scenario, this approach may not be appropriate (or viable) for receptors that have smaller exposure units (e.g. toddlers, residents).
* The ESA work completed for the RA property must be adequate to support this approach (e.g. the resolution of the environmental measurement data must align with the receptor’s exposure unit).
* This approach is not recommended when assessing the vapour intrusion or drinking water pathways.
* Contaminant hotspots (or areas of the RA property that are above risk-based health standards) may still require further remediation and/or risk management.

The software used to derive EPCs must be clearly identified (e.g. US EPA’s ProUCL) and all inputs (e.g. environmental data) and outputs must be provided in an appendix of the risk assessment, for Ministry review.

Due to the increased level of complexity, additional time for Ministry review will be required and the risk assessment will be designated as a new science risk assessment. Additional technical guidance can be found in the US EPA’s RAGS.

## Toxicity Assessment

A toxicity assessment is the determination of the quantitative relationship between the magnitude of exposure and the probability of occurrence of a particular adverse effect, as well as the uncertainties associated with this determination. A toxicity assessment is required for all COCs for which there are potential or completed exposure pathways as determined through the process described in Section 4.2, regardless of whether a qualitative or quantitative approach is being used.

Minimum requirements for the Toxicity Assessment component of the HHRA are provided in Table 1, Schedule C of the Regulation and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 4. Human Health Risk Assessment (HHRA) | (c) Toxicity Assessment | (i) Nature of Toxicity (Hazard Assessment) | For each contaminant of concern,  (a) state the potential adverse health effects on the human receptors associated with their exposure to those contaminants; and  (b) indicate whether the contaminants are carcinogenic or exhibit threshold or non-threshold characteristics. |
| 4. Human Health Risk Assessment (HHRA) | (c) Toxicity Assessment | (ii) Dose Response Assessment | For each contaminant of concern,  (a) describe the relationship between the magnitude of exposure to the contaminant from each route of exposure and the probability of the occurrence of the adverse health effects identified in the hazard assessment;  (b) if the data permits, identify the appropriate toxicity limit, from published limits available from a credible agency as described in subsection 9 (3) for each of the routes of exposure identified in clause (a); and  (c) analyze the sources of uncertainty in the data used to conduct the hazard assessment and the dose response assessment, including any gaps or variability in the data and state how such uncertainty could affect these assessments. |

Additional guidance is provided in the following sections of this Procedures document.

### Hazard Assessment

Hazard assessment must document the potential adverse effects to human health which are associated with COC exposure. Toxicological information must be provided that is being considered to evaluate potential human health effects for each of the COCs including information on toxicological end points (e.g. developmental/ reproductive) and time scale of effects (e.g. acute/ chronic), which are considered relevant for the pathways and receptors identified under the Exposure Assessment heading.

The hazard assessment section of a HHRA should consider, at a minimum, the following information for each COC that has been carried forward for quantitative assessment:

* The physical and chemical characteristics of the COC.
* A summary of key non-cancer effects from animal and human studies by routes of exposure.
* An evaluation of carcinogenicity (carcinogenic classification, if available; and/or summary of overall weight of evidence).
* A summary of hypothesized mode(s)-of-action.
* A brief discussion of susceptible populations (e.g. childhood susceptibility, gender differences).

### Dose-Response Assessment

Dose-response assessment must identify appropriate toxicity reference values (TRVs) by providing:

* A description of the relationship between the magnitude of exposure for different routes and the occurrence of adverse effects for the receptors, and
* An analysis of the major sources of uncertainty on both hazard assessment and dose response assessment, and how such uncertainty affects the outcome of the toxicity assessment. The combined use of uncertainty factors, for example, may result in a highly conservative estimate, or less conservative estimate, of the TRV.

Ministry selected TRVs are listed in the “Rationale for the Development of Soil and Ground Water Standards for Use at Contaminated Sites in Ontario” (2011 MOE). Note that the Ministry’s TRV selections may be updated from time to time, as new information becomes available. The Ministry will make every effort to share updated TRV selections with risk assessment practitioners and QPRA’s are encouraged to contact the Ministry directly should they have any questions regarding current Ministry selections.

It remains the QPRA’s responsibility to ensure that the most recent and relevant information is used in the risk assessment. A search of the most recent government agency TRVs data should be conducted prior to submission of the RA report.

Acceptable government agencies include those which incorporate one or more of the following:

* A rigorous peer review mechanism by credible experts/multiple regulatory bodies/jurisdictions and/or academia,
* Ongoing review and updating of values on the basis of new studies or advances in science, and,
* Published and/or publicly available TRV values with descriptions of their derivations.

Examples of credible regulatory agencies include but are not limited to the United States Environmental Protection Agency (US EPA), California Environmental Protection Agency (Cal EPA), World Health Organization (WHO) and Health Canada. TRVs values published by these agencies are generally considered acceptable to the Ministry with limited review.

The TRV selected for use in the HHRA should be:

* Relevant for the selected receptors, exposure parameters, and routes of exposure, and
* Identified for the correct chemical entity (e.g. isomer, oxidation state, speciation, chemical form of the contaminant) as identified on-site.

In the dose-response section of a HHRA, the following information should be presented for each TRV selected:

* Key study from which the selected TRV was derived.
* Model (animal/human) used and study design applied in key study (including route(s) of exposure).
* Critical endpoint(s) or effect(s) observed in key study (including target tissue/organ).
* Point of departure and/or dose-response modelling used in the derivation of the TRV (NOAEL/LOAEL approach, BMD modelling, PBPK modelling, etc.).
* Regime of uncertainty factors and modifying factor(s) used in the derivation of the TRV, and
* Rationale for using this TRV.

It may not be possible or appropriate to conduct quantitative calculations for risk assessments where there is insufficient data or no pre-existing toxicological assessment of the contaminant. In general, when a contaminant (or its surrogate) has not been assessed and an exposure limit, TRV or dose response relationship has not been established by credible regulatory agencies, quantitative calculations for risk assessment should not be undertaken without prior consultation with the Ministry. Analysis of published toxicity data other than described above by a credible agency is highly discouraged and will generally not be accepted by the Ministry. In the exceptional case where no TRVs are available for a contaminant but sufficient and defensible scientific information is available in the published literature and/or public domain, a proponent may be allowed to develop a TRV after consultation with Ministry toxicologists.

A lack of relevant data should lead to the following conclusions:

* The present status of scientific knowledge does not allow the quantitative evaluation of human health risk, and
* No property specific human health-based standard can be established.

Recommendations can be made that, for the protection of human health and in the absence of adequate knowledge of human health risk, exposure to humans be reduced as much as possible and property specific standards be based on other factors (e.g. the full depth background site condition standards in Table 1 of the Soil, Ground Water and Sediment Standards). When no site condition standard exists for a given chemical parameter, the property owner may choose to adopt a background-based or effects-based soil or groundwater value from another credible regulatory agency.

Caution should be exercised in converting toxicity data as follows:

* Converting the TRVs from one route of exposure to another must be supported with adequate rationale depending on the availability of route-specific studies, or scientific evidence indicating that the endpoints are based on systemic effects;
* When assessing inhalation of indoor air, most jurisdictions now report inhalation TRVs in terms of acceptable indoor air concentrations (e.g. in µg/m3). Using these TRVs to calculate dose (e.g. µg/kg/day) and risk levels may not be appropriate, as uncertainties regarding receptor characteristics (e.g. different inhalation rates and body weights for different receptor life-stages) are often already accounted for by the jurisdiction in the development of inhalation TRVs;
* Extrapolating toxic effects from short-term exposure to toxic effects expected from chronic exposure must be supported with TRVs from appropriate studies. Such an approach must clearly indicate that the toxicity endpoints of long-term and short-term exposure are consistent and mediated by the same mechanisms;
* Using Occupational Exposure Limits (OELs) for site-specific risk assessment purposes are not appropriate under the Regulation. In general, OELs may be developed using target risk levels other than those prescribed under the Regulation and apply strictly to workers under specific exposure patterns deemed to be appropriate in the labour regulation.

Finally, for contaminants with no Ministry standards, the QPRA will need to review TRVs available from other credible agencies, make selections and provide a clear rationale for the TRVs selections. In some cases, when assessing a contaminant for which there is no applicable site condition standard, the risk assessment may be considered as a new science risk assessment as per the Regulation, refer to Section 9.3.1 of this Procedures document for additional details.

## Risk Characterization

Risk characterization must include evaluation of the contribution from the different exposure routes and media to the overall risk. In the characterization of risk, the QPRA should describe the following:

* the nature and magnitude of the risk from each route of exposure, and from all routes combined if relevant and supported by the toxicity profile of COCs;
* whether current or future COC concentrations at or near the property are of potential concern to receptors, on and off the property;
* the populations and sub-populations at greatest risk; and
* the uncertainties associated with the overall analysis.

Minimum requirements for the Risk Characterization component of the HHRA are provided in Table 1, Schedule C of the Regulation and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 4. Human Health Risk Assessment (HHRA) | (d) Risk Characterization | (i) Interpretation of Health Risks | For each contaminant of concern, having regard to the exposure assessment and the toxicity assessment, state the risk attributable in respect of that contaminant to each exposure route for human receptors on the RA property, using either a quantitative or qualitative analysis. |

When determining risks from COC exposures, the QPRA should provide a clear, and complete description and interpretation of the risks to receptors on the RA property based on the available site-specific data.

Human health risk characterization should account for the following:

* When a compound is known to degrade/biodegrade in the environment to a relatively more toxic and persistent intermediate or by-product, any significant human health risk due to the biodegradation intermediate or by-product should be characterized (e.g. trichloroethylene to vinyl chloride).
* When characterizing risks, ensure that TRVs used in the assessment are appropriate for use with same chemical entity present on-site, where possible (as TRVs may have been developed for different chemical isomers, different speciation/oxidation state, different route of exposure).
* The human receptor(s) or sub-group(s) evaluated should correspond to the human population for which the TRV was developed.
* Intake rates should be compared to TRVs that are based on administered doses and uptake rates should be compared to TRVs based on doses absorbed systemically. If there are no demonstrable differences in uptake between the media used in the toxicity study and the media for the relevant pathway addressed in the risk assessment, adjustment to reference doses for bioavailability should not be made.
* If a QPRA chooses a probabilistic approach, in general, the resulting 95th percentile of the exposure term is recommended for characterizing the reasonable maximum exposure, while both the arithmetic mean and median (50th percentile) should be used to characterize the central tendency of the data. The QPRA should provide supporting information, including the statistical distribution and accompanying rationale for all input variables, correlation between relevant input variables, the statistical sampling method and number of iterations and sensitivity analysis. Note that the Regulation requires explicit calculation of risks at the property specific standard and risk management decisions are made with consideration to the property specific standards, and not other exposure point concentrations that may have been used in the risk assessment. See Section 6.2.5 of this Procedures document for additional detail.
* In the case of chemical mixtures inducing similar effects in the same target organs/tissues (e.g. similar types of liver tumors) and/or acting through similar mechanisms or modes of action, the QPRA should consider estimating the combined risk or hazard index for the mixture. A detailed discussion should accompany and support the proposed methodological approach.

If a quantitative analysis of toxicity and/or exposure assessment has been undertaken, risks values can then be derived in the risk assessment.

If a quantitative analysis of toxicity and/or exposure assessment was not undertaken, the justification for not providing a quantitative analysis must be provided and a qualitative characterization of risk must be provided.

### Quantitative Interpretation of Health Risks

When a quantitative assessment of health risk is one of the objectives of the HHRA, the minimum requirements, as specified in Table 1 of Schedule C of the Regulation (reproduced below), are to be included in the RA report.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 4. Human Health Risk Assessment (HHRA) | (d) Risk Characterization | (ii) Quantitative Interpretation of Health Risks | A quantitative analysis undertaken for a contaminant of concern must include the following:  i. Provide a comparison of the dose response assessment to the exposure estimate to derive the risk level or hazard quotient at the RA property in the absence of any measures that have been taken or are being proposed at the RA property which have the effect of reducing the risk from the contaminant of concern.  ii. For each contaminant of concern with non-threshold toxic effects and taking into consideration any risk management measures that are being proposed in the risk assessment, propose and justify a human health standard for the contaminant, ensuring that the standard meets a target risk level of 1 × 10–6 for each environmental medium.  iii. For each contaminant of concern with threshold toxic effects and taking into consideration any risk management measures that are being proposed in the risk assessment, propose and justify a human health standard for the contaminant, ensuring that each human receptor does not receive an estimated dose exceeding 0.2 × the limit dose (TDI, RfD or RfC) for each environmental medium. In this paragraph, “TDI” means tolerable daily intake, “RfD” means the reference dose, “RfC” means the reference concentration. The units used to measure the TDI, the RfD and the RfC must be specified and conform to acceptable conventions.  iv. If, under paragraph iii, given the circumstances of the human receptors and the characteristics of the contaminant, it is unreasonable to apply a hazard quotient of less than or equal to 0.2 for each environmental medium, a higher hazard quotient may be proposed, if the proposed quotient is accompanied with a detailed site specific multi-media exposure assessment that considers the transport of the contaminant across all environmental media to the human receptors by all exposure pathways and ensures that the standard achieves the same level of protection for each human receptor as is intended to be achieved by the applicable full depth generic site condition standard for that contaminant. |

The Regulation requires risk calculations to be performed and reported without consideration of risk management. The proportion of risk contributed by each media and exposure pathway should be identified on a purely science basis in order to inform risk management decisions.

As a second step, a proposed property specific standard may be back-calculated, using the same exposure equations, to propose a risk-based cleanup standard for a contaminant which currently exceeds an acceptable level of risk. Alternatively, existing contamination may be left in place and risk management measures may be proposed which will block the exposure pathway or limit exposure to the COC, and alter associated risk(s) from exposure to the COC.

Care should be taken in using back-calculations to estimate proposed property specific standards, as these calculations do not necessarily account for physical/chemical limitations such as the formation of pure chemical compound or movement of contaminants between media (e.g. leaching). A contaminant concentration which has been determined to result in an acceptable level of risk to human health may be proposed as a human health-based property specific standard. However, the Ministry also expects the proposed standard to reasonably represent no more than an upper estimate of the actual concentrations remaining on, in or under the property at the time the standards are to be used to file an RSC (refer to Section 3.3.2 of this Procedures document).

Explicit calculation of health effect risk due to background exposure is not generally required as part of risk assessment. Background exposure could be considered for some COCs where it is known to be significant. QPRA’s are requested to contact the Ministry for guidance in such cases.

Additional guidance on meeting the requirements for a quantitative assessment of risks is provided in the following sections of this Procedures document.

#### Non-Threshold Effects

For non-threshold COCs (carcinogens acting through mechanisms presuming the absence of a biological threshold) an incremental lifetime cancer risk (ILCR) of one-in-a-million (1 x 10-6) must be applied to each calculation similarly to the way the generic site condition standards are calculated. For each receptor, risks from exposures to soil and groundwater should each be calculated using an ILCR of 1 x 10-6. As with the generic site condition standards, there should be separate calculations for direct contact with soil, soil particulate inhalation, inhalation of volatile contaminants in soil, direct contact with groundwater, and inhalation of volatile contaminants in groundwater – each calculation using the target ILCR of 1 x 10-6 for each receptor.

#### Threshold Effects

For threshold COCs (including some carcinogens) acting through mechanisms that presume a biological threshold, potential adverse health effects should be evaluated and characterized by comparing an exposure level over a specified period of time (e.g. lifetime) with an appropriate TRV derived for a similar exposure period using the following formula:

Hazard Quotient (HQ) = exposure/TRV

As with the generic site condition standards, there should be separate calculations for direct contact with soil, soil particulate inhalation, inhalation of volatile contaminants in soil, direct contact with groundwater, and inhalation of volatile contaminants in groundwater – each calculation using the default source allocation factor (SAF) of 20% of the TRV for each receptor. The QPRA should consider using a default SAF of 20% of the TRV when developing the property specific standard as standard practice, which is consistent with the Ministry’s development of the generic site condition standards and the approved model.

