Ministry of Environment and Climate Change Strategy

PROTOCOL 1
FOR CONTAMINATED SITES

Detailed Risk Assessment

Version 4.0

Prepared pursuant to Section 64 of the
Environmental Management Act

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	Director of Waste Management	Date

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1.0 Definitions

Terms defined in the *Environmental Management Act* (EMA) and the Contaminated Sites Regulation (CSR) shall apply to this protocol, with the addition of the following:

"**acceptable risk**" means, in the context of detailed risk assessment (DRA), a level of exposure to contaminants which does not produce unacceptable risk.

"**bioaccumulation**" means the progressive increase in the amount of a substance in an organism, or part of an organism, which occurs because the substance's rate of intake by an organism exceeds the rate at which the organism is able to degrade or eliminate the substance.

"**bioaccumulation factor**" [**BAF]** means a number that is:
(a) assigned to a substance to measure bioaccumulation;
(b) calculated as the ratio of:
    (i) the concentration of the substance in an organism, to
    (ii) the sum of concentrations of the substance in environmental media and food; and
(c) is supported by a detailed rationale showing that the chosen factor represents best available science and is appropriate for relevant species and the site conditions including factors such as pH, hardness, range of concentrations.

"bioaccumulative substance" means a substance in which:
(a) the logarithm (base 10) of the octanol-water partition coefficient (log Kow) is greater than or equal to 4.5, or the bioaccumulation factor is greater than or equal to 2000, or the bioconcentration factor is greater than or equal to 2000; or
(b) the substance is determined by best professional judgment of the qualified professional preparing a report to have the potential to bioaccumulate based on relevant scientific information.

"**bioconcentration**" means the process leading to a higher concentration of a substance in an organism compared to the concentration of the substance in the aquatic environmental media to which the organism is exposed.

"bioconcentration factor" [BCF] means a number that is:
(a) assigned to a substance to measure bioconcentration;
(b) calculated as the ratio of:
    (i) the concentration of the substance in an organism, to
    (ii) the sum of concentrations of the substance in aquatic environmental media; and
(c) is supported by a detailed rationale showing that the chosen factor represents best available science and is appropriate for relevant species and the site conditions including factors such as pH, hardness, range of concentrations.

"**biomagnification**" means the incremental process through a food chain by which progressively higher contaminant concentrations are attained in organisms located at respective higher trophic levels in the food web.

"**complete exposure pathway**" means an exposure pathway for which all of the following five elements are present:

(a) a source of contamination;
(b) an environmental medium, and a transport mechanism for the contamination, such as movement through groundwater;
(c) a point of exposure for the contamination, such as a private well;
(d) a route of exposure to a receptor, such as drinking, and
(e) the presence of a receptor to be exposed.

"**conceptual site model**" means a written description and/or an illustrated diagram of the biologic, geologic, hydrogeologic, and environmental conditions of a site as it relates to actual or potential exposure to contamination which identifies all potential receptors and complete or incomplete exposure pathways for all contaminants of concern.

"**contaminant of concern**" means a substance that is present in media at a site at levels that exceed generic numerical standards prescribed for that media and the applicable land, water, vapour, and sediment use for the purposes of the definition of contaminated sites in CSR section 11, typically documented in the DSI or other investigation reports.

"**contaminant of potential concern**" **[COPC]** means any chemical for which the maximum concentration exceeds the appropriate screening benchmark (e.g., guideline and/or standard) in a risk assessment.

"***de novo* toxicity reference value**" **[*de novo* TRV**] means a toxicity reference value (TRV) that has a) been calculated by a qualified professional using an established procedure or method, and b) not previously been published by a regulatory agency.

"**detailed risk assessment" [DRA]** means an ecological risk assessment and/or human health risk assessment carried out in accordance with this protocol and Protocol 20 that provides a systematic and detailed evaluation of potential adverse effects and related risks on human health and/or ecological health resulting from exposure to contaminants in environmental media.

"**detailed risk assessment report**" means an environmental risk assessment report as referred to in section 18 and 18.1 of the CSR that includes both ecological risk assessment and human health risk assessment that is prepared in accordance with this protocol based on a detailed risk assessment.

"**ecological risk assessment**" means an assessment that quantitatively evaluates the actual or potential impacts, hazards, or risks of contaminants on biota other than humans completed in accordance with Protocol 20 and this protocol.

"**ecosystem services**" means the processes and conditions by which humans benefit from the natural or engineered ecosystems around us.

"**effect concentration on x% of organisms (ECx)**", the concentration of a substance causing a specified effect to a percentage of the organisms exposed.

"**engineering control**" means a risk management measure for controlling risks to human health and the environment resulting from exposure to substances at a site by the use of a technology that: (a) controls or contains the migration of a substance, or (b) prevents, minimizes or mitigates the release of a substance, and includes, without limitation: soil or sediment caps, solidification methodologies, chemically reactive barriers, impermeable artificial covers, surface water dikes, trenches, leachate collection systems, water treatment systems, vapour barriers, ventilation covers.

"**exposure pathway**" means the pathway through an environmental medium by which a contaminant is conveyed to a receptor.

"**food chain modelling**" means the quantitative estimation of the dose of contaminant received due to uptake from lower trophic levels within a food chain.

"**high water mark**" means:

(a) for freshwater; the visible high water mark of a stream where the presence and action of the water is so common and usual, and typically enduring, as to mark on the soil of the bed of the stream a character distinct from that of its banks, in vegetation, as well as in the nature of the soil itself, and includes the active floodplain associated with a site;
(b) for marine water: the high water mark as defined by the most elevated High Water Mean Tide by Fisheries and Oceans Canada and as mapped on Canadian Hydrographic Services navigational charts; and
(c) for estuarine water: the high water mark is whichever of the freshwater or marine water high water mark is further inland.

"**human health risk assessment**", means the process used to estimate the nature and probability of adverse health effects in humans who may be exposed to substances in contaminated environmental media, now or in the future.

"**Incomplete exposure pathway**" means an exposure pathway for which one or more of the five elements of a complete exposure pathway is not present.

"**Insignificant exposure pathway**" means a complete exposure pathway where a concentration of a substance in a medium is unquantifiable, the point of exposure is limited (e.g., dermal contact in some ecological receptors), or the route of exposure is unlikely such that the contribution from that pathway is likely to be negligible.

"**incremental lifetime cancer risk" [ILCR]** means an estimate of cancer risk from exposure to a substance through a specific exposure pathway.

"**institutional control**" means a risk management measure for controlling risks to human health and the environment from exposure to substances at a site or parcel by the imposition of legal or administrative requirements that (a) limit the use of soil, water, sediment, vapour or a resource at the site or parcel, or (b) limit access or exposure to substances at the site or parcel; and include, without limitation, fences, signs, easements, covenants, zoning restrictions, contingency or emergency response plans or actions, orders, notices in records, and notifications to persons and government agencies.