Note that modelled transport of contamination in the vapour phase originating from soil and groundwater sources are usually considered separately and do not need to be considered additive. In other words, a property specific standard proposed for soil should result in no more than 20% of the TRV allocated to exposure to vapours volatilized from soil. A property specific standard proposed for groundwater should result in no more than 20% of the TRV allocated to exposure to vapours volatilized from groundwater.

Alternate SAFs are allowed under the Regulation providing they are supported through a property-specific multi-media assessment of exposure where the total exposure does not exceed the TRV for each COC.

Note that for some contaminants and for some specific exposure scenarios, an allocation of other than 20% was used by the Ministry in the development of the generic site condition standards and/or included in the approved model. A multi-media assessment will not be required in cases where these Ministry SAFs are used.

#### Use of Toxic Equivalency Factors

The Ministry has selected a Toxicity Equivalency Factor (TEF) approach as the basis for standardizing the toxicity of some groups of structurally similar compounds displaying similar toxicity profiles. Examples include dioxin-like compounds and carcinogenic polycyclic aromatic hydrocarbons (PAHs), which are discussed below.

Dioxins, Furans, and Dioxin-like PCBs

Mixtures of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and polychlorinated biphenyls (PCBs) compounds are aryl hydrocarbon receptor agonists that share a common mechanism of action that is consistent with an additive model. This model uses the relative potency determined for individual PCDD, PCDF, and PCB compounds for producing toxic or biological effects relative to the reference compound, 2,3,7,8- tetrachlorodibenzo-p-dioxin (TCDD).

The total toxic equivalent (TEQ) is defined by the sum of the products of the concentration of each compound multiplied by its toxic equivalency factor (TEF) value and is an estimate of the total TEQ of the mixture. Mixtures and their TEF values should be listed along with the methodology used to derive the total TEQ for dioxins, furans, and dioxin-like PCBs.

Polycyclic Aromatic Hydrocarbons (PAHs)

Carcinogenic PAHs are considered additive and should be assessed using a TEF approach (based on potency relative to B[a]P) where risk should not exceed 1 x 10-6 for all carcinogenic PAHs combined.

Other Chemicals

For other COCs which do not have a similar mechanism of toxic action, the aggregation of risks is not required. Similarly, hazard quotients for contaminants for which the exposure limits are based on different adverse effects and mediated by different mechanisms of action should not be added. However, this approach is acceptable when adequate evidence suggests it is appropriate to aggregate risk levels to account for systematic effects in which multiple chemicals act by the same toxicity mechanism and/or on the same organs.

Examples of contaminant groups that may be aggregated this way include but are not limited to PCBs, organophosphorus insecticides and some volatile organics. Various jurisdictions have published general guidelines on risk assessment of mixtures. The QPRA should exercise best professional judgment when using these guidelines and in deciding which contaminants should be treated as a group.

#### Adjustment for Relative Bioavailability

As with the calculations of the site condition standards, adjustments may be made for relative bioavailability. If the QPRA can demonstrate that a COC’s bioavailability for the receptor, medium, and exposure conditions is considerably different from the bioavailability assumed or estimated for the subjects, medium, and exposure conditions in the key study of the TRV used, an adjustment is warranted. Bioavailability adjustments should be justified scientifically.

Guidance on methods for using bioaccessibility adjustments as a surrogate for bioavailability are available from Health Canada and US EPA.

### Qualitative Interpretation of Health Risk

The QPRA may make use of both quantitative and qualitative options in assessing risk. A qualitative assessment of risk relies primarily on a descriptive justification for the use of information not specific to the site. In a qualitative analysis, the QPRA should explain why a qualitative approach was used and justify why a quantitative analysis was not appropriate or not required. The QPRA must also indicate the process to be used in the qualitative analysis; for example, a non-numeric (descriptive) characterization of risk or a conservative numeric assessment of exposure or toxicity for screening purposes and risk prioritization (e.g. use of Ministry component values). Qualitative risk assessment must also address any risk management measures that are being proposed for the property, and justify a property-specific human health-based standard for the contaminant.

An example of a situation suitable for a qualitative interpretation of risk would include the following:

* Based on the exposure assessment and the toxicity assessment, the generic human health component values contained in the Ministry’s approved model are protective of the human receptors at the site.

The minimum requirements for reporting a qualitative characterization of risk are reproduced from the Regulation Schedule C Table 1, below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 4. Human Health Risk Assessment (HHRA) | (d) Risk Characterization | (iii) Qualitative Interpretation of Health Risks | A qualitative analysis undertaken for a contaminant of concern must include the following:  i. Provide a justification for why a quantitative analysis was not undertaken.  ii. Describe the justification process being used as part of the qualitative analysis. The justification process includes a non-numeric characterization of risk and may include a numeric assessment of exposure or toxicity for screening purposes and risk prioritization.  iii. Taking into consideration any risk management measures that are being proposed for the RA property, propose and justify a human health standard for the contaminant. |

### Special Considerations

Whether a qualitative or quantitative assessment of risk is undertaken, any risk characterization considerations associated with the site being defined as an environmentally sensitive area, shallow soil property and/or a property located within 30 metres of a water body must be highlighted in a separate section of the report. Conditions that trigger environmentally sensitive areas, shallow soil properties and properties near water bodies are included in the Regulation:

* Section 41 of the Regulation (Site condition standards, environmentally sensitive areas)
* Section 43.1 of the Regulation (Site condition standards, shallow soil property or water body)

The reason for the environmentally sensitive designation should be identified. For environmentally sensitive sites, shallow soil sites and sites located within 30 metres of water bodies, the expected impact this may have on the estimation of human health risk, if any, should be described.

For example, the reason for an environmentally sensitive designation may be due to the presence of susceptible contaminant transport pathways which may enhance human exposure to contaminants. If this is the case, this section of the RA report should reference how the susceptible pathways are addressed and indicate how the human health standards proposed for the site are expected to be protective of human exposure through those pathways.

Minimum requirements for reporting Special Considerations are found in Table 1 of Schedule C of the Regulation and reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 4. Human Health Risk Assessment (HHRA) | (d) Risk Characterization | (iv) Special Considerations | If section 41 or 43.1 of the regulation applies to a RA property, the justification for the health standard being proposed for the RA property must take into account the site conditions that make section 41 or 43.1 of the regulation apply to the RA property. |

### Interpretation of Off-Site Health Risks

Whether a qualitative or quantitative assessment of risk is undertaken, the QPRA must highlight in a separate section of the report any considerations associated with off-site human receptors. Specifically, the QPRA must indicate if the proposed human health standards, if applied to the RA property are likely to result in an exceedance of the applicable full depth generic site condition standards at the location of off-site human receptors.

The minimum requirements for interpretation of off-site health risks are found in Table 1 of Schedule C of the Regulation and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 4. Human Health Risk Assessment (HHRA) | (d) Risk Characterization | (v) Interpretation of Off-Site Health Risks | For each contaminant of concern, assess whether the human health standard being proposed for the RA property is likely to result in a concentration greater than the applicable full depth site condition standard at the nearest human receptor located off the RA property and, if this is the case for any contaminant, specify the contaminant, the applicable site condition for that contaminant and the property where the human receptor is located and describe the human receptors that may be impacted. |

For each COC, the QPRA must assess whether the human health standard being proposed for the RA property is likely to result in a concentration greater than the applicable full depth site condition standard at the nearest human receptor located off the RA property. If this is the case for any contaminant, the QPRA must specify the contaminant, the applicable site condition standard for that contaminant and the property where the receptor is located and describe the human receptors that may be impacted. It is recommended that this information be provided in tabular format.

In addition, for properties with volatile COCs in soil and/or groundwater, the QPRA should also discuss the potential for the migration of soil vapour off-site in this section of the report.

The information included in this sub-heading is expected to be consistent with the mandatory certifications made by the QPRA, (specifically whether the final certification statement listed in subsection 5 (3) of Schedule C, which is regarding potential for off-site migration, is included).

For a given COC, the outcome from any off-site exceedance of the applicable full depth site condition standards resulting from the property will be determined by the Ministry District Office, which will prioritize any action that may be warranted on a specific property on a case by case basis.

### Discussion of Uncertainty

There are areas of uncertainty in both toxicity and exposure assessment. Minimum requirements for the discussion of uncertainty in risk characterization are provided in Table 1 of Schedule C of the Regulation and reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 4. Human Health Risk Assessment (HHRA) | (d) Risk Characterization | (vi) Discussion of Uncertainty | Having regard to the discussions of uncertainty under Heading (b) (Exposure Assessment) and Heading (c) (Toxicity Assessment), state how such uncertainty could affect the interpretation of risk in this report section and the need to manage such risks. |

Uncertainty of the overall risk assessment process should be quantified where appropriate and discussed explicitly, including the following:

* Description of the risks in terms of magnitudes and types of uncertainties involved,
* Interpretation of the significance on the overall assessment of risk, and
* Factoring of information on the uncertainty in risk estimates, be it overestimation or underestimation, into the risk management decision in designing a suitable risk reduction strategy.

Uncertainty related to the toxicity assessment includes the accuracy of the TRV considering available toxicity data, the use of uncertainty factors to account for route to route and species to species extrapolation and the use of relative absorption factors to account for bioavailability. The combined effect of uncertainty on the conservatism of the TRV should be discussed in terms of the identification of significant risks.

Uncertainty related to the exposure assessment includes the accuracy of predicted contaminant concentrations in environmental media based on the availability of measured, site-specific data, fate and transport modelling and the ability to predict human exposure to the contaminated media. The combined effect of uncertainty on the exposure estimate should be discussed in terms of the possibility of a significant risk to go undetected and whether the risk should be managed in the absence of reliable data.

# Ecological Risk Assessment

## Levels of Assessment

The basic structure for conducting Ecological Risk Assessments (ERAs) under the Regulation is founded upon the CCME’s ecological risk assessment framework. For detailed descriptions of the steps or components for the different levels of ERA, and for more detailed guidance on conducting ERAs, the QPRA is referred to the CCME document entitled “A Framework for Ecological Risk Assessment: General Guidance” (CCME, 1996), and to “A Framework for Ecological Risk Assessment: Technical Appendices” (CCME, 1997). It should be noted that ERA “triggers”, which are listed on page 3 of CCME (1996), are good indicators of when a site should be considered “sensitive”. These “triggers” justify the use of a risk assessment approach rather than the use of site condition standards. However, once a risk assessment approach has been selected under the Regulation, these triggers cannot be used to justify the requirement or absence of an ERA. The CCME document “Ecological Risk Assessment Guidance Document” (CCME, 2020) provides additional guidance not included in the original CCME Framework documents, including discussion of a weight of evidence approach.

Persons conducting ERAs should be familiar with the CCME ERA procedures and documents above, as well as other more recent documents that may be of assistance in conducting ERA such as those listed in the bibliography in Section 11 of this Procedures document.

The Ministry recognizes three levels of investigation of potential ecological risk, as follows:

1. A Screening Level Ecological Risk Assessment (SL-ERA) is a primarily qualitative assessment of the potential environmental risk to specific ecological receptors that have been determined to be of major importance, i.e. valued ecosystem components (VECs). A SL-ERA is based primarily on data from literature reviews and from previous or preliminary studies at the property. It should provide sufficient information to determine whether or not remediation is required to protect ecological receptors, or it may provide a basis for determining what additional level of ERA is required and for focusing more detailed investigations of potential effects. If the SL-ERA concludes that remediation is not required, the QPRA must propose a property specific standard based on the outcome of the SL-ERA such as the maximum concentration of the COC at the RA property.
2. A Preliminary Quantitative Ecological Risk Assessment (PQ-ERA) uses a combination of literature information and property specific data which may be collected specifically for ERA purposes, to determine preliminary quantitative risk estimates for specified VECs exposed to the COCs. A PQ-ERA is focused on filling significant data gaps identified at the screening level. Methods used for a PQ-ERA are more complex than for a SL-ERA and are directed at producing quantitative assessments of risks.

At this level of assessment, bioassays and/or biological field studies can be useful tools for assessing the toxicity of the contaminants present at the RA property. In the large majority of cases where this level of assessment is used, it should produce sufficient information upon which property specific standards can be proposed for use at the RA property. In a few cases, data gaps or uncertainty may be of sufficient concern to warrant further detailed investigations.

1. A Detailed Quantitative Ecological Risk Assessment (DQ-ERA) uses more extensive and complicated field assessments, biological field studies and modelling of contaminant movement, exposure pathways, ecosystem characterization and assessment of toxicity to attempt to fill significant data gaps and uncertainties already identified, and to quantitatively assess risks. Bioassays or field surveys are likely to be important tools in assessing toxicity at this level of assessment.

An ERA should begin with an SL-ERA and may progress through the more detailed levels of assessment if property characteristics so warrant. The QPRA and risk assessment team should do the following:

* Determine whether the site is considered “environmentally sensitive” (according to section 41 of the Regulation), shallow soil and/or located within 30 metres of a water body (according to section 43.1 of the Regulation),
* Determine which level of assessment is appropriate for the RA property,
* Include at least one of the three levels of assessment in the ERA for each COC and justify the choice in the RA report, and
* Provide and justify a property specific standard for each COC for the VEC determined through the risk assessment process to be most at risk due to the presence of the COC.

The ERA process described above should be followed for all risk assessments which are submitted under the Regulation. Further details regarding the requirements of an ERA under the Regulation are described below.

## Problem Formulation

The problem formulation component is a critical step in the ERA process and, when conducted properly, has the greatest potential for improving overall ERA quality in risk assessments. It includes a discussion of the nature of the problem and the desired outcome of the ERA. This is followed by a discussion of how the risk assessment will be conducted to provide protection to all valued ecological receptors based on the selected assessment endpoints (e.g. reproduction, growth, survival, etc.). This discussion will include an analysis of the measurement endpoints which will be used in achieving the level of protection identified via the selected assessment endpoints (e.g. 50%ile of NOECs, LC50, EC50, etc.). In many cases, measurement endpoints can be equated with soil, water and/or sediment concentrations. If this is the case, the measurement endpoints will guide the development of the sampling and analysis plan. The Ministry’s Rationale Document (MOE, 2011) provides additional discussion relating to the assessment and measurement endpoints used in the derivation of the terrestrial and aquatic generic component values.

Principal products of the problem formulation step include a description of the conceptual site model as it relates to all VECs and identification of the ERA objectives based on that model and on the discussion referred to above.

Minimum requirements for reporting the Problem Formulation are provided in Table 1 Schedule C of the Regulation, and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 5. Ecological Risk Assessment (ERA) | (a) Problem Formulation | (i) Ecological Conceptual Site Model | Provide an ecological conceptual site model that,  (a) satisfies the requirements of clauses 3 (8) (b) and (c) and is consistent with the information upon which the diagrams referred to in that clause are based;  (b) explains how the information provided under Report Section 3 (Property Information, Site Plan and Geological Interpretation) was incorporated into and is consistent with the ecological conceptual site model; and  (c) was relied upon in the preparation of the risk assessment. |
| 5. Ecological Risk Assessment (ERA) | (a) Problem Formulation | (ii) Risk Assessment Objectives | 1. State the objectives of the ecological risk assessment and include an indication of,  (a) the proposed use of the RA property;  (b) which ecological receptors on the RA property are considered to be valued ecosystem components, the degree to which they must be protected and a justification to support such decisions;  (c) the exposure pathways to be assessed in the ecological risk assessment;  (d) whether a qualitative or quantitative assessment of risk or both will be used in the ecological risk assessment;  (e) the type of approach used for the ecological risk assessment.  2. Demonstrate that the data used for the ecological risk assessment are sufficient to meet the objectives of the assessment, having regard to,  (a) the data quality objectives specified in the reports on the sampling program summarized in the appendices to the risk assessment report; and  (b) any other relevant information that the qualified person has gathered or obtained in conducting the assessment.  3. State how any uncertainty resulting from variable data, poor data quality or gaps in data in relation to the RA property affected,  (a) the setting of objectives for the ecological risk assessment; and  (b) the ability to meet those objectives. |

Additional guidance is provided in the following sections of this Procedures document.