"**intrinsic control**" means an inherent feature at a site or parcel which without the use of engineering or institutional controls, controls risks to human health and the environment from exposure to substances and includes, without limitation (a) a natural physical barrier, and (b) an inherent feature which modifies (i) the physical, chemical or biological behaviour or properties of a substance, or (ii) the environmental media in which a substance is contained.

"**maintained watercourse**" means a constructed ditch or constructed pond that:
(a) conveys irrigation water on agricultural land,
(b) contains, conveys or treats effluent, or
(c) conveys, drains or stores storm water or surface water on agricultural, residential, commercial, or industrial land;
unless the constructed ditch or constructed pond:
a) has been designated as critical habitat for aquatic species at risk under the *Federal Species at Risk Act*, or
b) constitutes sensitive habitat for designated endangered or threatened aquatic species under the *British Columbia Wildlife Act*.

"**potential contaminant of concern**" [**PCOC**] means any contaminant which might be expected to occur at a site based on the historical use of the site, whether or not that substance has been measured in any environmental medium or determined to exceed the numerical standards of the Contaminated Sites Regulation (CSR).

"**potentia**l **terrestrial habitat**" means, in the context of detailed risk assessment (DRA), land on any part of the contaminated site (the source parcel or the off-site affected parcel(s)) that satisfies any of the following conditions:
(a) the agriculture, wildlands, or urban park land use classification applies; or
(b) contains over 50 m^2 (where residential land use applies at the site) or over 1,000 m^2 (where commercial or industrial land use applies at the site) of contiguous undeveloped land; or
(c) lies within 300 m of sensitive habitat where residential, commercial or industrial land use applies at the site.

"**qualified professional**", in relation to a duty or function under this protocol, means an individual who:
(a) is registered in British Columbia with a professional organization, acts under that organization's code of ethics and is subject to disciplinary action by that organization; and
(b) through suitable education, experience, accreditation and knowledge may reasonably be relied on to provide advice within the individual's area of expertise, which area of expertise is applicable to the duty or function.

"receiving environment" means any air, land, water, sediment (including porewater), wetland, or muskeg containing receptors, excluding artificial watercourses or impoundments that are maintained and whose primary purpose is to convey or contain storm water or treat and convey effluent, or natural water courses in circumstances approved by the director.

"**receptor**" means a living organism that may be exposed to a substance.

"**risk-based standards**" means the standards prescribed in CSR sections 18 and 18.1.

"**risk control**", an institutional control, intrinsic control, engineering control or monitoring which exists or is implemented to mitigate, eliminate or observe risks from the exposure of receptors to contaminants.

"**screening benchmark**" is the concentration of a substance in an environmental medium, above which that substance is identified as a COPC in a risk assessment. This concentration may be based on regulatory standards or guidelines, toxicity effects levels, or background concentrations that apply to the site.

"**screening level risk assessment**" [SLRA], a screening level risk assessment and report made in accordance with Protocol 13.

"**sediment porewater**", the interstitial water within the uppermost 1 metre of sediment within an aquatic receiving environment.

"sensitive habitat" includes**:**
(a) national, provincial, regional and municipal parks;
(b) sensitive ecosystems identified by Federal, Provincial Sensitive Ecosystem Inventories, or local governments;
(c) habitat supporting red and blue listed species identified via BC Species and Ecosystem Explorer;
(d) habitat used for sensitive sediment use as defined in the Regulation; or
(e) riparian assessment areas as defined in the Riparian Areas Protection Regulation.

"**species at risk**", an extirpated, endangered, threatened species, or a species of special concern as designated under the authority of the B.C. *Wildlife Act* or Canadian *Species at Risk Act.*

"**toxicity reference value**" [TRV], means a maximal estimate of exposure to a substance which would not elicit an unacceptable adverse toxicological effect in an organism, including without limitation: acceptable daily intake [ADI], benchmark dose [BMD], cancer potency slope factor [CPSF], ecological soil screening level [Eco-SSL], lowest observed adverse effect level [LOAEL], minimum risk level [MRL], no observed adverse effect level [NOAEL], reference dose [RfD], reference concentration [RfC], risk specific dose [RSD], tolerable daily intake [TDI], tumorigenic concentration 05 [TC05], tumorigenic dose 05 [TD05] and unit risk [UR].

"unacceptable risk" means either:
(a) a combination of contamination and complete exposure pathways that result in levels of human health risks exceeding levels specified in CSR sections 18(1) (3) or (5), 18.1(1) (4) and (5.1), or
(b) the existence of potential risks to human or ecological receptors (which will not be mitigated by implementation of the measures specified in a DRA) to levels:
    (i) for humans, where the cumulative hazard index is greater than or equal to one for all substances that share a common target organ or mechanism for toxicity;
    (ii) for ecological receptors, where the total of all effects of all contaminants on any receptor is exceeding the level of protection identified in Section 4.4.6, Table 1 for the relevant land and water uses.

"undeveloped land" means any bare or vegetated soil, excluding
(a) gravelled walkways,
(b) roadways or highways and associated roadside or highway margins,
(c) parking areas,
(d) soil contained and isolated in planters and similar structures, and
(e) storage areas at active commercial and industrial operations.

"**weight-of-evidence**", a structured framework approach for evaluating and assigning the relative or proportional contributions or weightings to each of multiple lines of evidence influencing the qualitative or quantitative estimation of risk or hazard in a risk assessment.

2.0 Introduction

2.1 Authority for and Purpose of this Protocol

This protocol is made under the authority of the EMA section 64 (1)(c),(d) and 64 (2)(e),(f),(g),(h) and (o).

Consistent with EMA and the CSR this protocol:

1. establishes substantive and procedural requirements for persons conducting detailed risk assessment for the purposes of Part 4 of EMA; and
2. provides a mechanism for demonstrating no unacceptable risks exist, or will exist, in relation to a site and provides information required for the purposes of CSR section 18 (6), 18 (7), 18.1 (5), 18.1 (6), 47 (2), 47 (3) and 49 (2) as applicable.

This protocol applies to the preparation and contents of ecological risk assessments and human health risk assessments conducted as part of a detailed risk assessment (DRA). Protocol 20, "Detailed Ecological Risk Assessment Requirements" (Protocol 20) establishes additional requirements for the ecological risk assessment component. The resulting detailed risk assessment report may be submitted as an environmental risk assessment report for the purposes of CSR section 18 (6) or 18.1 (5).

Except where a Screening Level Risk Assessment (SLRA) has been completed in accordance with Protocol 13,"Screening Level Risk Assessment" (Protocol 13), an applicant for an Approval in Principle or Certificate of Compliance that is based on the site being remediated in accordance with risk-based standards must provide the director with a detailed risk assessment report.

2.2 Risk Assessment to Support Certificates of Compliance

Section 53 of the EMA authorizes the director to issue a Certificate of Compliance if various conditions are met. Those conditions include the contaminated site being remediated to numerical or risk-based standards. Risk-based standards are set out in the CSR section 18, or 18.1 for substances and sources specified for an environmental management area.

CSR section 18 (6) also requires the applicant for a Certificate of Compliance that is relying on risk-based standards to prepare a detailed risk assessment report that identifies the potential on- and off-site environmental risks of substances causing contamination. As per CSR section 18 (6), and in order to maintain satisfactory public records for contaminated sites, it is necessary to quantify the magnitude and severity of risks from residual contamination before and after risk controls are implemented. Clear statements indicating how risk management or mitigation measures have been factored into calculations must be included.

The director may impose additional requirements to prevent or mitigate the identified risks. Requirements may be imposed through conditions in Certificates of Compliance, restrictive covenants on land titles and/or requirements to prepare Performance Verification Plans (see Section 5.0, Risk Management). Remediation orders may also be used.

2.3 Risk Assessment as Remediation

It is not the intent of the EMA, the CSR, or this protocol to recommend risk assessment as a remedial strategy in preference of other options that may remediate a contaminated site permanently to the maximum extent practicable. Remedial strategies must be selected in accordance with EMA section 56. Risk assessment is generally intended to address residual contamination on a contaminated site. Risk based remediation that does not provide a permanent solution to contamination should only be used where alternatives that provide permanent solutions are not practicable.

Two types of risk assessment may be used as a remedial strategy at B.C. contaminated sites. SLRA and DRA are discrete tools and cannot both be used in the same submission in a contaminated sites application under the CSR. For example, risk assessors cannot eliminate exposure pathways in SLRA and then initiate a DRA for the remaining complete exposure pathways. The completion of a DRA requires that all exposure pathways be considered, regardless of whether a SLRA has been previously completed. A DRA that ends at the problem formulation may be an acceptable risk assessment report submission. This protocol and Protocol 20 contain requirements for DRA. For more information on SLRA refer to Protocol 13.

The primary goal of ecological risk assessment and/or ecological risk management is to ensure the continued presence, or successful re-introduction, of a biologically diverse, functional, self-sustaining, and interdependent community or ecosystem as an essential component of the remediation of contaminated sites as appropriate to the land use.

Remediation by way of risk assessment is considered complete when, based on a detailed risk assessment report, the director determines that there are no unacceptable risks present on the site.

2.4 Conditions for Selecting Risk Assessment as Remediation

To select risk assessment as a remedial strategy, at minimum the below conditions must be met:

1. A Detailed Site Investigation (DSI) must be completed and a DSI report prepared by a qualified professional (QP) according to EMA section 41 and CSR section 59.

2. The DSI must assert, in addition to the general requirements for a DSI,

(a) that for each contaminant of concern, the horizontal and vertical extent of contamination has been delineated, and

(b) that the contamination present at the site is stable or decreasing in concentration and extent.

3. A QP must be responsible for all aspects of the risk assessment. Risk assessment is a systematic process that integrates toxicology, chemistry, ecology, statistics and modelling into an estimate of hazard or risk to organisms. To be considered qualified, a person and/or the team conducting risk assessment must have demonstrable expertise in these fields of science.

3.0 Environmental Quality Standards and Risk Assessment

3.1 Application of Risk-Based Standards

Two types of environmental quality standards apply at contaminated sites in B.C.: generic numerical standards prescribed in CSR Schedules 3.1 - 3.4, and risk-based standards. Risk-based standards pertain both to the protection of the ecological and human health. The risk-based standards take the form of specified risk levels for human health risk assessments. For ecological risk assessments, the director requires that risks are at or below the acceptable protection levels listed in Table 1. Human health and ecological risk assessment reports may be combined into one environmental risk assessment report that meets CSR 18 (6) and 18.1 (5).

Unlike numerical standards, risk-based standards cannot be used to determine if a site is contaminated. However, they can be used to confirm if a site has been remediated as per CSR section 18 and 18.1.

3.2 Risk-Based Standards in the Aquatic Receiving Environment

This section describes how to specifically apply risk-based standards and B.C. Water Quality Guidelines (WQG) to water, porewater, and sediment in the aquatic receiving environment. B.C. has Approved and Working WQG to protect water quality, biota, and sediment. WQGs must be considered in a risk assessment for submission of an application regarding a decision affecting water quality made within the ministry (Water Quality Guidelines Policy, 2019). WQGs apply in the aquatic receiving environment, which is defined herein as a receiving environment that lies within the boundaries of the high water mark and captures both surface water, porewater, and the biologically active zone of sediment.

A site is considered to meet numerical standards for aquatic life where the following can be demonstrated:

- the dilution of substance concentrations along the groundwater to surface water flow pathway results in concentrations less than the aquatic life standards in schedule 3.2 of the CSR at all depths that are at least 10 metres inland from the high water mark of any receiving environment (where the source of contamination is located at least 10 metres inland from the high water mark); and,
- where substance concentrations as specified above are not met, concentrations of substances are less than the WQGs at all depths at the high water mark.

If the above criteria cannot be met, a detailed risk assessment report can demonstrate that no unacceptable risks to aquatic life exist or will exist by showing one of the following:

- the dilution of substance concentrations along the groundwater to surface water flow pathway results in concentrations less than 1/10th of the aquatic life standards in schedule 3.2 of the CSR at all depths before the groundwater enters the aquatic receiving environment;
- groundwater quality meets a site-specific risk-based standard in a detailed ecological risk assessment with a protection level appropriate for aquatic receiving environments (i.e., protection levels listed in Table 1 in Section 4.0);
- substance concentrations are below BC WQGs at the location where groundwater with the highest contamination levels enters the aquatic receiving environment; or
- if substance concentrations in the receiving environment are above BC WQGs, then site-specific risk-based standards must demonstrate no unacceptable risks in a detailed ecological risk assessment with a protection level appropriate for aquatic receiving environments (i.e., protection levels listed in Table 1 in Section 4.0).

Substance concentrations in the receiving environment and groundwater must be determined in accordance with Technical Guidance 15, version 2.0.

For sediment and sediment porewater, if the DSI demonstrates that concentrations of contaminants exceed applicable numerical limits as set out in Table 2 of Technical Guidance 15, version 2.0, detailed ecological risk assessment must demonstrate that no unacceptable ecological risks exist. Detailed human health risk assessment must demonstrate no unacceptable human health risks exist when the exposure pathway is considered complete.