### Ecological Conceptual Site Model

The ecological conceptual site model is a physical description of the potential contamination problem from an ecological risk perspective. The ecological conceptual site model must meet the requirements of the Regulation as described in:

* Clauses 3 (8)(b) and (c) of Schedule C
* Table 1 of Schedule C, Report Section 5. Ecological Risk Assessment

Potential receptor populations for the proposed property use must be identified along with all associated potential exposure routes and pathways. For each of the sources of COCs for the RA property, the QPRA must ensure that the conceptual site model identifies: 1) the release mechanisms and transport pathways and 2) all VECs located both on and off the RA property, as well as exposure points and routes of exposure.

The QPRA should consider receptors for the ERA including but not limited to terrestrial plants, terrestrial animals and soil dwelling organisms, aquatic species that could be affected through surface water or groundwater discharging to surface water and avian species that may be affected by contamination at the RA property. The CCME document “A Framework for Ecological Risk Assessment: General Guidance” (CCME 1996) provides the following guidance for identification of VECs:

“VECs are resources or environmental features that:

* Are important to human populations,
* Have economic and/or social significance,
* Have intrinsic ecological significance,
* Serve as a baseline from which the impacts of development can be evaluated, including changes in management or regulatory policies.”

For the purpose of the Regulation, potential receptors on and off site should be evaluated as VECs on the basis of importance or significance to future site users, including individual property owners. For example, the ability to provide a lawn or ornamental garden may be economically or socially significant to an individual property owner, regardless of whether or not it is significant at a regional or provincial level.

As noted above, ecological receptors may be described as a group rather than individual species where appropriate. For example, “garden vegetables” may be identified as a VEC group, rather than listing individual vegetables. It is appropriate, however, to list individual species as VECs where these species are the basis for designation of an environmentally sensitive area under section 41 of the Regulation.

The ecological conceptual site model must identify potential exposure pathways for those receptors based on physical/chemical characteristics of the COCs and geological characteristics of the site as identified in the subsurface transport component of the conceptual site model in Report Section 3.

The ecological conceptual site model must clearly distinguish between pathways which are naturally incomplete and those which may be rendered incomplete through risk management measures.

For each applicable receptor, the risk assessment team should identify all potential on-site and off-site exposure pathways (e.g. soil ingestion) based on the characteristics and anticipated activities of the VECs and the expected mobility of the COCs under the geological conditions present at the site. For each receptor and exposure pathway, the risk assessment team should indicate further if a man-made barrier or measure to interrupt this pathway is present or anticipated.

Any exposure pathways which can be anticipated based on chemical properties and site geology should be included in the risk assessment. Elimination of these pathways from assessment will require justification in the form of pathway-specific site assessment evidence. Pathways which can be anticipated but which will be mitigated by a barrier or other measure must be included for the assessment of risk level. The barrier or other measures can then be identified as risk management measures in the development of property specific standards.

### Risk Assessment Objectives

As is the case for HHRA, the QPRA must provide risk assessment objectives which describe the approach to studying the potential contamination problem (refer to Section 4.2 of this Procedures document) with reference to the ecological conceptual site model (Section 7.2.1) and demonstrate that data used in the ERA are sufficient to meet those objectives. It is important to state whether the risk assessment is a qualitative or quantitative assessment of risk and the type of approach used for the ERA.

Examples of ERA Objective Statements would be;

Example 1: “The objective of the ERA is to provide a qualitative demonstration that the Ministry component values used in the development of the Table 8 site condition standards are appropriate to protect ecological receptors at this site using a screening level approach. The site is located in an Environmentally Sensitive Area according to section 41 of Ontario Regulation 153/04 as it is located within an area of natural significance. The site also includes a water body. The proposed property use is residential and parkland, in an urban setting. The valued ecosystem component to be protected is a stream habitat within the property boundary.

On-site terrestrial habitat will be largely disturbed through paving and construction of underground parking facilities. The Ministry component values used in the development of the Table 8 site condition standards will be protective of urban lawns and gardens in potential green spaces.

The pathway of concern in this ERA is migration of contaminants to the stream through the groundwater pathway and exposure to benthic and aquatic organisms. Receptors to be assessed in the stream will include fish, aquatic plants and benthic organisms. Due to the presence of fish spawning habitat in the immediate vicinity of the site, the assessment endpoint for fish VECs will be reproduction success; whereas growth and survival will be the targeted assessment endpoints for both the aquatic vegetation and benthic VECs.”

Example 2: “The objective of the ERA is to provide a quantitative evaluation of risk of 1,3,5-trinitro-1,3,5-triazine (RDX), a chemical for which there is no site condition standards, and to propose an ecological risk-based Property Specific Standard using a New Science risk assessment approach. The proposed property use is for single family residential. There is no groundwater use on-site, drinking water is provided through a municipal water supply.

VECs and exposure pathways to be evaluated include:

* Soil uptake by ornamental plants and garden vegetable plants and direct soil contact exposure to soil invertebrates. VECs will include lawn grasses and earthworms;
* Direct contact with soil, soil ingestion and inhalation exposure to terrestrial animals. VECs will include small mammals and song birds that frequent residential neighbourhoods (i.e. grey squirrel, robin);
* Assessment of the inhalation exposure pathway will be qualitative due to lack of a suitable TRVs;
* Contamination of groundwater and surface water and migration of contaminants to off-site ecological receptors. VECs will include fish, aquatic plants and benthic organisms.

For each of the above VECs, the assessment endpoint will be survival and growth.”

### Discussion of Data Quality

As indicated in the table above, the Regulation requires that the QPRA demonstrate that the data used for the ERA and described in Section 3 of the RA report is sufficient to meet the objectives of the assessment. Data quality or availability may be insufficient for a quantitative assessment, for example, and a qualitative approach may be proposed. Examples of data quality problems which may impact on the risk assessment approach include;

* Detection limits above the Ministry generic site condition standards (selection of COC),
* Low analytical recovery,
* High relative standard deviation,
* Variable monitoring data, inconsistent year-to-year trend,
* Assumption for one or more pathway relies on old data, data based on an analytical method that does not comply with section 47 of the Regulation, insufficient monitoring or no supporting data.

Uncertainty in the data resulting from variable or poor data quality, as well as any data gaps should be discussed in terms of the risk assessment approach used to accommodate them. The QPRA should explicitly discuss the extent to which suspect data can and will be relied upon in the risk assessment.

## Receptor Characterization

Minimum requirements for reporting Receptor Characterization are provided in Table 1 of Schedule C of the Regulation, and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 5. Ecological Risk Assessment (ERA) | (b) Receptor Characterization | not applicable | Describe in detail the characteristics of every valued ecosystem component, both on and off the RA property, identified in the ecological conceptual site model. |

Additional guidance is provided in the following sections of this Procedures document.

Receptor characterization for ERA should discuss and characterize the ecological receptors of concern and the degree to which they must be protected.

The Receptor Characterization should, at a minimum, include the characteristics of all VECs that are associated with common urban (or rural) landscaping and green space as well as any endangered or threatened species that have been identified on or off the RA property. In the case of endangered or threatened species, the common and scientific names should be provided.

For example, even if a decision has been made by the property owner to develop the site in such a way that landscaping and green space are eliminated through paving or other construction, the risk to landscaping and green space must still first be assessed. The effect of paving or other construction can then be accounted for as a risk management measure. In this way, future property development decisions can be made without any restrictions and with an appreciation of the site’s ability to support landscaping and green space. If there is uncertainty related to the design of future development and how it may impact ecological receptors, this should be accounted for in the assessment and also documented under the heading Discussion of Uncertainty.

Receptor Characterization should identify the VECs, the effects against which it is desirable to protect the VECs (“assessment endpoints”) and the pathways specific to each VEC by which it may come into contact with contaminants. The Receptor Characterization process should document the following:

* The VECs (species or habitats) that the ERA should protect,
* The effects that the ERA should protect these species against (referred to as “assessment endpoints”),
* The measurements that can be used to assess the effects (referred to as “measurement endpoints”), and
* The characteristics of the VECs that influence their exposure to the potential contaminant.

If surrogate species are to be used in the study of the VECs, these should be clearly identified together with the VEC species they are to represent.

The QPRA should include the following considerations:

* The current use of the RA property, distance to the closest receptor and receptor activities and patterns (including but not limited to the proportion of time the potentially exposed populations spend in the area; variation due to seasonal changes; any property-specific population characteristics that might influence exposure; and what ecological habitats exist on-site);
* Future use of the RA property, use of the groundwater under future conditions, and potential for more or different habitat for ecological receptors (including, but not limited to, changes in the proportion of time the potentially exposed populations spend in the potentially contaminated area; population characteristics and ecological habitats);
* The receptor sub-populations of potential concern: any group with increased sensitivity, either due to, for example, the behaviour, activity pattern or health status of the sub-population or to the inherent toxicity of the COC; distance to specific VECs, including threatened or endangered species, at or near the property; and
* Uncertainty that exists in terms of characterization of complete exposure pathways and potential receptors (extent and quality of supporting site data, understanding of proposed land use and knowledge of uses and likely uses of adjacent or potentially impacted sites).

## Exposure Assessment

Exposure assessment is a detailed analysis of the potential for a receptor to be exposed to the COCs as described in the ecological conceptual site model (Section 7.2.1 of this Procedures document). Exposure Assessment for ERA must evaluate the potential exposure of the VECs to COCs. Qualitative or quantitative exposure assessment may be undertaken according to the risk assessment objectives as described in Sections 4.2 and 7.2.2 of this Procedures document. Methods of estimating exposure point concentrations (including but not limited to modelling of contaminant movement) should be compatible with those used for HHRA (i.e. the hydrogeological interpretation and method of calculation of exposure point concentration via transport modelling must be consistent for both ERA and HHRA).

Minimum requirements for the Exposure Assessment component of the ERA are provided in Table 1 of Schedule C of the Regulation, and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 5. Ecological Risk Assessment (ERA) | (c) Exposure Assessment | (i) Pathway Analysis | Describe in detail every exposure pathway identified in the ecological conceptual site model. Justify which exposure pathways are incomplete. |
| 5. Ecological Risk Assessment (ERA) | (c) Exposure Assessment | (ii) Exposure Estimates | For every complete exposure pathway, state,  (a) the relative frequency and duration of actual or potential exposures;  (b) the relative magnitude of exposure to the valued ecosystem components, using measured contaminant exposure concentrations or concentrations predicted through fate and transport modelling in a manner compatible with that used in the human health risk assessment; and  (c) given the uncertainty described under the heading of “Problem Formulation”, how does this uncertainty affect the outcomes of the exposure assessments conducted under clauses (a) and (b). |

Further guidance is provided in the following sections of this Procedures document.

### Pathway Analysis

In the RA report, the pathway analysis must identify the exposure routes and pathways considered potentially complete or complete without risk management measures. Any exposure pathways which can be anticipated based on chemical properties and site geology should be included in the exposure assessment. Elimination of these pathways from assessment will require justification in the form of pathway-specific site assessment evidence. Pathways which can be anticipated but which will be mitigated by a barrier or other measure must first be included for the assessment of risk level. The barrier or other measure can then be identified as risk management measures in the development of property specific standards. The analysis should address the exposure pathways of concern, including exposures via all potential media, and considering the current and/or future condition of the RA property without risk mitigation measures, including the following:

* Exposure pathways of concern according to the ecological conceptual site model (Section 7.2.1 of this Procedures document);
* The sources for all potential releases (past, present and future);
* The potential receiving media (air, surface water, groundwater, soil, sediment, biota), and
* Evaluation of the physical and chemical fate and transport properties of the COC to identify the media that are receiving or may receive the COC;
* The exposure points (i.e. where the potentially exposed population can come into contact with the COC);
* The exposure routes, which could include but may not be limited to ingestion of soil/water and/or food, inhalation of vapour, inhalation of soil particles and dust, dermal contact with soil/water and other routes that may be associated with the contaminated media.

The following points should be considered when evaluating exposure pathways.

* Discuss the environmental fate of the contaminants including possible degradation. When sufficient laboratory and field evidence indicates that a contaminant could be degraded/biodegraded (transformed/biotransformed) to a relatively more toxic and persistent intermediate/product, the future concentration of the potential degradation product/intermediate should be estimated from the present concentration of its precursors, if possible (e.g. the anaerobic biodegradation of chlorinated aliphatics in groundwater).
* Identify direct and indirect routes (via intermediate receptors such as food/prey) and pathways of exposure for each VEC.
* Taking into account the proposed property use, plans for construction and the fate and transport of the contaminant in the environment, identify and document relevant exposure scenarios and exposure route/pathways to on-site and off-site VECs.
* Justify the exclusion (if any) of receptors and exposure route/pathways associated with development of the component values for the full depth generic site condition standards (refer to the “Rationale for the Development of Generic Soil and Ground Water Standards for Use at Contaminated Sites in Ontario”, (2011 MOE).

### Exposure Estimates

The exposure assessment should document the COCs to be assessed for specific VECs and follow through with pathway analysis and quantification.

In many cases, quantification of exposure estimates will be required to meet the risk assessment objectives. Quantification of the exposure to the receptors refers to the calculation of intake or uptake rates or delivered target dose for each exposure pathway/route and the total aggregate exposure if relevant. Quantification of the contaminant intake and uptake should be done for each potentially complete exposure pathway. Quantification should include the following information:

* Exposure concentration that is contacted over the exposure period at the external exposure point for each pathway,
* Contact rate (amount of contaminated medium contacted per unit time or event) and/or absorption rate, and
* Total time of exposure (estimated from exposure frequency and duration).

Reasonable maximum as well as average estimates of exposure or distribution for relevant populations should be developed based on both current and future property use assumptions, and measured concentrations on, in or under the property.

Care should be taken if COC concentrations are characterized with an estimate of the average of the data (e.g. using the 95% upper confidence limit (UCL) of the mean concentration). The range of the VECs being considered, the area of the site that might be considered foraging habitat and the relative size of the RA property in relation to a VECs home range all need to be considered. The use of a one sided 95% UCL for the mean is not considered appropriate for vegetation or soil organisms which are essentially immobile and may not be appropriate for smaller animals with limited home ranges. Rather, consideration should be given on a sample location-by-location basis to the areas of the site which exceed a given TRV or risk-based concentration (e.g. spatial distribution of exceedances). It is acknowledged that a risk assessment for plants and soil organisms is not meant to protect receptors at the individual level, except in the cases of rare or endangered species or where the individual species is of importance to the owner. The ecological significance of the spatial distribution of exceedances of a TRV or risk-based concentration therefore should be evaluated. It should be noted that any methods chosen for use in the development of property specific standards should be determined by the quality and quantity of data available. If using a 95% UCL of the mean (or any other estimate of the mean or maximum concentration), the software used to derive the value must be clearly identified (e.g. US EPA’s ProUCL) and all inputs (e.g. environmental data) and outputs must be provided in an appendix of the risk assessment, for Ministry review.

Fate and transport models are frequently used to predict the likely current extent of contamination as well as to assess the behaviour of contaminants under potential future scenarios. Such modelling can be useful to direct sampling programs and draw conclusions regarding the potential for off-site migration of contaminants. When a fate/transport model is utilized in the risk assessment to predict contaminant concentrations in soil or groundwater, the predicted concentrations should be verified through field sampling wherever possible.

Quantification may also include exposure from other sources/pathways/routes not specifically associated with the RA property, such as food ingestion, water supply and ambient air (i.e. typical background exposures), if sufficient information is available.