CSR numerical and risk-based standards apply on a contaminated site and B.C. Water Quality Guidelines apply in the aquatic receiving environment. Risk-based standards may be used for off-site migration to the aquatic receiving environment, if acceptable to the director.

4.0 Risk Assessment Components

Risk assessment is inherently related to standards derivation; however, Protocol 1 and Protocol 28, "2016 Standards Derivation Methods," have distinct objectives. The purpose of Protocol 28 is to document the derivation of numerical standards used to define a contaminated site (CSR section 11). The purpose of Protocol 1 is to outline the requirements for using DRA as remediation of a contaminated site. Practitioners using Protocol 1 can modify the toxicological equations in Protocol 28 using site-specific information and additional toxicological information to calculate risk estimates.

The complexity of the risk assessment must correspond to the complexity of the contaminated site. A deterministic or probabilistic risk assessment may be used. When probabilistic methods are used, the ministry expects that rationale related to the selection of input parameter distributions and their applicability to B.C. will be adequately documented.

Aside from where Protocol 28 is identified as a preferred source, QPs must consider the following Health Canada documents for deterministic human health risk assessment:

- Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0 (2012)
- Part II: Health Canada Toxicological Reference Values (TRVs), Version 2.0 (2010)
- Part III: Guidance on Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada, Version 2.0 (2010)
- Part V: Guidance on Complex Human Health Detailed Quantitative Risk Assessment for Chemicals ($DQRA_{CHEM}$) (2010)
- Part VI: Guidance on Human Health Detailed Quantitative Radiological Risk Assessment for Chemicals ($DQRA_{RAD}$) (2010)
- Part VII: Guidance for Soil Vapour Intrusion Assessment at Contaminated Sites (2010),
- Interim Guidance: Human Health Risk Assessment for Short-Term Exposure to Carcinogens at Contaminated Sites (2013)
- Supplemental Guidance on Human Health Risk for Country Foods (HHRA Foods) (2010)
- Supplemental Guidance Checklist for Peer Review of Detailed Human Health Risk Assessments (HHRA) (2010)
- Supplemental Guidance on Human Health Risk Assessment of Oral Bioavailability of Substances in Soil and Soil-Like Media (2017)
- Supplemental Guidance on Human Health Risk Assessment on Contaminated Sediments: Direct Contact Pathway (2017)

For ecological risk assessment the ministry requires the use of Protocol 20.

The risk assessment report must be organized in consideration of, and include pertinent and comprehensive information related to, the following risk assessment components:

- problem formulation (see Section 4.1)
- conceptual site model for current and/or future land, soil, vapour, water, and sediment uses (see Section 4.2)
- exposure assessment (see Section 4.3)
- toxicity/effects assessment (see Section 4.4)
- risk characterization (see Section 4.5)
- uncertainty analysis (see Section 4.6), and
- conclusions (see Section 4.7).

4.1 Problem Formulation

All contaminant-pathway-receptor combinations must be identified and described in the problem formulation component of the detailed risk assessment report. All relevant environmental media must be included.

4.1.1 Contaminants of Potential Concern (COPC)

Contaminants of concern identified in a DSI supporting risk assessment must be carried forward to COPC screening in the detailed risk assessment report. All COPCs must be listed in the problem formulation component of the detailed risk assessment report and a detailed rationale must be provided for each COPC not carried through to the risk assessment.

While there is no requirement under EMA or CSR to include in a risk assessment a substance which does not have a prescribed numerical standard or does not have a prescribed applicable use, such a substance may be listed as meeting the risk-based standards in a Certificate of Compliance as long as the site is or was a contaminated site as defined under EMA due to the presence of some other prescribed substance, but only if:

1. the substance is included and evaluated in the risk assessment, and
2. the results of that risk assessment are shown to comply with the risk-based standards of the CSR.

For prescribed substances with a no applicable standard for use in sediment, (e.g., there are no human health protection numerical standards in the CSR for sediment), these substances should be addressed for human health in the risk assessment if the concentrations of the substances exceed background concentrations and are attributed to uses at the site or neighbouring the site; unless:

1. concentrations of non-bioaccumulative substances are less than the corresponding human health numerical soil standards for the nonprescribed use in Schedule 3.1 (only applicable to the intertidal zone); or
2. concentrations of bioaccumulative substances are less than the corresponding ecological-protection sediment standards for the substances in Schedule 3.4 (applicable to both the subtidal and intertidal zones).

The land use applicable to the upland foreshore (i.e., above the high water mark) determines for human health in the intertidal zone, which land use soil standards under Schedule 3.1 applies to nonprescribed and nonprescribed use substances in the intertidal sediment. If the land use applicable to the upland foreshore is unknown or cannot be conclusively determined, then residential soil standards apply.

4.1.2 Beneficial Use

The QP conducting a DRA must consider if any beneficial use scenarios apply as described in Protocol 13, “Screening Level Risk Assessment”. If contamination caused by a beneficial use would be covered by the beneficial use exemption in Protocol 13, the problem formulation component of the DRA report must identify these (if any) eligible beneficial uses (including associated contaminants and contaminated media) including location and extent of contamination; and, despite anything else in this protocol, the QP is not required to consider ecological or health risks associated with the current beneficial use.

4.1.3 Exposure Pathways

The detailed risk assessment report must identify and provide scientific justification for what the QP considers (a) all relevant environmental media, and (b) the potential exposure pathways to receptors. For ecological exposure pathways, Protocol 20 requirements and the Federal Contaminated Sites Action Plan (FCSAP) "Ecological Risk Assessment Guidance (2012)" must be considered.

Human Health - Drinking water

Where contaminated water is used as a drinking water source, (i.e., where a current or future drinking water exposure pathway is considered to be complete or operative), the ministry expects the detailed risk assessment report to contain an assessment of risks and hazards associated with the drinking water pathway (including fully documented exposure risk calculations). For volatile substances, additional inhalation exposure pathways (e.g. inhalation during showering, etc.) must be evaluated if applicable.

If the current and future drinking water exposure pathway is considered incomplete or inoperative (e.g., a municipal water supply is present as the main drinking water source, all site impacted drinking water wells have been decommissioned, or the risk management approach for the site is ongoing prohibition of use of site impacted water as drinking water), exposure risk calculations and associated risk estimates for the future drinking water pathway may optionally not be included in the risk assessment for the site. Note, as per CSR section 18(6) and 18.1(5), which requires that calculations be provided before and after remediation, the director may require this information (CSR section 52 (1)).

If the drinking water pathway is deemed incomplete and risk estimates are not provided, it is required that the risk assessment clearly state that "future drinking water risks were not calculated" and provide full documentation of the rationale by which the future drinking water pathway was determined to be incomplete or inoperative.