In conducting quantitative exposure assessment, the following should be considered;

* Document the exposure models, model assumptions and characteristics of the VECs, used for evaluation of exposures.
* Provide general equations and sample calculations for evaluating VEC exposure for the various pathways.
* Calculate exposures to the different VECs from various pathways identified for different contaminants.
* Consideration of background exposures other than exposure to on-site contamination (soil, air, water, etc.) should also be discussed with reference to the property specific exposure (this may be particularly relevant for VECs that only spend a fraction of time at the RA property). However, the off-site exposure conditions need to be supported with analytical data of COC concentrations from within the off-site portion of the VEC’s home range – i.e. it is not acceptable to assume background soil or other medium concentrations in the estimation of exposure while not on the RA property.
* Analysis of the major sources of uncertainty and how they affect (quantitatively, if possible) the exposure estimates. Uncertainty in the pathway analysis, for example, should be discussed in terms of the dependency of the exposure estimates on pathway assumptions that are unconfirmed or beyond the knowledge and control of the proponent.

If computer models (that are not in the public domain or that have not been used by the Ministry) or probabilistic models are used in the ERA, note that the risk assessment will be designated as a new science risk assessment and may require additional review time, as per the Regulation (refer to Section 9.3.2 of this Procedures document).

If computer models are utilized, ensure the models have been validated and/or are considered acceptable based on scientific principles. These computer models should also be available in the public domain. Use of proprietary models may be considered only when sufficient documentation of the modelling is provided. Such models (validated and/or accepted) should be accompanied by available technical support documentation of basic principles, user instructions, etc. The documentation should include all mathematical expressions and assumptions used in the model(s).

If proprietary models and any supporting documentation are considered confidential, such material should be clearly marked confidential. In either case, review of an RA report will be facilitated by provision of any computer software being utilized for the exposure calculations. The Ministry will require evidence that such software models are provided in a manner that will not infringe any third person’s copyright. The rationale for the suitability of any chosen model to the problems posed by a property should also be documented.

When conducting probabilistic modelling, statistical distributions developed from site-specific data or obtained from published peer reviewed scientific literature applicable to the site in question should be used for parameters associated with receptor characteristics (refer to Section 9.3.3 of this Procedures document). The statistical distribution used in probabilistic modelling may require additional Ministry review.

## Hazard Assessment

The section in the RA report pertaining to hazard assessment should provide documentation relating to the nature of toxicity and dose response for each COC as they apply to VECs (exposed individuals or populations) including:

* The potential adverse effects on the VECs associated with exposure to the specific contaminants, and
* The relationships between the magnitude of exposure from relevant exposure pathways and the probability of occurrence of adverse effects on the receptors.

Minimum requirements for the Hazard Assessment component of the ERA are provided in Table 1 of Schedule C of the Regulation, and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 5. Ecological Risk Assessment (ERA) | (d) Hazard Assessment | not applicable | 1. State the potential adverse effects on the valued ecosystem components associated with their exposure to each contaminant of concern.  2. For each contaminant of concern,  (a) describe the relationship between the magnitude of exposure to the contaminant from each route of exposure and the probability of the occurrence of the adverse ecological effect identified in the hazard assessment;  (b) if the data permits, propose a toxicity reference value for each of the routes of exposure identified in clause (a); and  (c) analyze the sources of uncertainty in the data used to conduct the hazard assessment, including any gaps or variability in the data and state how such uncertainty could affect the assessment. |

The QPRA must identify the potential adverse effects (assessment endpoints) selected for each chosen VEC (e.g. mortality, growth, reproduction).

Ministry ecological TRVs that were used in the development of the generic site condition standards are published in the “Rationale for the Development of Generic Soil and Ground Water Standards for Use at Contaminated Sites in Ontario” (2011 MOE) and the most up-to-date Ministry ecological component values are included in the Ministry’s approved model (and updated from time to time). These values should be considered by the QPRA when selecting screening values and TRVs for use in an ERA. Note that there may be more recent (and relevant) values published by other credible agencies, and these should also be considered during the TRV selection process. A search of the most recent toxicity data should have been conducted within two years prior to submission of the RA report. For those contaminants for which the Ministry has not developed any TRVs, values published by other credible regulatory agencies may be used if it can be demonstrated that the TRV/media concentration benchmark was developed in a manner consistent with the Ministry’s development of the TRVs used in the generic site condition standards development process and will provide the level of protection considered appropriate for the site based on the VECs and the assessment and measurement endpoints established in the Problem Formulation stage.

Toxicity values published by the CCME in Canadian Soil Quality Guidelines supporting documents (publications specific for individual contaminants) and toxicity values published by the US EPA for Ecological Soil Screening Levels are generally considered acceptable to the Ministry with limited review. Toxicity values from other sources for contaminants without Ministry site condition standards may require additional Ministry review time. Note that in some cases, when risk assessing a contaminant for which there is no applicable site condition standard, the risk assessment may be considered as a new science risk assessment as per the Regulation, refer to Section 9.3.1 of this Procedures document for additional details.

Credible agencies are those which have incorporated the following in developing TRVs:

* A rigorous peer review mechanism by credible experts/multiple regulatory bodies/jurisdictions and/or academia,
* Ongoing review and updating of values on the basis of new studies or advances in science, and,
* Published and/or publicly available TRV values, together with the basis for the value selection.

Examples of credible agencies include but are not limited to CCME, US EPA, Oak Ridge National Laboratory. If the data from a credible agency is utilized, the data should be accompanied by:

* A discussion of the rationale used by the agency in the choice of data and the critical study,
* A description of how the considerations of the agency are applicable to the receptors and site conditions of the RA property (e.g. dose-response model, uncertainty factors, etc.),
* Documentation of the description and evaluation of the toxicity assessment and provision of a rationale for adopting that particular toxicity assessment.

The Ministry also supports the development of new ecological TRVs based on the best available science. TRVs should be developed using the following process:

* A search of toxicological databases for toxicological literature pertaining to the given chemical parameter and VECs of interest;
* A review of the quality of the studies and their applicability to the RA property;
* Selection of a LOEL, from existing dose-response data;
* Selection of a NOAEL for threatened or endangered species.

In selecting toxicity data from which a TRV is derived, preference will be given to:

* Toxicity data derived from the species which are closely related to each VEC (e.g. laboratory mouse data for small mammals, quail data for grouse);
* Feeding studies using multiple exposure levels (not single dose, or gavage, or injection studies);
* Chronic exposure studies, particularly if duration is over several months, and/or over sensitive life stages (e.g. during reproduction);
* Studies which evaluate a reproductive endpoint (e.g. number of live births, number of eggs hatched) – these data are preferred as these assessment endpoints most closely relate to wildlife success. In cases where there are differences in the most protective versus the preferred toxicity data, there needs to be some discussion of how the decision was made – i.e. a weighing of the evidence discussion to support the selected values.
* Secondary preference will be given to survival and growth data.
* The Ministry does not recommend that allometric dose scaling be used for chronic effects data.

For the levels of ERA other than the SL-ERA, bioassays or field surveys may become important tools for hazard assessment. If bioassays or field surveys are conducted, they should:

* Be chosen to include species and endpoints that are relevant to the property being assessed and that are known or thought to be sensitive to the potential contaminants, and
* Include generally accepted standardized procedures and species.

A lack of sufficient relevant toxicity data should lead to the following conclusions:

1. The present status of scientific knowledge does not allow for the quantitative evaluation of ecological risk, and
2. No property specific ecologically based standard can be established.

Recommendations can be made that, for the protection of the natural environment and in the absence of adequate knowledge of ecological risk, exposure to environmental receptors be reduced as much as possible and property specific standards be based on other factors (e.g. the full depth background site condition standards in Table 1 of the Soil, Ground Water and Sediment Standards). When no site condition standard exists for a given chemical parameter, the property owner may choose to adopt a background-based or effects-based soil or groundwater value from another credible regulatory agency. Under the Regulation, adopting a standard or guideline for environmental media (soil, groundwater, sediment) from another jurisdiction, if there is no Ministry site condition standard, is considered a new science risk assessment.

## Risk Characterization

The section in the RA report relating to ecological risk characterization should document the following:

* An estimate of the degree of risk that is present from specified contaminants to the VECs present, or which will be present, at a property.
* A property specific standard that results in the same level of protection to the environment as intended by the generic site condition standards.

Measured and predicted contaminant concentrations are compared with toxicity information to determine the potential for adverse effects. Minimum requirements for the Risk Characterization component of the ERA are provided in Table 1 Schedule C of the Regulation, and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 5. Ecological Risk Assessment (ERA) | (e) Risk Characterization | (i) Interpretation of Ecological Risks | For each contaminant of concern, having regard to the exposure assessment and the hazard assessment, state the risk attributable in respect of that contaminant to each exposure route for the valued ecological components on the RA property, using either a quantitative or qualitative analysis. |

Additional guidance is provided in the following sections of this Procedures document.

### Quantitative Interpretation of Ecological Risk

When a quantitative assessment of risk is the objective of the ERA, the minimum requirements, as specified in Table 1 of Schedule C of the Regulation (reproduced below), are to be included in the RA report. Additional guidance on meeting these requirements is provided in the following sections.

If a quantitative analysis of toxicity and/or exposure assessment has been undertaken, contaminant-specific toxicity information must be compared against measured contaminant exposure levels and levels predicted through fate and transport modelling from which risk values can be derived.

A comparison of the TRV identified through hazard assessment (as described in Section 7.5) with the exposure estimate (Section 7.4 of this Procedures document) provides a “forward driven” science-based estimation of risk. The Regulation requires this risk estimation or calculation to be performed and reported without consideration of risk management.

As a second step, a proposed property specific standard may be back-calculated, using the same exposure equations, to propose a risk-based concentration, for which risk management measures are not needed (e.g. cleanup value). Alternatively, risk management measures may be proposed which modify the exposure equations, resulting in a reduced (acceptable) estimate of risk.

Care should be taken in using back-calculations to estimate proposed property specific standards, as these calculations do not necessarily account for physical/chemical limitations such as the formation of pure chemical compound. A contaminant concentration which has been determined to result in an acceptable level of risk to the environment may be proposed as an ecological effects-based standard for a property. However, the Ministry also expects the proposed standard to reasonably represent no more than an upper estimate of the actual concentrations remaining on, in or under the property at the time the standards are to submit an RSC for filing.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 5. Ecological Risk Assessment (ERA) | (e) Risk Characterization | (ii) Quantitative Interpretation of Ecological Risks | A quantitative analysis that has been undertaken for a contaminant of concern must include the following:  i. For each valued ecosystem component, provide a comparison of the toxicity reference value proposed in the “Hazard Assessment” to the exposure estimate proposed in the “Exposure Assessment” to derive an estimate of the degree of risk at the RA property in the absence of any measures that have been taken or are being proposed at the RA property which have the effect of reducing the risk from the contaminant of concern.  ii. Provide narrative to describe all magnitudes, comparisons and limitations relied upon to derive the risk under paragraph i.  iii. Taking into consideration any risk management measures being proposed in the risk assessment, propose and justify an ecological standard for the contaminant, ensuring that the standard achieves the same level of protection for each valued ecosystem component that is intended to be achieved by the applicable full-depth generic site condition standard for that contaminant. |

### Qualitative Interpretation of Ecological Risk

The QPRA may make use of both quantitative and qualitative options in assessing risk. A qualitative assessment of risk relies primarily on a descriptive justification for the use of information not specific to the site. In a qualitative analysis, the QPRA should explain why a qualitative approach was used and justify why a quantitative analysis was not appropriate or not required for a given VEC. The QPRA must also indicate the process to be used in the qualitative analysis; for example, a non-numeric (descriptive) characterization of risk or a conservative numeric assessment of exposure or toxicity for screening purposes and risk prioritization. Qualitative risk assessment must also address any risk management measures that are being proposed for the property, and justify a property-specific ecological effects-based standard for the contaminant.

The minimum requirements for reporting a qualitative characterization of risk are reproduced below from Table 1 of Schedule C of the Regulation.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 5. Ecological Risk Assessment (ERA) | (e) Risk Characterization | (iii) Qualitative Interpretation of Ecological Risks | A qualitative analysis that has been undertaken for a contaminant of concern must include the following:  i. Provide a justification for why a quantitative analysis was not undertaken.  ii. Describe the justification process being used as part of the qualitative analysis. The justification process includes a non-numeric characterization of risk and may include a numeric assessment of exposure or toxicity for screening purposes and risk prioritization.  iii. Taking into consideration any risk management measures being proposed for the RA property, propose and justify an ecological standard for the contaminant, ensuring that the standard achieves the same level of protection for each valued ecosystem component that is intended to be achieved by the applicable full-depth generic site condition standard for that contaminant. |

An example of a situation suitable for a qualitative interpretation of risk would include the following:

* Based on the results of the exposure assessment and the toxicity assessment, the ecological component values contained in Ministry’s approved model are protective of the ecological receptors at the site.

### Special Considerations

As indicated in the table below, the ecological standard being proposed for the RA property must be protective of the conditions that cause the property to be designated as environmentally sensitive, a shallow soil property and/or a property located within 30 metres of a water body.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 5. Ecological Risk Assessment (ERA) | (e) Risk Characterization | (iv) Special Considerations | If a RA property is,  (a) located within 30 metres of an “area of natural significance”, includes such an area, is adjacent to such an area or part of such an area, the justification for the ecological standard being proposed for the RA property must ensure that the standard is protective of the conditions that causes the area to be an area of natural significance; and  (b) subject to section 41 or 43.1 of the regulation, the justification for the ecological standard being proposed for the RA property must take into account the site conditions that make section 41 or 43.1 of the regulation apply to the RA property. |

The conditions that trigger these designations are described in section 41 and 43.1 of the Regulation:

* Section 41 of the Regulation (Site condition standards, environmentally sensitive areas)
* Section 43.1 of the Regulation (Site condition standards, shallow soil property or water body)

Whether a qualitative or quantitative assessment of risk is undertaken, any risk characterization considerations associated with the site being defined as an environmentally sensitive area, a shallow soil property and/or a property located within 30 metres of a water body must be highlighted in a separate section of the report. The expected impact of these conditions on the estimation of ecological risk for each VEC must be described.

For example, the reason for an environmentally sensitive area designation may be due to the presence of or proximity to specific ecological receptors, such as threatened or endangered species or ecosystems. If this is the case, this section of the RA report should reference how the specified ecological receptors are addressed if surrogate VECs were used and how the ecological standards proposed for the site are expected to be protective of those receptors.

### Interpretation of Off-Site Ecological Risks

Whether a qualitative or quantitative assessment of risk is undertaken, the QPRA must highlight in a separate section of the report any considerations associated with off-site ecological receptors. The QPRA must identify whether the proposed ecological standards, if applied to the RA property are likely to result in an exceedance of the applicable full depth generic site condition standards at the location of the nearest off-site ecological receptors.

The minimum requirements for interpretation of off-site ecological health risks are found in Table 1 of Schedule C of the Regulation and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 5. Ecological Risk Assessment (ERA) | (e) Risk Characterization | (v) Interpretation of Off-Site Ecological Risks | For each contaminant of concern, assess whether the ecological standard being proposed for the RA property is likely to result in a concentration greater than the applicable full depth site condition standard at the nearest ecological receptor located off the RA property and, if this is the case for any contaminant, specify the contaminant, the applicable site condition standard for that contaminant and the property where the ecological receptor is located and describe the ecological receptors that may be impacted. |

For each COC, the QPRA must assess whether the ecological standard being proposed for the RA property is likely to result in a concentration greater than the applicable full depth site condition standard at the nearest ecological receptor located off the RA property. If this is the case for any contaminant, the QPRA must specify the contaminant, the applicable site condition standard for that contaminant and the property where the ecological receptor is located and describe the ecological receptors that may be impacted. It is recommended that this information be provided in tabular format.

The information included in this sub-heading is expected to be consistent with the mandatory certifications made by the QPRA, (specifically, the final certification statement listed in subsection 5 (3) of Schedule C, regarding potential for off-site migration).

As is the case for HHRA, for a given COC, the outcome from any off-site exceedance of the applicable full depth site condition standards resulting from the property will be determined by the Ministry District Office, which will prioritize any action that may be warranted on a specific property on a case by case basis.

### Discussion of Uncertainty

There are areas of uncertainty in both hazard and exposure assessment. When conducting ERAs, it is often necessary to utilize results from dose-response studies using test species as surrogates for VECs selected for the RA property. Data in the literature may also be limited or incomplete such that it is necessary to extrapolate data for one endpoint to another (e.g. estimating a Lowest Observed Adverse Effects Level from LD50 data). These extrapolations add uncertainty to both the toxicity and exposure assessment.

Uncertainty related to the exposure assessment also includes the accuracy of predicted contaminant concentrations in environmental media based on the availability of measured, site-specific data and the ability to predict VEC exposure to the contaminated media. The combined effect of uncertainty on the conservatism of the TRV and the estimated exposure should be discussed in terms of the significance of identified risks, the possibility of a significant risk to go undetected and whether the risk should be managed in the absence of reliable data.

Uncertainty in the ERA process should be quantified where appropriate and discussed explicitly, including the following:

* Description of the risks in terms of magnitudes and types of uncertainties involved,
* Interpretation of the significance on the overall assessment of risk, and
* Factoring of information on the uncertainty in risk estimates, be it overestimation or underestimation, into the risk management decision in designing a suitable risk reduction strategy.

Minimum requirements for the discussion of uncertainty in risk characterization are provided below in Table 1 of Schedule C of the Regulation and reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 5. Ecological Risk Assessment (ERA) | (e) Risk Characterization | (vi) Discussion of Uncertainty | Having regard to the discussions of uncertainty under headings “Exposure Assessment” and “Hazard Assessment”, state how such uncertainty could affect the interpretation of risk advanced in this report section and the need to manage such risks. |

# Risk Management Plan

In the context of risk assessment conducted under Part XV.1 of the EPA, risk management refers to the development and implementation of one or more risk management measures which control or mitigate the level of risk to human health and the environment. The risk to be managed is that determined by other components of the risk assessment associated with contaminants proposed to be left on a property after an RSC has been submitted. Risk management involves the integration of the results from HHRA and ERA, including the uncertainty associated with those results, with information about technical resources, social/economic factors and control options in order to decide how to manage the redevelopment of the property. This management decision may also include other factors and community input in some cases.

The Regulation provides for the QPRA to make recommendations regarding the need for risk management to reduce ecological and/or human health risk to acceptable levels. Risk management measures may include mechanical measures or techniques for reducing exposure, or eliminating or blocking exposure pathways. Examples of such methods include, but are not limited to:

* Utilizing a layer of clean soil above otherwise unacceptably contaminated materials to reduce exposure (e.g. maintaining a stratified approach),
* The placement of hard caps, soft caps or any other surface barriers to reduce exposure to contaminants,
* The need for building(s) to incorporate vapour mitigation measures (e.g. passive/active sub-slab venting systems),
* The implementation of a Health and Safety Plan when undertaking specific activities (e.g. trenching),
* The need for fencing to prevent access to contaminated areas of an RA property, and
* The need for pump and treat equipment and/or groundwater containment barriers to reduce exposure or to prevent movement of contaminants.

Risk management measures also include administrative controls such as limitations on the use of the property that are outside of the normal restrictions for the type of property use to reduce exposure, eliminate or block exposure pathways due to contamination. Such limitations may need to be included in the CPU, and notice of the CPU may be registered on the title of the property through a certificate of requirement. Examples of limitations include, but are not limited to:

* Restrictions on the ability of the property to support plants or other forms of life that would be reasonably expected to occur on the type of property use involved,
* Restrictions on specific activities and/or uses (e.g. prohibit community gardening),
* Restrictions on the use of surface water or groundwater from the property that is more limiting than would normally be expected for that property use, and
* Restrictions on the types of building (e.g. prohibit basements).

Risk management may or may not be required if the property meets property specific standards. Risk management is required in those cases where the other components of the risk assessment identify that risk management measures are necessary to ensure that the recommended property specific standards result in an acceptable level of risk. When this is the case, the RA report must include a risk management plan which provides details about hydrogeological and engineering needs, as well as requirements for monitoring, maintenance, replacement and contingency.

Requirements of a Risk Management Plan are included in the following parts of the Regulation:

* Section 4 of Schedule C (Mandatory requirements of risk assessment reports)
* Table 1 of Schedule C (Report Section 7. Risk Management Plan)

In addition, the mandatory certifications set out in section 5 of Schedule C of the Regulation include statements regarding whether a risk management plan is needed.

Minimum requirements for a Risk Management Plan (Report Section 7) are provided in Table 1 of Schedule C of the Regulation, and are reproduced below.

| **Column 1 Report Section** | **Column 2 Heading** | **Column 3 Sub-Heading** | **Column 4 Minimum Requirements** |
| --- | --- | --- | --- |
| 7. Risk Management Plan (if applicable) | (a) Risk Management Plan | (i) Risk Management Performance Objectives | 1. State the exposure pathways and environmental media that risk management measures are intended to address.  2. State the required reduction in exposure concentration that the risk management measures are intended to achieve. |
| 7. Risk Management Plan (if applicable) | (a) Risk Management Plan | (ii) Risk Management Measures | 1. To achieve the specified performance objectives,  (a) propose risk management measures on the RA property that are designed to prevent, eliminate or ameliorate any adverse effects on or off the RA property;  (b) propose restrictions on the use of the RA property, including any restriction that applies to the construction of a building on the property; or  (c) propose a combination of measures specified in clauses (a) and (b).  2. State the implications of the risk management plan for off-site health and ecological receptors. |
| 7. Risk Management Plan (if applicable) | (a) Risk Management Plan | (iii) Duration of Risk Management Measures | Specify the duration the proposed risk management measures are required to remain in place to ensure the specified performance objectives are achieved. |
| 7. Risk Management Plan (if applicable) | (a) Risk Management Plan | (iv) Requirements for Monitoring and Maintenance | 1. Specify the designed lifespan of the measure, if applicable.  2. Propose a program for one or more of the following activities, if the program is necessary to achieve the specified risk management performance objectives:  i. A program which includes procedures for the ongoing maintenance, monitoring and replacement of the risk management measures to ensure they remain operable for the period identified in this report under the sub-heading “Duration of Risk Management Measures”.  ii. A program which includes procedures for the ongoing monitoring of contaminants of concern.  iii. A contingency plan for meeting the Risk Management Performance Objectives if the Risk Management Measures fail. |

The risk management component of a risk assessment must include, but may not be limited to the items discussed below.

## Risk Management Performance Objectives

Risk management may be necessary for some recommended property specific standards to result in an acceptable level of risk. A risk management measure must be maintained for some specified duration to ensure that the property specific standard continues to result in an acceptable level of risk. Performance objectives are measurable criteria against which the performance of the risk management measure can be evaluated to determine if the measure is meeting the required reduction in risk for the required duration of time. Where risk management is proposed, risk management performance objectives for each risk management measure must be clearly articulated within the RA report.

Performance objectives for risk management must include:

* The exposure pathway and target media that risk management measures must address, and
* The required reduction in exposure concentration that risk management measures must achieve.

The required reduction in exposure concentration should be determined based on an assessment of risk assuming no risk management measures. It should address the exposure pathways which contribute most significantly to unacceptable risk, or which can most efficiently be managed to reduce risk to an acceptable level. Identification of the reduction in exposure (e.g. expressed as a percent change or a target exposure route concentration or dose) is required for each managed pathway to achieve an acceptable level of exposure. Examples of risk management performance objectives include:

* Control of the vapour intrusion pathway to achieve a reduction in indoor air concentration from an estimated concentration of [specified] (determined without risk management) to an acceptable indoor air concentration of [specified].
* Control of the direct contact with soil pathway to achieve a reduction in surface soil / dust concentration from an estimated concentration of [specified] (determined without risk management) to an acceptable soil / dust concentration of [specified].
* Restriction of use of the property by refraining from [specified use or construction method] which would result in an estimated unacceptable dose of [specified] (determined without risk management) and thereby control the [specified] pathway and reduce exposure to [specified receptor].

The risk management objective should be stated in way which provides a criterion which is;

* Measurable through monitoring and record keeping,
* Suitable to trigger a specified contingency plan or other action, and
* Suitable for inclusion in a CPU, which is a control document that the Director may issue to the property owner.

## Risk Management Measures and Ongoing Monitoring

The design and implementation of risk management measures must also be described and submitted in the RA report in the form of a risk management plan. Where additional site assessment is required to support the design and operation of risk management measures, this assessment should be clearly identified and documented.

The risk management plan, if applicable, is a mandatory section of the RA report. In cases where the risk assessment recommends a risk management measure that involves engineering or hydrogeological controls, the risk assessment’s appendices must include an engineering or hydrogeological report (with detailed plans or specifications) prepared by a QP who has the qualifications set out in clause (a) or (b), as the case may be, of subsection 5 (2) of the Regulation. This requirement is included in the following part of the Regulation:

* Paragraph 7 of subsection 4 (6) of Schedule C

In addition to the above, if engineering controls are proposed as risk management measures, the risk management plan (including all detailed plans and specifications) must be provided as a separate stand-alone document, signed and sealed by the Professional Engineer responsible for its preparation and included as an appendix to the RA report. The risk management plan must include:

* Risk Management Measures to be implemented following achievement of the property specific standard;
* Design and procedures for ongoing maintenance, monitoring and replacement of the risk management measures;
* A contingency plan; and
* Risk management responsibilities and obligations.

Where property characterization has identified the potential for movement of contaminants from the RA property to off-site receptors, the anticipated impact of the risk management plan on those off-site receptors must be described.

## Additional Guidance

If it has been demonstrated that contaminants on, in or under some portion of the property do not require risk management, or requires a different risk management strategy, it may be possible to pursue one of the following approaches:

* Risk management measures may be limited, through a CPU, to parts of the property that require such measures. These parts of the property would need to be clearly indicated on the plan of survey and be consistent with the delineation information included in the phase two conceptual site model.
* The RA report may propose more than one set of property specific standards to support submitting more than one RSC for filing. This will require a clear delineation in the risk assessment, including the identification of the different RSC properties in the legal description and plan of survey. Refer to section 3.3.3 of this Procedures document for additional details regarding this approach.

Risk to all receptors (human and ecological) resulting from each concentration proposed as a standard, on and off site and in the absence of risk management, therefore must be explicitly identified in the RA report in order to justify the extent of the proposed risk management measures. However, further consultation with the Ministry’s local District Office is recommended if considering one of these approaches, as appropriateness of these approaches will depend on the circumstances of each case.

## Financial Assurance

In some cases, the Ministry may require financial assurance (FA) to be provided to the Ministry to ensure that specific risk management measures described in the CPU are implemented and remain in place for their required duration, in the event that the property owner is no longer able to do so. Additional details regarding FA are available in the following Ministry document “Guideline F-15: Financial Assurance Guideline”, PIBS 0226e04. Further consultation with the Ministry’s local District Office is recommended, as the need for FA will depend on the circumstances of each case.

## Certificate of Property Use

If a risk assessment has been accepted, the Director may issue a control document known as a CPU to the owner of the property. The risk management plan, and the level of risk controlled by risk management measures as set out in the risk assessment, are reflected in the content of the CPU. A CPU is a prescribed instrument under the *Environmental Bill of Rights, 1993* (EBR) and as such a proposal for the CPU must be posted on the ERO for public comment (except for a CPU in respect of an MGRA, which is not a prescribed instrument and is therefore not required to be posted). Under the EBR, the Director is required to take every reasonable step to ensure that all comments relevant to the proposed CPU that are received as part of the public participation process are considered when deciding whether to issue the CPU.

Registration of a Certificate of Requirement on title to the property under subsection 197 (2) of the EPA may be required, in order to ensure that those acquiring an interest in the property are provided with a copy of the CPU and are thereby made aware of property restrictions or requirements.

Once the CPU has been issued, the Director may alter or impose new conditions in a CPU or revoke the CPU. Finally, note that a copy of the CPU must be provided when submitting the RSC for filing and will be included with the RSC once filed to the Environmental Site Registry.

# Alternative Risk Assessment Procedures

The Ministry recognizes that the way in which the mandatory requirements of the risk assessment procedures described in this Procedures document are met may vary according to the situation for the development of a property specific standard. Certain approaches based on variations to the standard Tier 3 risk assessment approach have been identified by the Ministry which would result in a risk assessment of less or greater complexity and either a shorter or longer time requirement for review. All regulatory requirements must be followed when conducting every risk assessment. However, certain risk assessment procedures may be modified to result in an alternative timeline as set out in the Regulation.

Alternative risk assessment procedures are described in the Regulation:

* Sections 6 to 10 of Schedule C (Alternative risk assessment procedures)

Where combinations of alternative approaches are used in a risk assessment, the timeline for review will be determined by the approach requiring the longest timeline.

In general terms, the Ministry’s risk assessment program identifies two main risk assessment approaches: Tier 2 and Tier 3. Tier 2 risk assessment refers to the MGRA, which is a type of limited scope risk assessment defined under the Regulation. Tier 3 risk assessment includes the standard approach, wider area of abatement and new science risk assessments. Other types of risk assessment include limited scope risk assessment based on a community assessment report and estimation of natural background concentration.

Further guidance on the use of alternative risk assessment approaches is provided below.

## Limited Scope Risk Assessment

Conditions which must be met for conducting a limited scope risk assessment are provided in the following section of the Regulation:

* Section 7 of Schedule C

The Ministry review timeline for limited scope risk assessments is 8 weeks. There are two types of limited scope risk assessment approaches that may be used:

1. Modified generic risk assessment (i.e. Tier 2 risk assessment), and
2. Risk assessment based on a community assessment report

Additional guidance for each type of limited scope risk assessment approach is provided below.

### Modified Generic Risk Assessment

The first type of limited scope risk assessment is a modified generic risk assessment (MGRA, also known as Tier 2 risk assessment). MGRA allows for the development of property specific standards using only the Ministry’s approved model. The approved model uses the same risk assessment approach (including modelling and exposure assumptions) used by the Ministry in the development of the generic site condition standards, however the QPRA has the ability to modify some parameters to better reflect property specific conditions. The approved model also includes a limited set of predefined risk management measures.

Since the release of the approved model in 2011, uptake for this type of risk assessment has increased substantially and MGRA now represent an important part of the Ministry’s risk assessment program. Refer to the following parts of the Regulation regarding the MGRA:

* Section 1 of Schedule C (Definitions – “approved model”)
* Subsection 7 (3) of Schedule C

For MGRAs, the PSF must be submitted at the same time as the MGRA, refer to subsection 3 (1.1) of Schedule C of the Regulation. All other mandatory requirements of a PSF that are included in section 3 of Schedule C still apply.

MGRAs must use the Ministry’s reporting template (which is embedded within the approved model) and include a copy of the approved model with their submission. Note that there are some additional requirements specific to the MGRA report (see paragraph 4.1 of section 4 (6) of Schedule C). All other mandatory requirements of an RA report (included in section 4 of Schedule C) still apply, unless otherwise noted.

When changing a modifiable parameter in the approved model, the phase two ESA report must include proper justification, as required in the following:

* Table 1 of Schedule E (Mandatory Requirements for Phase Two Environmental Site Assessment Reports – Report Section 10; Heading d) Modified Generic Risk Assessment)
* Table 4 of Schedule E (Phase Two Environmental Site Assessment Requirements for Modified Generic Risk Assessments)

Further guidance on the preparation and submission of MGRAs (including a user guide, the most recent version of the approved model and limitations of MGRA) is available on the Ministry’s brownfields website.

Pre-consultation with the Ministry on a site’s suitability to proceed as an MGRA is strongly recommended. Consultation with the local Ministry District Office is especially important in cases where risk management measures such as “no installation of potable groundwater drinking wells” or pathway modifiers (that modifies the GW2 component values) are being considered. Ultimately, a site’s ability to proceed as an MGRA will be determined by the Ministry and some sites may be required to proceed as Tier 3 risk assessments.