Human health - Pathway to subsurface media

It is not required to include acute/subchronic exposures for subsurface (utility, trench, and construction) workers in quantitative human health risk assessments for CSR regulatory purposes. Worker health and safety is the responsibility of WorkSafeBC under the *Workers Compensation Act* and the Occupational Health and Safety Regulation. WorkSafeBC requirements must be met at contaminated sites. Operative chronic (> 90 days) occupational exposure pathways must be included for subsurface workers in risk assessments for CSR regulatory purposes.

Human Health - Inhalation pathway of exposure

Worst case conditions for current and potential future breathing zone air for human health must be evaluated when vapour contamination is present at the site. Evaluation of the vapour pathway must be completed in accordance with Protocol 22, "Application of Vapour Attenuation Factors to Characterize Vapour Contamination" Version 1.0. In addition, Technical Guidance 4, "Vapour Investigation and Remediation" Version 2 must be followed.

Bioaccumulative Substances

When a complete exposure pathway exists between a receptor and bioaccumulative substance, the potential for food chain impacts must be evaluated and quantified. Even when a substance is not considered to biomagnify to higher trophic levels, food chain impacts from lower trophic level organisms must be evaluated. Detailed rationale must be provided if food chain impacts are not quantitatively evaluated.

A rationale must be provided when bioaccumulation factors and bioconcentration factors are cited in a risk assessment to ensure the values are appropriate for the site conditions. Site-specific bioaccumulation factors and bioconcentration factors are preferred when the scope and complexity of the site allows.

Ecological Exposure Considerations

Soil in the top 1 m must be characterized with a high level of confidence to adequately assess exposure to ecological and human receptors. Where deep-rooting vegetation or burrowing animals are present, soil characterization beyond 1 metre may be required.

Sediment within the biologically active zone must be characterized with a high level of confidence to adequately assess exposure to ecological receptors.

For many wildlife receptors, fur and feathers are effective at blocking exposure to environmental media and prevent direct contact with the skin unless the animal becomes soaked in water or other carrier. Dermal exposure of wildlife should be considered for some species (e.g. amphibians and reptiles) when relevant and reliably quantifiable for COPCs that can be absorbed readily through this pathway.

The inhalation pathway of exposure is not usually evaluated for ecological receptors unless site-specific conditions indicate that the pathway can be considered the primary exposure route for a population of a species, or if an individual of a rare and endangered species frequents or resides (e.g., burrows, hibernates) at the site.

4.1.4 Field Study

Sample Collection and Analysis

Sampling methodologies for the risk assessment must follow the ministry's B.C. Field Sampling Manual or any applicable protocols. The number of samples collected must be commensurate with the complexity of the site undergoing risk assessment. The number of samples must ensure a high level of confidence in any relevant toxicological, chemical, or statistical calculations in the risk assessment report including modelling.

Substances in environmental media samples analysed for the purpose of a DSI or other investigation made for the purposes of DRA must be analysed:

(a) by a "qualified laboratory", as defined in the Environmental Data Quality Assurance Regulation.

(b) in accordance with B.C. Environmental Laboratory Manual.

Ecological Study Requirements

An ecological field study of the site must be completed where it has been determined that potential terrestrial habitat and/or an aquatic receiving environment is present. The level of detail required in this field study should be commensurate with the complexity of the site. Rationale outlining the study design should be provided.
In addition to the requirements in Protocol 20, the field study must:

1. be completed by a qualified professional who has relevant demonstrable experience.
2. contain a seasonally appropriate sampling/survey program to evaluate the target species of concern.
3. be included and documented in the detailed risk assessment report, including the rationale for selection of and use of all ecological surveys such as plant and/or soil invertebrate community analysis, birds, fish, and benthic community analysis (including methods, sampling locations and relevant seasonality, etc.).

Field studies must be designed to, as far as practicable, obtain data appropriate for exposure and food chain modelling, and to reduce uncertainty by measuring specific data, such as chemical concentrations, types of organisms inhabiting the area, and toxicity.

4.1.5 Receptor Identification

Detailed risk assessments must identify all potential human and ecological receptors known, or reasonably inferred, to be present at a site under the current or future scenario, including uniquely sensitive or exposed human or ecological receptor subgroups such as:

- sensitive life stages (e.g., young and elderly people, pregnant women; egg and larval stages),
- vulnerable individuals known to suffer compromised health impacts (e.g., chemical hypersensitivity, impaired pulmonary function, immunodeficiency),
- uniquely exposed individuals (e.g., subsistence consumers such as Indigenous Peoples), and species at risk as per Protocol 20.

Rationale for site-specific inclusion or exclusion of any relevant receptor is required.

Selection of Ecological Receptors

Ecological receptors which are identified as being of cultural significance must be specifically addressed in accordance with any requirements set out by the director. Additional context can be found on the “Technical Guidance for Risk Assessors” website.

Ecological receptors must be selected based on the potential for their presence at the site. Protocol 20 requires the site be assessed for likely use by red and blue listed species. Aquatic ecological receptors must be assumed to be present in aquatic receiving environments. However, terrestrial receptors are

only considered to be present when potential terrestrial habitat is available, which must be determined using the habitat assessment procedure described in Protocol 13. The habitat assessment (including for habitat specific to red and blue listed species) must be completed by a qualified professional whose area of practice includes demonstrable experience in the assessment of habitat and these habitat assessment forms must be included in the detailed risk assessment report.

When potential terrestrial habitat has been identified using the habitat assessment procedure for the site, a qualified professional must identify and assess potential species to include in the risk assessment. Wildlife receptors, including higher trophic levels, must be considered in DRA where appropriate in order to meet risk-based standards. Further consideration must be given to the Canadian government's FCSAP, "Ecological Risk Assessment Guidance (2012)" to support specific species selection requirements.

Selection of Human Health Receptors

In human health receptor selection, QPs must include all relevant receptors and most sensitive life stages. When selecting human health receptors, QPs must follow recommendations in Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0 (2012), except where the QP completing the assessment considers it inappropriate. Where the selection process deviates, the detailed risk assessment report must justify the variation.

4.2 Conceptual Site Model

The detailed risk assessment report must include a complete conceptual site model identifying all complete or incomplete exposure pathways for all contaminants of concern. It is recognized that these models are unique to each site and presentation may differ due to differences in the chemical, physical, and environmental fate and transport properties of the contaminants.

The ministry's website "Technical Guidance for Risk Assessors" lists guidance documents to support risk assessment at B.C. contaminated sites

4.3 Exposure Assessment

Contamination at the site must be adequately characterized to evaluate all identified receptors and exposure pathways. For every complete exposure pathway and receptor combination the DRA report must assess exposure, effects and risk. Current and reasonable potential future land, soil, water, sediment, and vapour uses must be evaluated in both ecological and human health risk assessment.

The detailed risk assessment report must specify how the exposure concentration used in the risk assessment was determined for each complete exposure pathway and receptor combination (e.g., identify whether the maximum or 95% upper confidence limit of the mean concentration of the contaminant in soil was used). Averages are not acceptable or rarely acceptable as exposure concentrations. Detailed rationale must be provided to support the statistic selected for the exposure point concentration.

4.3.1 Human Health Exposure Assessment

Evaluation of both non-carcinogenic and carcinogenic effects related to exposure to contamination at a site is a necessary component of detailed human health risk assessment performed under the EMA. Refer to Protocol 30, "Classifying Substances as Carcinogenic" (Protocol 30) for details on carcinogenic classification. For carcinogenic substances that elicit both carcinogenic and non-carcinogenic effects, both endpoints must be assessed in human health risk assessments where suitable TRVs are available. However, it should be carefully considered which route(s) of exposure are relevant for each endpoint.

4.3.2 Human Health Bioavailability

Oral bioavailability must be assumed to be 100% (gastrointestinal absorption factor of 1) for all substances, with the exception of arsenic where 60% absorption may be assumed with supporting rationale. Site-specific bioavailability adjustments based on robust data may be considered by the director.

4.3.3 Exposure Parameters and Scenarios

Human Health

The human health exposure assessment must:

1. consider Protocol 28: "2016 Standards Derivation Methods" (Protocol 28) as the default source of human health risk exposure parameters and scenarios, when applicable;
2. consider whether site specific human receptors and their intake characteristics are appropriate; and
3. identify in the detailed risk assessment report any human receptor characteristics that are different from those identified in Protocol 28 and provide justification (e.g. Health Canada value).

Human health exposure scenarios and their associated intake parameters not presented in Protocol 28 (e.g. human inhalation of volatiles in shower) must be evaluated if applicable. Additional resources to address some of these scenarios are available on the "Technical Guidance for Risk Assessors" website.

Ecological Health

In additional to the requirements set out in Protocol 20, the ecological exposure assessment must:

1. consider and evaluate wildlife exposure factors, taking into account guidance published by FCSAP "Ecological Risk Assessment Guidance, Module 3: Standardization of Wildlife Receptor Characteristics", United States Environmental Protection Agency, California Environmental Protection Agency, United States Geological Survey, Environment and Climate Change Canada, and California Department of Toxic Substances Control.
2. consider which site specific wildlife receptors and intake characteristics are appropriate;
3. identify chosen wildlife characteristics; and
4. provide scientific justification for the chosen wildlife characteristics.

The ministry's website "Technical Guidance for Risk Assessors" provides some resources to evaluate additional exposure parameters for ecological receptors. Rationale related to the selection of these supplemental exposure parameters must be included in the detailed risk assessment report.

4.3.4 Food Chain Models

A detailed food chain model or other exposure model may be used to supplement the field study and to further assess substances found at a site. A food chain model must be completed at large or complex contaminated sites where habitat is present unless it can be show that concentrations in lower trophic levels are insignificant or other rationale can be provided. All exposure parameters used in the model must be referenced and explained.

4.4 Effects Assessment

The most appropriate human health and ecological TRVs must be selected based on criteria set out below.

4.4.1 Human Health TRVs

The HHRA report must identify and provide scientific justification for the most appropriate TRV. The ministry requires the consideration of human health TRVs as listed in Protocol 28, Chapter 8 for soil, and vapour. For drinking water, TRV sources provided in Chapter 5 of Protocol 28 must be considered.

The source of the selected TRV as well as relevant study details on which it is based (including target organ or system) must be provided in the detailed risk assessment report.

If TRVs in Protocol 28 are not selected, the detailed risk assessment report must:

1. identify potential TRVs;
2. consider whether the TRV is appropriate for the site;
3. identify a chosen TRV based on the following criteria:
   a) existence of a comprehensive and contemporary published science assessment on which the TRV is based,
   b) extent of supporting rationale and documentation pertaining to the scientific derivation of the TRV, and
   c) extent and rigor of scientific peer review provided for the TRV.
4. provide scientific justification for the chosen TRV.
5. include exposure assumptions and/or target risk levels and adjustments (e.g., adjustment from 1/1,000,000 cancer risk to 1/100,000 cancer risk)

In the case where no credible human health TRV can be found, a *de novo* TRV may be derived using an established procedure and based on the scientific literature related to the toxicity of the substance. The detailed risk assessment report must provide justification for derivation and selection of any *de novo* TRVs. For any derivation of a *de novo* TRV to support DRA as remediation of a non-high risk site,

QPs must submit a Protocol 6, “Applications with Approved Professional Recommendations and Preapprovals” application.

4.4.2 Ecological TRVs

Ecological TRVs (EcoTRVs) for each substance and ecological receptor must be selected with consideration for the best available science and obtained from a peer-reviewed source, preferably regulatory. EcoTRVs must be equivalent to or more protective than the protection levels listed below in Table 1. The detailed risk assessment report must identify and provide scientific justification for the selection of each EcoTRV.

QPs must consider the following preferred sources of EcoTRVs:

Soil

- Canadian Council for Ministers of the Environment: Scientific Criteria Documents for Deriving Soil Guidelines
- United States Environmental Protection Agency: Interim Ecological Soil Screening Level Documents
- Oak Ridge National Laboratory: Toxicological Benchmarks for Contaminants of Potential Concern for Effects on Soil and Litter Invertebrates and Heterotrophic Process: 1997 Revision; Toxicological Benchmarks for Screening Contaminants of Potential Concern for Effects on Terrestrial Plants: 1997 Revision
- Ontario Ministry of Environment: Rationale for the Development of Soil and Groundwater Standards for use at Contaminated Sites in Ontario, 2011

Water - Aquatic Life

- British Columbia Ministry of Environment and Climate Change Strategy: Approved and Working Water Quality Guidelines
- Canadian Council for Ministers of the Environment (CCME): Canadian Environmental Quality Guidelines
- Canadian Ministry of the Environment and Climate Change: Federal Environmental Quality Guidelines (FEQGs)

Sediment – Aquatic Life

- Canadian Council for Ministers of the Environment, 1999, Environmental Quality Guidelines: Scientific Criteria Documents for Deriving Sediment Guidelines

Where EcoTRVs from the above preferred sources are lacking for a substance, the QP must consider the following supplemental sources:

- Oak Ridge National Laboratory: The Risk Assessment Information System, Ecological Benchmark Tool
- United States Environmental Protection Agency, Region 9: Biological Technical Assistance Group (BTAG) Recommended Toxicity Reference Values for Mammals and Birds

- Centre d'Expertise en Analyse Environnementale du Québec: Valeurs de Référence pur les Récepteurs Terrestres
- CCME: Canadian Tissue Residue Guidelines for the Protection of Wildlife Consumers of Aquatic Biota

The most stringent applicable EcoTRV from the above preferred sources or supplemental sources, must be selected unless it can be shown by the QP that an alternate value is more appropriate based on:

1. the existence of a more comprehensive and contemporary published scientific assessment,
2. enhanced relevance (study design, exposure route, etc.) to the site,
3. enhanced scientific credibility, or
4. greater extent of supporting rationale and documentation.