### Risk Assessment Based on a Community Assessment Report

The second type of limited scope risk assessment is a risk assessment based on a community assessment report. Risk-based intervention values are sometimes developed outside of the Regulation through a risk assessment conducted by a responsible party for a predefined study area (typically with multiple properties and owners); however until 2011 individual property owner(s) located within the study area could not use these values directly to support RSC submissions. The Regulation was amended in July 2011 to allow for property owners located within the study area of a Community Assessment Report (CAR) to utilize an intervention value developed in the CAR, as part of a limited scope risk assessment. Refer to the following parts of the Regulation for additional details regarding a risk assessment based on a CAR:

* Section 1 of Schedule C (Definitions – “community assessment report”)
* Subsection 7 (2) of Schedule C

The purpose of a CAR is to facilitate the submission of RSCs for filing by the individual property owners within the CAR study area. The CAR can only be submitted as a result of a Ministry order or draft order. Once the CAR has been completed to the Ministry’s satisfaction, a property owner located within the CAR study area can then prepare a limited scope risk assessment for their own property which utilizes the intervention value(s) previously developed in the CAR.

Note that phase one and two ESAs (conducted in accordance with the Regulation) are still required for the limited scope RA property and any COCs identified in the phase two ESA that are not addressed in the CAR will need to be addressed via the applicable risk assessment approaches described in this Procedures document.

Procedures for conducting CARs are beyond the scope of this document; further guidance can be provided upon request. For additional information regarding CARs and limited scope risk assessments based on a CAR, the Ministry should be contacted directly.

Note that community based risk assessment (CBRA) is another term sometimes used by the Ministry, however, this is considered to be different from a CAR. CBRAs are generally prepared to address specific concerns of the Ministry, local Public Health Units and/or the public related to off-site contamination. The scope of CBRAs is typically more focused and is usually defined by the Ministry’s abatement objectives. CBRAs are not defined or conducted under the Regulation and cannot be directly used by individual property owners within the impacted area to support RSC submissions.

## Estimation of Natural Local Background Concentration Risk Assessment

Local background is defined as the ambient concentration of a contaminant in the soil, groundwater or sediment of the local environment that is representative or typical of the conditions in an urban or rural setting. Local background concentrations result from either chemicals that occur naturally in the environment or chemicals that are emitted by anthropogenic activities other than from activities being carried out on, in or under the property being assessed.

Conditions which the Regulation states must be met for the estimation of natural local background concentrations as an alternative risk assessment approach are provided in the Regulation:

* Section 8 of Schedule C

If the situation allows for the use of estimation of natural local background concentrations as a risk assessment approach, a property owner may propose a natural local background concentration soil standard for a COC by undertaking a soil sampling and analysis program in accordance with subsections 8 (4) to (8) of Schedule C of the Regulation.

The sampling program, as described the Regulation, is intended to collect information from at least 10 different geographical locations that have not been affected by local point sources of air or land pollution, by local roads or highways, or by other known sources of contamination. These locations may be in rural (agricultural property use) or urban (all other property uses) settings in Ontario. Suitable sites may include parks, cemeteries, forests, wood lots or large undeveloped tracks of land.

A sampling location is defined in the Regulation to mean an area of the property that does not have a radius larger than two metres:

* Section 48 of the Regulation (Meeting standards)

This is an area within which multiple samples may be collected and composited to create a single sample representative of that sampling location. A minimum of 30 such sampling locations must be sampled, resulting in at least 30 separate samples for individual analysis. Sampling and analysis must be replicated in 1 out of 10 sample locations, therefore resulting in at least a further 3 samples from the same 30 sample locations.

Sampling data is then used to develop a property specific standard through a statistical calculation of the 90th percentile of the analytical results. If the analytical results show large variability that cannot be attributed to a contaminant source, increased replicate sampling (i.e. more than two replicate samples from 1 out of 10 sample locations), and averaging the analytical results from the replicate sampling may be used to establish the 90th percentile.

Provision is made in the Regulation (subsection 8 (5) of Schedule C) for areas of known, widespread soil contamination, where it is not possible to avoid the influence of historical, industrial emissions to soil surfaces. The sampling program may still be undertaken if it is designed to determine the change in COC concentration as it varies with increased depth from the surface. The use of this approach must be justified, for example on the basis of regional history and geology. A sampling program that establishes the variation in COC contamination from the surface soil to the subsurface soil may better reflect the soil conditions of the area. This may be used to establish remediation targets that are consistent with the change in COC concentrations with depth.

The Regulation also provides an alternative procedure for use if sufficient natural local background concentration data have already been collected as part of another program. This provision is included in subsection 8 (9) of Schedule C.

Existing geological summary data may be provided to the Ministry with the PSF for consideration by the Director for use in justifying property specific standards based on local background concentrations. The Ministry publication entitled “Ontario Typical Range of Chemical Parameters in Soil, Vegetation, Moss Bags and Snow”(MOE 1993) provides additional guidance on sampling and analysis procedures which property owners may use when developing property specific standards based on local soil background concentrations.

At the PSF stage, note that the requirements relating to human and ecological receptors and exposure pathways do not apply for this type of risk assessment. Provisions relating to a PSF where the risk assessment approach is identified as an estimation of natural local background concentration are included in the Regulation in:

* Subsection 3 (10) of Schedule C

In these cases, the site plan and cross sections of the property are intended to convey the rationale for attributing elevated concentrations to natural geological features and to support and describe any planned sampling program.

Note that phase one and two ESAs (conducted in accordance with the Regulation) are still required for the property for this type of RA; any COCs identified in the phase two ESA that are not addressed in the estimation of natural local background concentrations risk assessment will need to be addressed via the applicable risk assessment approaches described in this Procedures document.

The Ministry review timeline for estimation of natural local background concentration risk assessments is 8 weeks.

## New Science Risk Assessment

Situations may arise in which a QPRA decides to use risk assessment parameters, methods or models that have not previously been reviewed by the Ministry or do not fit within the current policy framework. These risk assessments may be considered as new science risk assessments under the Regulation and require additional time for review. The Ministry review timeline for new science risk assessments is 22 weeks. The Ministry will identify, through comment on the PSF, if the risk assessment will be considered a new science risk assessment.

A risk assessment is considered a new science risk assessment if it satisfies one or more conditions as set out in the Regulation:

* Section 9 of Schedule C

If the situation allows for the use of a new science risk assessment, then the following alternative procedures may be used in conducting that new science risk assessment. The following sections provide guidance for the three types of new science risk assessment approaches. These approaches may be used individually or in combination with other approaches.

### No Applicable Site Condition Standard for a COC

When a contaminant is identified during a phase two ESA for which there is no applicable generic site condition standard, it may be that there was insufficient toxicity data on which to base a site condition standard at the time of generic standards development. If such a contaminant is determined to be a COC during the phase two ESA, the Regulation requires that a property specific standard be developed for this COC:

* Subsections 43 (2) and (3) of the Regulation

In these circumstances, the Regulation allows for the development of property specific standards in the risk assessment using either a quantitative approach in the HHRA and ERA or by adopting a standard from another credible agency; the requirements are specified in the following parts of the Regulation:

* Subsections 9 (2) and (3) of Schedule C

If toxicity information (e.g. TRV) or a standard is adopted from another credible agency, the risk assessment should include an evaluation of how the basis for the value selection by that agency fits the specific requirements of the property under evaluation. This approach should only be considered when a quantitative assessment is not possible.

It remains the Ministry’s expectation that the risk assessment be based on the best available and most recent science. There may also be cases where the QPRA is not satisfied with using the Ministry’s most recent TRV selections for a given contaminant. For example, if the QPRA is aware that new toxicity data has been published and reviewed by credible agencies (and new human health TRVs published by these agencies), such information should be considered within the risk assessment and used, if appropriate. These cases will generally not result in the risk assessment being designated as a new science risk assessment.

However, if the QPRA uses toxicity data to develop a *de novo* TRV, the Ministry will consider the risk assessment a new science risk assessment.

Ministry comment on the approach to using new toxicity data and/or new TRVs can be obtained through identification of the approach in the PSF. For example, if the Ministry has already reviewed or considered the new TRVs, the risk assessment review may not require a 22 week timeline.

### Use of Proprietary Computer Models

Requirements for use of proprietary computer models as part of a new science risk assessment are specified in section 9 of Schedule C of the Regulation, specifically:

* Subsections 9 (4), (5) and (6) of Schedule C

The development of property specific standards often involves the use of commercially available contaminant/media transport as well as various types of exposure scenario models. These models are considered proprietary when they are not available free of charge in the public domain. Many of these computerized models and their underpinning algorithms and assumptions have undergone extensive testing and verification. Others have been developed as an outcome of limited research studies and have not been widely used or validated under a variety of property conditions.

The Regulation provides for the use of proprietary models in the development of property specific standards provided they are provided to the Ministry for review to determine applicability with the proposed conceptual site model. When providing comment on the PSF, the Ministry will identify if a proprietary model requires further review as part of a risk assessment. If the Ministry has already accepted the use of the proprietary model for the conditions specified in the conceptual site model, the Ministry response to the PSF may advise that the 22 week review timeline will not be required. Requirements for use of proprietary models in the development of property specific standards as part of a new science risk assessment are specified in section 9 of Schedule C of the Regulation.

The following information should be provided in the PSF and RA report to support the selection and use of proprietary models in risk assessments submitted for review:

* An accurate description of the model (i.e. the computational approach to solving a question, not the computer program within which the model is found) and the version of the model (including date of release), as well as a description of any changes to customize the application. The description does not have to be a lengthy, detailed discussion; however, it should provide a clear and concise summary of what the model does, how it functions (the mathematical expressions incorporated in the model) and what its limitations are (i.e. when it is and is not appropriate to use the model).
* A list of assumptions used in the development of the model and a discussion of the validity of the assumptions for the property (including the effect invalid assumptions will have on model results). This is an essential component in defining the sensitivity and uncertainty associated with the model.
* A description of all input parameters, including default parameters, together with the respective units of measure. If all the necessary units and references are provided, a list of parameters in tabular form will suffice.
* A sensitivity analysis which maintains the parameters at set values while each one of the parameters is individually varied to include at least the low range and high range of possible values for that parameter (i.e. one-at-a-time sensitivity analysis). The input values and the results for the sensitivity analysis of each parameter should be reported. For models with large numbers of inputs, a detailed sensitivity analysis may be impractical. In this case, the QPRA should provide an analysis of the various parameters that have been changed from default values, which includes a brief rationale relating these changes to conditions at or expected at the property, sensitivity of the model to these changes conducted as described above and the likely effect this will have in terms of uncertainty associated with the results and conclusions.
* For hydrogeological exposure pathways (e.g. soil/groundwater to indoor air), a validation of the model output should be provided, where possible, by using field results at the property, if the field data are representative of the property. Fate and transport models are frequently used to predict the likely current extent of contamination as well as to assess the behaviour of contaminants under potential future scenarios. When a fate/transport model is utilized in the risk assessment to predict contaminant concentrations in soil or groundwater, the predicted concentrations should be verified through field sampling wherever possible. For example, when modelling indoor air concentrations, field sampling of soil gas, sub-slab and indoor air may be warranted. It is recognized that there are factors that can contribute to indoor air quality that may not be related to COCs in the groundwater or soil.
* On request, provide the Ministry with information used to generate the proprietary model inputs, including but not limited to field measurements/parameters and clear references to assumptions. Some computer software use public domain models in a proprietary package or interface. If a copy is requested by the Ministry, such software must be provided to the Ministry in a manner which will not breach any person’s copyright or other intellectual property right.

If proprietary models and any supporting documentation are considered confidential, such material should be clearly marked as confidential.

### Use of Probabilistic Models

Requirements for use of probabilistic models as part of a new science risk assessment are specified in section 9 of Schedule C of the Regulation, specifically:

* Subsections 9 (7) and (8) of Schedule C

Probabilistic or stochastic analytical methods, such as Monte Carlo or Latin-Hypercube sampling, use probability density functions in the risk assessment and to support the development of property specific standards. These methods are useful in analyzing the variability and uncertainty in risk assessments, provided that the analysis is supported by adequate data and sufficient technical documentation.

The Regulation provides for the use of probabilistic methods in risk assessment. It requires, however, that probability density functions are applied only to the exposure assessment components of the risk assessment as specified in the Regulation. Additional review time may be required for the Ministry to determine if the use of the proposed probability density functions is appropriate in the context of the proposed conceptual site model. If the Ministry has already accepted the proposed probabilistic approach for the conditions specified in the conceptual site model, the use of this approach may not require a 22 week review timeline.

Probabilistic analysis may or may not support risk management decisions during a risk assessment with respect to the remediation of contaminated properties. The use of probabilistic methods may not reduce the uncertainty inherent in risk assessments. However, when properly conducted, the use of these methods can better illuminate the range of risk mitigation associated with various property management options.

In the conduct of human health risk assessments, application of the probabilistic method should be restricted to the exposure assessment, as the application of stochastic methods to the dose-response analysis is not considered acceptable practice at this time. A probabilistic approach should be sufficiently supported by data and should add value to the assessment.

## Wider Area of Abatement Risk Assessment

A risk assessment is considered a wider area of abatement risk assessment if the Ministry, upon review of the PSF (or at any time during the review of the risk assessment), identifies the RA property as being located within a wider area of abatement based on off-site regional information and considering the potential for additional responsible parties and multiple affected parties. Requirements specific to wider area of abatement risk assessments are specified in the Regulation:

* Section 10 of Schedule C
* Table 1 of Schedule C (Public Communication Plan)

These risk assessments may require additional time for the involvement of District staff in the risk assessment review and for adequate consultation with the community and other interested parties. For this reason, the Ministry review timeline for wider area of abatement risk assessments is 22 weeks.

The property owner is encouraged to consider public communication as early in the site assessment and redevelopment process as possible, regardless of whether the Ministry designates the risk assessment as part of a wider area of abatement. In many cases the interest of the local community beyond the immediate neighbours of the RA property is a factor the Director will consider in deciding whether to accept a risk assessment. The Ministry can require the development and implementation of a public communication plan as part of the risk assessment process through identification of the property within a wider area of abatement.

Ministry District staff will review the potential for a property to be located within a wider area of abatement at the time of PSF submission, based on the property location and any previous history of Ministry orders and involvement in the area, off-site regional information, other risk assessments undertaken in the area and any other information deemed to be relevant by the Ministry. Contamination issues that may potentially involve off-site receptors may require the involvement of a wider scope of stakeholders.

If additional issues are identified at the time of reviewing the RA report, the Director also has the ability to advise the property owner that the risk assessment is in a wider area of abatement risk assessment through a notice issued under subsection 46 (2) of the Regulation.

Planning for public communication is a benefit to the proponent as it may reduce the likelihood of delays in the redevelopment process. Public communication provides the proponent the opportunity to gain the support of key stakeholders by:

* Ensuring the affected stakeholders understand the process for site assessment, risk assessment, redevelopment and Ministry approval,
* Providing an opportunity for engagement of the public with clear rules and expectations for process and timing and,
* Addressing stakeholder concerns, if any, before plans are finalized.

Where multiple properties are affected, public communication may lead to negotiation of joint remediation activities at the RA property or in the area.

Where the Ministry has identified the property to be within a wider area of abatement, public communication required by the Regulation should be at a level and of a type determined in consultation with Ministry staff. Communication with District staff may begin before submission of the PSF and a proposed communication plan may be provided with the PSF for Ministry comment.

The wider area of abatement RA report must include documentation of the plan for communication with the Ministry and the public and the outcome of the communication plan as specified in the Regulation. This must include a copy of any written public input.

Additional guidance on public communication is provided in Section 2.5 in this Procedures document.