For all EcoTRVs, the QP must include the following in the report:

1. Toxicity profiles of the contaminants to be evaluated. These toxicity profiles should form the basis for the selection of appropriate EcoTRVs to be used in the toxicity assessment component of the ecological risk assessment. At a minimum, QPs must consider including the following information in the toxicity profiles:
   a) toxic effects expected from exposure,
   b) sensitivities of the different receptor groups exposed, and
   c) the range of toxicities reported in the scientific literature for similar species to those present at the site under assessment.

2. The form of exposure on which the EcoTRV is based (e.g., dose, tissue residue, concentration, environmental media).

3. The specified effects levels on which the EcoTRVs are based (e.g., Effective Dose (EDx), Lethal Dose (LDx), Effective Concentration (ECx) or Lethal Concentration (LCx) for a set percent (x) of exposed organisms).

4.4.3 *De novo* Derived EcoTRVs

In the case where no credible EcoTRV can be found, a *de novo* EcoTRV may be derived. In deriving a *de novo* EcoTRV for a substance lacking an EcoTRV from a preferred source, the QP must consider the best available science for sources of ecological toxicity data. The detailed risk assessment report must demonstrate that the creation of the de novo EcoTRV and the procedure used for derivation was scientifically justified based on:

1. the scientific literature related to the ecotoxicity of the substance, or
2. ecotoxicological experimental data obtained for the substance on a site specific basis (e.g., *in-situ* bioassay data obtained for a site).

QPs must consider the following documents in derivation of a *de novo* EcoTRV:

- Protocol 28 "2016 Standards Derivation Methods" Appendix 8

- United States Environmental Protection Agency: Guidance for Developing Ecological Soil Screening Levels (Eco-SSLs), Eco-SSL Standard Operating Procedure #6: Derivation of Wildlife Toxicity Reference Value (TRV) (June 2007)
- Environment and Climate Change Canada: FCSAP Supplemental Guidance for Ecological Risk Assessment, Module 2: Selection or Development of Site-Specific Toxicity Reference Values (June 2010)

In deriving *de novo* EcoTRVs, arbitrary uncertainty factors must not be used except where the risk assessor considers it professionally appropriate given limited data, or where extrapolations are required among taxonomic groups. Where uncertainty factors are used, the report must document how factors have been chosen in a manner consistent with the FCSAP "Ecological Risk Assessment Guidance (2012)".

QPs must submit a Protocol 6, "Applications with Approved Professional Recommendations and Preapprovals" application in order to use a de novo EcoTRV to support DRA as remediation at a non-high risk site.

4.4.4 Toxicity Testing for Ecological Risk Assessment

The ministry requires the use of toxicity test methods established by the following agencies in ecological risk assessment:

- BC Ministry of Environment: British Columbia Environmental Laboratory Manual (2020)
- Environment and Climate Change Canada: Biological Test Method Series
- United States Environmental Protection Agency: Whole Effluent Toxicity – Methods for Measuring Acute Toxicity to Freshwater and Marine Organisms
- United States Environmental Protection Agency: Office of Chemical Safety and Pollution Prevention: OCSPP Harmonized Test Guidelines
- American Society for Testing and Materials (ASTM): Environmental Toxicology Standards,
- Organization for Economic Cooperation and Development (OECD): OECD Guidelines for the Testing of Chemicals, Section 2: Effects on Biotic Systems, and
- International Organization for Standardization (ISO): TC 147/SC 5 – Biological Methods

Toxicity test selection rationale must be provided in the detailed risk assessment report. In selecting appropriate toxicity tests from the above-mentioned agencies, the ministry requires QPs to select the best available toxicity test for the contaminated site based on:

1. relevance of test species to species present at the site;
2. sensitivity of test species to the contaminant(s) of concern for the site;
3. relevance of test exposure duration;
4. use of test or toxicological effect endpoints appropriate to the mechanism of toxicity of the contaminant(s) of concern for the site; and
5. extent and representativeness of site phylogenetic diversity when batteries of toxicity tests are used.

4.4.5 Toxicological Endpoints

In ecological risk assessment, all relevant toxicological endpoints (effects concentrations, ECx) must be considered. Preference must be given to sub-lethal endpoints. The toxicological endpoints selected must be applicable to receptors at the site. Toxicological endpoints include but are not limited to:

- any reproductive endpoint (e.g., number of offspring, number of eggs laid, eggshell quality, fruit size and yield, presence of deformities in embryos or young),
- growth rates,
- lethality,
- tumour formation or other gross deformities in embryos or young,
- phototoxicity,
- olfactory impacts,
- hypoxia; or scoliosis.

4.4.6 Ecological Effects Concentrations

Ecological receptors must be protected to levels equivalent to or, more protective than, the levels of protection (Effect Concentration; ECx) identified in Table 1 below. The detailed risk assessment report must include specific details of the selected ECx levels.

Table 1: Protection levels by land and water use for ecological receptors in risk assessment on contaminated sites in B.C.

Land or Water Use	Level of Protection
Industrial	Concentration causing effects to 50% of the organisms exposed (EC_{50})
Commercial	EC_{50}
Residential*	Concentration causing effects to 20% of the organisms exposed (EC_{20})
Urban Park	EC_{20}
Agriculture	EC_{20}
Wildlands	Natural: concentration causing effects to 15% of the organisms exposed (EC_{15}); Reverted: concentration causing effects to 25% of the organisms exposed (EC_{25})
Sediment	Typical: a 50% probability of observing an EC_{20} Sensitive: a 20% probability of observing an EC_{20}
Aquatic life	EC_{20}
Irrigation Water	No adverse effect over the course of one growing season
Livestock Watering	No adverse effect to population of livestock from chronic exposure
Species at Risk (all land and water uses)	Protected at the individual level (to live, reproduce and thrive)

* Both high density and low density land uses.

4.4.7 Weight-of-Evidence in Ecological Risk Assessment

Weight-of-evidence ecological risk assessments use a method for decision-making that involves consideration of multiple sources of information and lines of evidence. Using a weight-of-evidence approach avoids relying solely on any one piece of information or line of evidence in describing risk on

a contaminated site. Weight-of-evidence is a tool QPs can use in DRA to describe a fulsome risk scenario.