# Risk Assessment Submission and Review Process

## Summary of Risk Assessment Process

In general, a simplified version of the risk assessment process under the Regulation can be summarized as follows:

1. ESA phase one and phase two work is completed by QPESA;
2. PSF is completed by the QPRA and submitted to the Ministry. Note that for MGRAs, the PSF must be submitted to the Ministry at the same time as the MGRA report;
3. Ministry provides feedback/comments on the ESA work and PSF;
4. RA report is completed and submitted to the Ministry;
5. Ministry reviews and Director decides whether to accept (if all requirements have been met) or to request for additional information/resubmission of the risk assessment (if requirements have not been met). Note that the Ministry review process is iterative and that resubmission(s) of the risk assessment may be required before it can be accepted by the Director.

Once a risk assessment has been accepted by the Ministry, a CPU may be issued by the Director, if required (e.g. if risk management measures are required to support the property specific standards). Property specific standards can then be used to submit an RSC for filing.

If the risk assessment is accepted by the Director, and if remediation is required to meet the property specific standards set out in the RA report, the owner of the RA property would retain the QPESA to undertake the remediation and/or verification sampling. Remediation activities must be completed in a manner consistent with the requirements of the Regulation and fully documented in the phase two ESA (including the phase two conceptual site model).

If no further remediation is required, the phase two ESA (including the phase two conceptual site model), together with the property specific standards included in the accepted RA report would serve as the basis for completion of an RSC. The RSC may then be submitted to the Ministry for filing on the brownfields Environmental Site Registry.

Note that the property owner may abandon the risk assessment process and remediate the property to the applicable generic site condition standard, at any time in the risk assessment process. The owner may also choose not to remediate, provided they are not otherwise obligated to remediate, and abandon the RSC process altogether. In cases where the property owner elects to abandon the risk assessment, the Ministry should be advised of this decision.

The typical risk assessment submission and review process is summarized in Figure 10.1, included below. For additional details regarding the RSC filing process and conducting phase two ESAs, property owners and QPs are referred to the following guidance Ministry document: “Records of Site Condition - A Guide on Site Assessment, the Cleanup of Brownfield Sites and the Filing of Records of Site Condition”, dated xx 2020.

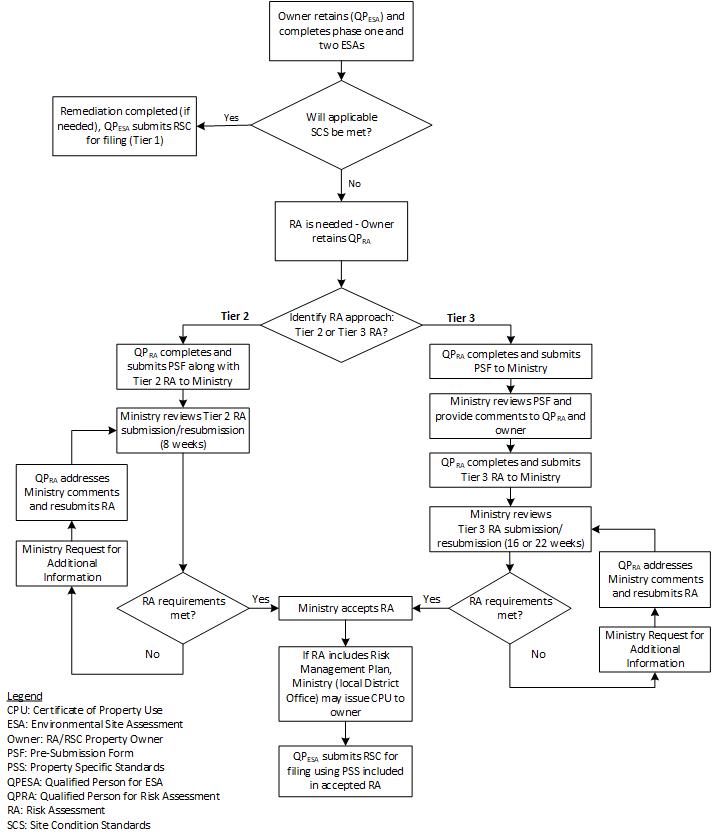


Figure 10.1 Typical Risk Assessment Submission and Review Process

## Ministry Review and Decision Making

Ministry requests for information or RA report revision during the risk assessment review process are discussed in further details below. Note that for Tier 3 risk assessments, the RA report can only be submitted once Ministry comments on the PSF have been provided to the property owner and QPRA.

### Notice of Circumstance

On receiving the completed RA report, the Ministry will review the risk assessment. The time prescribed by the Regulation for the risk assessment review will not begin until all the risk assessment components listed in the Regulation have been received by the Director (i.e. RA report is considered complete).

The Ministry will advise the QPRA and property owner as early as possible in the review process if either additional information or a full revision is needed before the Director makes a decision. The type of request (i.e. additional information or full revision) will have an impact on the time required for Ministry review. Provisions for the Ministry to request additional information and revisions to the RA report are set out in the Regulation:

* Section 46 of the Regulation (Time to respond to risk assessment)

At the Director’s discretion, proponents will have the opportunity to provide the requested information (addendum) within a certain time period or revise and resubmit the entire report. The Director will advise the QPRA and property owner of the request to provide additional information (addendum) or to revise and resubmit the report by way of a notice (i.e. Director’s Notice of Circumstance).

Alternatively, the property owner may choose to withdraw the submission at any time. Failure to respond to the Director’s notice to provide the requested revision (i.e. Director’s Notice of Circumstance) may prevent the risk assessment from being accepted by the Director.

### Decision to “Accept” or “Not Accept” the Risk Assessment

Under the EPA, if a property owner submits a risk assessment to the Director, the Director shall either give a notice in writing to the property owner that the Director “accepts” the risk assessment, or that the Director “does not accept” the risk assessment for the reasons specified in the notice:

* Section 168.5 of the EPA

Only property specific standards developed in a risk assessment that has been accepted by the Director can be used to support RSC filing. In cases where the Director’s decision is to “not accept” (i.e. reject) the risk assessment, the proponent may still choose to pursue the risk assessment option. However, in such cases, a new risk assessment, starting with a new PSF, will need to be provided to the Ministry.

## Additional Considerations

Other regulatory and compliance tools also may be required to address other aspects of redevelopment for many properties, including:

* Management of excess soil (e.g. under Ontario Regulation 406/19). Note that there are specific requirements for phase one and two ESAs relating to excess soil under the Regulation;
* Minister’s approval for reuse of a former waste disposal site,
* Potential for release of contaminants to the environment during remediation and construction,
* Remediation activities which require Environmental Compliance Approvals (ECAs), and
* Abatement and addressing off-site impacts.

# Resources and References for Risk Assessment

## Ministry Guidance and Resources

The following Ministry resources include useful information for risk assessment practitioners. Documents that are not available on the Ministry’s brownfields website can be provided upon request.

**Ministry’s Brownfields Website**

The Ministry’s [brownfields website](https://www.ontario.ca/page/brownfields-redevelopment) includes overview of the Regulation, link to the Environmental Site Registry, general brownfields guidance, guidance for the completion of phase one and two ESAs and Ministry guidance documents related to the development of generic site condition standards and risk assessment.

URL: https://www.ontario.ca/page/brownfields-redevelopment

**RSC Guide**

“Records of Site Condition - A Guide on Site Assessment, the Cleanup of Brownfield Sites and the Filing of Records of Site Condition” (MECP 2020).

Provides a general overview of the RSC process and includes a high level discussion of generic site condition standards and risk assessment under the Regulation. Available on the Ministry’s brownfields website.

**Rationale Document**

“Rationale for the Development of Soil and Ground Water Standards for Use at Contaminated Sites in Ontario” (MOE 2011).

Details the development of Ministry’s generic site condition standards, includes generic conceptual model, assumptions and models used.

**Approved Model**

Includes generic component values, assumptions and models. The approved model can be used to generate site-specific standards in a Tier 2 risk assessment and can also be used in a Tier 3 risk assessment (e.g. to generate site-specific component values). The approved model and supporting guidance documents are available on the Ministry’s brownfields website. Note that the approved model may be updated from time to time and only the most recent version may be used when preparing a risk assessment.

**MGRA User Guide**

“MGRA User Guide: A Guide to Using the “Approved Model” (November 2016) When Submitting a Modified Generic Risk Assessment (MGRA)” (MOECC 2016).

Provides guidance on the preparation and submission of MGRAs (including use of the approved model and limitations of MGRA).

**Vapour Intrusion Assessment Guidance**

“Technical Guidance: Soil Vapour Intrusion Assessment” (MECP 2020)

Provides technical guidance for assessing the vapour intrusion pathway at contaminated sites.

**Sediment Assessment Guidance**

“Guidelines for Identifying, Assessing and Managing Contaminated Sediments in Ontario” (MOE 2008).

Provides guidance for identifying, assessing and managing contaminated sediment.

**Ontario Typical Range - Background**

“Ontario Typical Range of Chemical Parameters in Soil, Vegetation, Moss Bags and Snow”(MOE 1993).

Includes Ontario Typical Range (OTR) data and provides additional guidance on sampling and analysis procedures used by the Ministry in the development of the OTR values.

**Environmental Registry**

The [Environmental Registry](https://ero.ontario.ca/) is a public registry under the *Environmental Bill of Rights, 1993*. CPUs for Tier 3 risk assessments are posted to the Environmental Registry in draft for public comment and in final version when issued to the property owner; registry listings are publicly viewable and searchable.

URL: https://ero.ontario.ca/

**Ministry Contacts – Local District Offices**

The Ministry’s [local District locator](https://www.ontario.ca/environment-and-energy/ministry-environment-district-locator) can be consulted when determining which local Ministry District Office the RA property is located in.

URL: https://www.ontario.ca/environment-and-energy/ministry-environment-district-locator

## Useful References for Human Health Risk Assessment

For additional information the reader can refer to the Ministry’s “Rationale for the Development of Soil Ground Water Standards for Use at Contaminated Sites in Ontario” (MOE 2011) and the United States Environmental Protection Agency document titled “Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)” (US EPA, 1989b) for more detailed guidance on conducting human health risk assessment.

A list of other useful resource literature on various aspects of human health risk assessment is provided in this section. This list is not meant to be exhaustive and does not represent endorsement by the Ministry. These documents also contain specific jurisdictional policies and default values which may not be applicable to Ontario. Sound scientific judgment should be exercised in utilizing any of the documents.

Note that the following list of references for human health risk assessment was originally included in the 2005 version of the Procedures document. Although the Ministry has added a few additional references since 2005, overall this list has not been formally reviewed or updated since then.

Angus Environmental Ltd. 1991. Review and Evaluation of Receptor Characteristics for Multi-media Assessments. Final Report. Prepared for Ministry of National Health and Welfare, Environmental Health Directorate, Ottawa.

Burmaster, D.E. and P.D. Anderson. 1994. Principles of good practice for the use of Monte Carlo Techniques in Human Health and Ecological risk assessments. Risk Analysis. 14: 477-481.

Canadian Council of Ministers of Environment (CCME). 1996. A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines. Subcommittee of the CCME on Environmental Quality Criteria for Contaminated Sites. CCME, Winnipeg, Manitoba.

CAPCOA. 1993. Air Toxics "Hot Spots" Program. Revised 1992 Risk Assessment Guidelines. Toxics Committee of the California Air Pollution Control Officers Association, California. A Framework for Ecological Risk Assessment: General Guidance.

CCME. April, 1996 (c/o Manitoba Statutory Publications, 200 Vaughn St. Winnipeg, Manitoba, R3C-1T5, phone 204-945-4664). A Technical Appendix to this document is also available from Health & Welfare Canada. 1990. Health Risk Determination: The Challenge of Protection. Ministry of National Health and Welfare, Health Protection Branch, Canada.

Health Canada. 1994a. Canadian Environmental Protection Act. Human Health Risk Assessment for Priority Substances. Environmental Health Directorate, Ottawa, Canada.

Health Canada. 1994b. Human Health Risk Assessment of Contaminants from Contaminated Sites. Volume 1. Risk Assessment Guidance Manual. Draft. Environmental Health Directorate, Ottawa, Canada.

Health Canada. 1994c. Human Health Risk Assessment of Contaminants from Contaminated Sites. Volume 2. Risk Assessment Application Manual. Draft. Health and Welfare Canada, Environmental Health Directorate, Ottawa, Canada.

Health Canada. 1995. Investigating Human Health Exposure to Contaminants in the Environment: A handbook for exposure calculations. Health Canada, Ottawa, Canada, Cat. No. H49-96/1-1995E.

Health Canada. 2017. Supplemental Guidance on Human Health Risk Assessment for Oral Bioavailability of Substances in Soil and Soil-Like Media. Federal Contaminated Site Risk Assessment in Canada. Prepared by Contaminated Sites Division, Safe Environments Directorate, Health Canada. August 2017.

MDEP. April, 1994. Background Documentation for the Development of the MPC Numerical Standards. Massachusetts Department of Environmental Protection, Bureau of Waste Site Clean-up and Office of Research and Standards.

MOE. 1996a. Guidance on Sampling and Analytical Methods for Use at Contaminated Sites in Ontario. (Marsh, M., R. Lall, S. Capstick, A. Lewis, E. Pastorek and A. Kuja) Ontario Ministry of the Environment, Standards Development Branch. December, 1996.

MOE. 2005. Guidance on Oral Bioavailability Adjustments in Human Health Risk Assessment. Standards Development Branch, Position Paper. Final draft Sept 2005.

National Research Council (U.S.). 1983. Risk Assessment in the Federal Government: Managing the Process. National Academy Press, Washington, D.C.

National Research Council (U.S.). 1993. Issues in Risk Assessment. National Academy Press, Washington, D.C.

National Research Council (U.S.). 1994. Science and Judgment in Risk Assessment. National Academy Press, Washington, D.C.

Quebec Ministry of the Environment. 1991. Guidelines for Toxicological Risk Assessment: Summary and Supporting Documents. Preliminary. Risk Assessment Service, Montreal.

Richardson, G.M. 1997. Compendium of Canadian Human Exposure Factors for Risk Assessment. O’Connor and Associates Environmental Inc., Ottawa, Ontario.

Richardson, G.M. and Stantec Consulting Ltd. 2013. 2013 Canadian Exposure Factors Handbook. Toxicology Centre, University of Saskatchewan, Saskatoon, SK, CANADA.

US Environmental Protection Agency. 1986a. Guidelines for Mutagenicity Risk Assessment. Federal Register. Vol. 51, No. 185, September 24, pp. 34006-34012.

US Environmental Protection Agency. 1986b. Guidelines for the Health Risk Assessment of Contaminant Mixtures. Risk Assessment Forum, US EPA, Washington, DC, EPA/630/ R-98/002.

US. Environmental Protection Agency. 1986c. Guidelines for Carcinogen Risk Assessment. Federal Register. Vol. 51, No. 185, September 24, pp. 33992-34003.

US. Environmental Protection Agency. 1988. Superfund Exposure Assessment Manual. Office of Remedial Response, Washington, DC EPA/540/1-88/001.

US Environmental Protection Agency. 1989. Risk Assessment Guidance for Superfund. Volume I: Human Health Evaluation Manual (Part A); Interim Final. Office of Emergency and Remedial Response, US EPA, Washington, DC EPA/540/1-89/002.

US Environmental Protection Agency. 1991a. Guidelines for Developmental Toxicity Risk Assessment. Federal Register. Vol. 56, No. 234, December 5, pp. 63798-63828.

US Environmental Protection Agency. 1991b. Risk Assessment Guidance for Superfund. Volume I: Human Health Evaluation Manual (Part B): Development of Risk-based Preliminary Remediation Goals; Interim. Office of Emergency and Remedial Response, Washington, DC Publication 9285.7-01B.

US Environmental Protection Agency. 1991c. Risk Assessment Guidance for Superfund. Volume I: Human Health Evaluation Manual (Part C): Risk Evaluation of Remedial Alternatives; Interim. Office of Emergency and Remedial Response, Washington, DC Publication 9285.7-01C.

US Environmental Protection Agency. 1991d. Risk Assessment Guidance for Superfund. Volume I: Human Health Evaluation Manual, Supplemental Guidance, Standard Default Exposure Factors. Office of Emergency and Remedial Response, Washington, DC.

US Environmental Protection Agency. 1992a. Dermal Exposure Assessment: Principles and Applications. Interim Report. Office of Health and Environmental Assessment, Exposure Assessment Group, Washington, DC EPA/600/8-91/011B.

US Environmental Protection Agency. 1992b. Guidelines for Exposure Assessment. Federal Register. Vol. 57, May 29, pp. 22888-22938.

US Environmental Protection Agency. 1994. Draft Revisions to Guidelines for Carcinogenic- Risk Assessment. Contaminant Regulation Reporter. August 12, pp. 556-600.

US Environmental Protection Agency. 1994. Methods for Development of Inhalation Reference Doses. Environmental Criteria and Assessment Office, Office of Health and Environmental Assessment, US EPA, research Triangle Park, N.C.

US Environmental Protection Agency. 1996. Proposed Guidelines for Carcinogen Risk Assessment. Office of Research and Development, US EPA, Washington, DC, EPA/600/P-92/003C.

US Environmental Protection Agency. 1996. Reproductive Toxicity Risk Assessment, Federal Register 61(212):56274-56322.

US Environmental Protection Agency. 1998. Guidelines for Neurotoxicity Risk Assessment, US EPA, Washington, DC, Federal Register 63(93): 26926-26954.

US Environmental Protection Agency. 2000. Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures. Risk Assessment Forum, US EPA, Washington, DC, EPA/630/R-00/002.

US Environmental Protection Agency. 2002. Integrated Risk Information System (IRIS). Online. National Centre for Environmental Assessment, US EPA, Washington, DC, http:www.epa.gov/iris.

US Environmental Protection Agency. 2011. Exposure Factors Handbook: 2011 Edition. National Center for Environmental Assessment, Washington, DC; EPA/600/R-09/052F.

## Useful References for Conducting Ecological Risk Assessments

For additional information on the Ministry’s approach to developing ecological component values, refer to the Ministry’s “Rationale for the Development of Soil Ground Water Standards for Use at Contaminated Sites in Ontario” (MOE 2011).

A list of other useful resource literature on various aspects of ecological health risk assessment is provided in this section. This list is not meant to be exhaustive and does not represent endorsement by the Ministry. These documents also contain specific jurisdictional policies and default values which may not be applicable to Ontario. Sound scientific judgment should be exercised in utilizing any of the documents.

Note that the following list of references for ecological risk assessment was originally included in the 2005 version of the Procedures document; the Ministry has not reviewed or updated this list since 2005.

Bartell, S.M., R.H. Gardner, and R.V. O’Neill. 1992. Ecological Risk Estimation. Lewis Publishers, Ann Arbor, Michigan.

BC MELP. 1998. Protocol for Contaminated Sites, Guidance and Checklist for Tier 1 Ecological Risk Assessment of Contaminated Sites in British Columbia. British Columbia Ministry of Environment, Lands and Parks.

BJC (Bechtel Jacobs Company). 1998a. Empirical models for the uptake of inorganic chemicals from soil by plants. BJC/OR-133. Oak Ridge, TN. http://www.esd.ornl.gov/programs/ecorisk/guidance\_docs.html

BJC (Bechtel Jacobs Company). 1998b. Biota Sediment Accumulation Factors for Invertebrates: Review and Recommendations for the Oak Ridge Reservation. BJC/OR-112. Oak Ridge, TN. http://www.esd.ornl.gov/programs/ecorisk/guidance\_docs.html

Buchman, M. 1992. How to Design an Ecological Risk Assessment. in HMC/Superfund '92 Proceedings, Hazardous Materials Control Resources Institute, Maryland.

CCME. 1996. A Framework for Ecological Risk Assessment at Contaminated Sites: General Guidance, CCME Subcommittee on Environmental Quality Criteria for Contaminated Sites, March, 1996. Available c/o Manitoba Statutory Publications 200 Vaughn St., Winnipeg, Man., R3C-1T5.

CCME. 1997. A Framework for Ecological Risk Assessment: Technical Appendices, CCME Subcommittee on Environmental Quality Criteria for Contaminated Sites. March, 1997. Winnipeg, Man.

Chapman, P.M. and Anderson, J. 2005. A Decision-Making Framework for Sediment Contamination Integrated Environmental Assessment and Management Vol ,1, No.3, pp. 163-173. SETAC 2005.

Efroymson, R.A., M.E. Will, G.W. Suter II and A.C. Wooten. 1997a. Toxicological benchmarks for screening potential contaminants of concern for effects on terrestrial plants: 1997 revision. ES/ER/TM-85/R3. Oak Ridge National Laboratory, Oak Ridge, TN. http://www.esd.ornl.gov/programs/ecorisk/contaminated\_sites.html#reports

Efroymson, R.A., M.E. Will, and G.W. Suter II. 1997b. Toxicological benchmarks for screening potential contaminants of concern for effects on soil and litter invertebrates and microbial processes: 1997 revision. ES/ER/TM-126/R2. Oak Ridge National Laboratory, Oak Ridge, TN. http://www.esd.ornl.gov/programs/ecorisk/contaminated\_sites.html#reports

Ford, K.L., F.M. Applehans, and R. Ober. 1992. Development of Toxicity Reference Values for Terrestrial Wildlife. in HMC/Superfund '92 Proceedings. Hazardous Materials Control Resources Institute, Maryland.

Freshman J.S. and Menzie C.A. 1996. Two wildlife exposure models to assess impacts at the individual and population levels and the efficacy of remedial actions. HERA: Vol. 2, No. 3, pp. 481-498.

Mayernick, J.A. and K. Fehrenkamp. 1992. A New Model for Conducting Quantitative Ecological Risk Assessments at Hazardous Waste Sites. in HMC/Superfund '92 Proceedings, Hazardous Materials Control Resources Institute, Maryland.

Menzie et al. 2000. An Approach for Incorporating Information on Chemical Availability in Soils into Risk Assessment and Risk-based Decision Making. Human and Ecological Risk Assessment. Vol 6, No 3, pp 479-510.

Nagy, KA.2001. Food requirements of wild animals: Predictive equations for free-living mammals, reptiles and birds. Nutrition Abstracts and Reviews. Series B Livestock Feeds and Feeding. 71(10):21R-31R.

Sample, B.E., Opresko, D.M. and Suter II, G.W. 1996. Toxicological Benchmarks for Wildlife: 1996 Revision. ES/ER/TM-86/R3. Oak Ridge National Laboratory, Oak Ridge, TN. http://www.esd.ornl.gov/programs/ecorisk/contaminated\_sites.html#reports

Sample, B.E., Aplin, M.S., Efroymson, R.A., Suter II, G.W. and Welsh, C.J.E. 1997. Methods and tools for estimation of the exposure of terrestrial wildlife to contaminants. ORNL/TM-13391. Oak Ridge National Laboratory, Oak Ridge, TN. http://www.esd.ornl.gov/programs/ecorisk/guidance\_docs.html

Sample, B.E., Beauchamp, J.J., Efroymson, R.A., Suter II, G.W. and Ashwood, T.L. 1998a. Development and validation of bioaccumulation models for earthworms. ES/ER/TM-220. Oak Ridge National Laboratory, Oak Ridge, TN. http://www.esd.ornl.gov/programs/ecorisk/guidance\_docs.html

Sample, B.E., Beauchamp, J.J., Efroymson, R.A. and Suter II, G.W. 1998b. Development and validation of bioaccumulation models for small mammals. ES/ER/TM-219. Oak Ridge National Laboratory, Oak Ridge, TN. http://www.esd.ornl.gov/programs/ecorisk/guidance\_docs.html

Suter, G.W. 1993. Ecological Risk Assessment, Lewis Publishers, Chelsea, Michigan.

Suter, G.W., Efroymson, R.A., Sample, B.E., and Jones, D.S. 2000. Ecological Risk Assessment for Contaminated Sites. Lewis Publishers, CRC Press LLC.

US Environmental Protection Agency. 1989a. Ecological Assessment of Hazardous Waste Sites: a Field and Laboratory Reference. Warren-Hicks, W., B.R. Parkhurst and S.S. Baker, (eds). EPA/600/3-89/013. Prepared by Kilkelly Environmental Associates for USEPA.

US Environmental Protection Agency 1993. Wildlife Exposure Factors Handbook. Volume I. EPA/600/R-93/187a. Office of Research and Development, Washington, DC.

US Environmental Protection Agency. 1998. Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F. April 1998. Risk Assessment Forum, Washington, DC.

US Environmental Protection Agency Ecological Soil Screening Levels http://www.epa.gov/ecotox/ecossl/

US Geological Survey, Columbia Environmental Research Centre website http://www.cerc.cr.usgs.gov/data/acute/multiselect.asp

U.S. Navy. 2003. US Ecological Screening and COPC Refinement for Sediment, Soil, and Surface Water. http://web.ead.anl.gov/ecorisk/issue/pdf/Navy\_Screening\_White\_Paper\_7-22-03.pdf.

# Appendix A – Lawyer’s Letter Template

**LAWYER’S LETTER TEMPLATE FOR RISK ASSESSMENTS**

RE Property that is the subject matter of a Risk Assessment (the “Property”)

[DESCRIBE i.e. municipal address]

We are the solicitors for [CLIENT] in respect of the above-noted matter and have reviewed the following, a copy of each of which is attached hereto:

1. Plan of Survey prepared, signed and sealed by \*, Ontario land Surveyor [DESCRIBE] which has thereon an outline of the Property;
2. Transfer Instrument No. XX whereby [CLIENT] acquired the Property;
3. Parcel Register(s) (PIN abstract(s)) regarding the Property;
4. Documentation regarding the owners of the Property; and, if applicable

[SEE NOTES BELOW]

1. A draft of a “certificate in preparation” that can be used regarding the filing of the “Certificate of Requirement” after a certificate of property use is issued.

[SEE NOTE 4 BELOW]

The current legal description and property identification number(s) of the Property [Indicate that it is All or Part of the PINs] are the following:

The following lists the owners of the Property and a description of the nature of their interest:

1. Registered owner(s):
2. Beneficial owner(s):

The Lands have the following municipal address:

The Lands have the following assessment roll number(s):

If you have any questions or concerns, do not hesitate to contact the undersigned.

Yours very truly,

FIRM NAME

Lawyer name and signature

**NOTES**

1. **If the Property is not the entire Lands as described in the original Transfer with the same PIN number(s), then add additional information explaining the reason for the differences.**
2. **Documentation regarding any beneficial ownership that should be attached is a copy of the signed Nominee Agreement or Trust Agreement, as appropriate, or in the case of a Limited Partnership, the Limited Partnership Report.**
3. **Documentation regarding the owners that will be required when a record of site condition is submitted should be attached to the lawyer’s letter at this Risk Assessment stage and will need to be updated as required by section 5 of Schedule A of O. Reg. 153/04:**

* **For a corporation, the documentation is a Certificate of Status or, in the case of a corporation incorporated under a special act, reference to the legislation.**
* **For a general partnership, the Master Business Licence for the partnership.**
* **For a limited partnership, the Limited Partnership Report for the partnership.**

1. **If the Risk Assessment involves risk management measures that will require that a certificate of property use be issued, see the attached outline (in Appendix B) of the procedure that will be followed which describes the “certificate in preparation”.**

# Appendix B – Procedure to Register a Certificate of Requirement

**PROCEDURE TO REGISTER A CERTIFICATE OF REQUIREMENT**

*The following describes the documentation involved in registering a Certificate of Requirement regarding a CPU and how it should be completed:*

(1) Attached is a copy of the form of the first page of a three-page Acknowledgement and Direction document that will be signed by the District Manager when issuing the CPU.

(2)  The second page will be a copy of a "certificate in preparation" document to be prepared by the lawyer which must include an up-to-date complete registrable description of the Property and the following:

-     The "Party From(s)" information in the "certificate in preparation" should be completed as follows:

"Name:                         HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO AS REPRESENTED BY THE MINISTER OF THE ENVIRONMENT, CONSERVATION AND PARKS

                                              Acting as a company

Address for Service:   XX, District Manager

                                XXX, District Office

                                 Ministry of the Environment, Conservation and Parks

                                 XX ADDRESS

  [THE XX INFORMATION WILL BE PROVIDED WHEN THE CPU IS ISSUED]

This document is not authorized under Power of Attorney by this party.

This document is being authorized by a representative of the Crown."

* No “Party To” information should be included in the “certificate in preparation”.

(3)     Attached is a copy of the form of the third page of the Acknowledgement and Direction document, the Schedule - Certificate of Requirement, which will be prepared by the Ministry and described in the CPU.

**ACKNOWLEDGEMENT AND DIRECTION**

TO: XXX\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

RE: APPLICATION TO REGISTER – CERTIFICATE OF REQUIREMENT ISSUED TO XXX regarding Certificate of Property Use number XXX concerning XX, ON and legally described as all [or part of] of PIN

**This will confirm that:**

* The undersigned has reviewed the information set out in this Acknowledgement and Direction and in the documents described below (the “Documents”), and that this information is accurate.
* You, your agent or employee, are authorized and directed to sign, deliver, and/or register electronically, the Documents in the form attached.
* The effect of the Documents has been fully explained to the undersigned by legal counsel at the Ministry of the Environment, Conservation and Parks.
* The undersigned is in fact the party named in the Documents and has not misrepresented the identity of the undersigned to you.
* You are completing and registering the Documents and are not acting as legal counsel for, or providing legal advice to, the undersigned.
* In the event of any investigation by the Director of Land Registration (the “Director”) regarding suspected fraudulent or unlawful activity or registration in connection with the Documents attached to this Acknowledgement and Direction, the undersigned hereby irrevocably consents to you releasing to the Director a true copy of this Acknowledgement and Direction upon request by the Director.
* The execution of this Acknowledgement and Direction may be communicated by way of electronic or facsimile transmission, and receipt of such transmission by the addressees herein shall be deemed to be good, sufficient and fully effectual as if an original executed copy of this Acknowledgement and Direction had been delivered.

**DESCRIPTION OF ELECTRONIC DOCUMENTS**

The Documents described in the Acknowledgement and Direction are the documents selected below which are attached hereto as “Certificate in Preparation” and are:

\_\_\_ A Transfer of the land described above.

\_\_\_ A Charge of the land described above.

\_x\_ Other documents set out in the Schedule attached – Certificate of Requirement, subsection 197(2) Environmental Protection Act

DATED at \_\_\_\_\_\_\_\_\_\_\_, Ontario this \_\_\_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO AS REPRESENTED BY THE MINISTER OF THE ENVIRONMENT, CONSERVATION AND PARKS

Per: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

XX, District Manager

XX, District Office

Ministry of the Environment, Conservation and Parks

**CERTIFICATE OF REQUIREMENT**

**s.197(2)**

***Environmental Protection Act***

This is to certify that pursuant to item X.1 of Certificate of Property Use number XXX issued by XXX, Director of the Ministry of the Environment, Conservation and Parks, under sections 168.6 and 197 of the Environmental Protection Act, on XXX, being a Certificate of Property Use and order under subsection 197(1) of the Environmental Protection Act relating to the property municipally known as XXX, being all of Property Identifier Number XXX (LT) [or being part of Property Identifier Number XXX (LT), namely LEGAL DESCRIPTION TO BE INSERTED] (the “Property”) with respect to a Risk Assessment and certain Risk Management Measures and other preventive measure requirements on the Property

XXX

and any other persons having an interest in the Property, are required before dealing with the Property in any way, to give a copy of the Certificate of Property Use, including any amendments thereto, to every person who will acquire an interest in the Property.

Under subsection 197(3) of the Environmental Protection Act, the requirement applies to each person who, subsequent to the registration of this certificate, acquires an interest in the Property.