QPs must document in the detailed risk assessment report the use of scientifically defensible approaches and sources of information for any risk assessment using a weight of evidence approach. QPs must consider the following guidance:

- Science Advisory Board for Contaminated Sites in B.C.: Guidance for Weight of Evidence Approach (2010)
- Environment and Climate Change Canada's (FCSAP): Ecological Risk Assessment Guidance (2012), Chapter 5.5

4.5 Risk Characterization

For detailed risk assessment reports, the calculation of risk metrics is required to estimate the magnitude and severity of risks and inform risk management and decision making. Risk metrics include hazard quotients (HQs), hazard indices (HI), and/or human lifetime cancer risks (known as incremental lifetime cancer risks (ILCRs)). Protocol 30 contains requirements on identifying a carcinogenic substance.

The following must be included in the risk characterization section of the detailed risk assessment report for **human receptors**:

1. Non-carcinogenic substances
   a) A calculation of HQs for each COPC and complete exposure pathway with and without risk controls;
   b) A calculation of hazard index for each COPC equal to the sum of HQs for each substance over all exposure pathways (regardless of whether COPC concentrations exceed CSR standards in all exposure media), unless toxicity is pathway specific; and
   c) When a common target organ or mechanism of toxicity is shared by multiple exposure pathways or COPCs, a cumulative hazard index for those COPCs.

2. Carcinogenic substances
   a) A calculation of ILCRs for each carcinogenic substance for each complete exposure pathway with and without risk controls. If applicable to the site, ILCRs may be required to evaluate each sensitive lifestage; and,
   b) A calculation of total lifetime cancer risk due to exposure to each carcinogenic COPC.

Note: For carcinogens, both carcinogenic and non-carcinogenic risk estimates must be provided unless robust rationale can be provided for the exclusion.

The following must be included in the risk characterization section of the detailed risk assessment report for **ecological receptors**:

1. For each COPC,

   a. calculation of a HQ for lower trophic level organisms with direct immersion in the environmental media and no measurable ingestion pathway (e.g. invertebrates and plants, etc.), and
   b. calculation of a cumulative hazard index for higher trophic level organisms where multiple exposure pathways are complete and can be summed (e.g. soil and food ingestion); and
2. Where best available science indicates a common target organ or mechanism of toxicity is shared by multiple COPCs, a cumulative hazard index for all those COPCs.

Where a QP preparing a DRA considers that the requirements specified in items 1 or 2 above for either human or ecological receptors is inappropriate or unfeasible, the DRA must provide an explanation of why this is true and provide analysis and justification for whether the risks are acceptable or unacceptable. A clear interpretation of all cumulative risk estimates must be provided and risk estimates must be categorized as acceptable or unacceptable as defined in Section 1.0.

4.6 Uncertainty Analysis

Uncertainty in the risk assessment must be stated as a number or in prose explicitly, including implications of the identified uncertainties. Uncertainties for the exposure and effects assessment datasets (e.g., uncertainty in TRVs) and statistical analysis, and risk characterizations must be identified. The complexity of the uncertainty analysis must be commensurate with the complexity of the DRA.

4.7 Risk Interpretation and Conclusions

Risk assessment conclusions must be clearly summarized and categorized as acceptable or unacceptable risk as defined in Section 1.0. Conclusions must correspond to measurement and assessment endpoints identified in the problem formulation.

The detailed risk assessment report must include interpretation of statistics (and trends where applicable) for contamination. Tools may be used to assist with risk characterization and interpretation (e.g., graphical or tabulated communication of risk assessment conclusions).

5.0 Detailed Risk Assessment Report Submission Requirements

This protocol must be followed in the preparation and submission of a complete detailed risk assessment report as required by the EMA, and CSR section 18 and 18.1 described in Section 2.0 above.

5.1 Requirements for Report Completeness

To be considered complete, detailed risk assessment reports must:

1. Take the form of a stand-alone document that provides all results pertinent to the risk assessment performed, contains all the parts set out in Section 4.0 and meets all the

requirements of this protocol. If the results of previous investigations, reports or assessments are referenced, a complete summary of the previous results must be included and evaluated.

2. Be accompanied by a DSI indicating that the site meets the criteria set out in Section 2.4 of this Protocol. A QP preparing a detailed risk assessment report is not responsible for ensuring that a DSI was completed according to the requirements of the CSR; however, a risk assessment that is not based on a comprehensive DSI as per Section 2.4 of this protocol is considered incomplete.

3. Follow, as applicable, ministry risk assessment protocols, policy and associated guidance (e.g., including but not limited to Protocol 20, Protocol 30, and Technical Guidance 15 (to the extent that it is incorporated into this Protocol). It is also strongly recommended that detailed risk assessments and reports follow ministry guidance, including the Technical Guidance for Risk Assessors and Technical Guidance 15 in order to facilitate approvals.

4. Contain the Protocol 20 checklist where an ecological risk assessment has been completed.

5. Provide sample calculations to demonstrate the determination of risk for each receptor and pathway.

6. Include the professional statement in Appendix 1 of this Protocol; is duly signed and where applicable bears the Professional Society stamp of the QP risk assessor(s) who completed the risk assessment.

5.2 Errors and omissions

Table 2 lists the most frequently noted errors and omissions specific to detailed risk assessment reports. The detailed risk assessment report must be sufficiently comprehensive and sufficiently recent to reflect current site contaminants, conditions, receptors, exposures, and risks and present information on future site conditions and risk.

Table 2. Most frequently noted examples of errors and omissions in contaminated site detailed risk assessment reports submitted to the ministry

Common examples of major errors or omissions	Common examples of minor errors or omissions
• Risk assessment does not evaluate risk before and after risk controls are implemented • Risk assessment does not include or evaluate all contaminant: sources, contaminants, transport or exposure pathways • Vapours addressed in the detailed site investigation with attenuation factors other than those described in Protocol 22 "Application of Vapour Attenuation Factors to	• Risk assessment lacks an analytical data summary including: minimum, maximum, median, mode, average, 90th percentile and 95% upper confidence limit of the mean estimates

Common examples of major errors or omissions	Common examples of minor errors or omissions
Characterize Vapour Contamination" Version 1.0 were not included in the risk assessment • Risk assessment lacks a conceptual site model or the conceptual site model provided does not evaluate all site exposure pathways and/or site receptors • Risk assessment does not evaluate the potential for bioaccumulation, bioconcentration and/or biomagnification • Risk calculations are not included for all receptors, environmental media or COPCs • Risk assessment does not assess credible exposure scenarios and/or uses unrealistic exposure assumptions, resulting in risk estimates that are either excessively simplistic or unreasonably over-conservative for use in risk management decisions • Exposures are not summed for all contaminants of concern (1) that share an identical mechanism of toxicity and target organ, (2) across exposure pathways and/or (3) across environmental media	• Conceptual site model for current and/or future land, vapour, and water use(s) contains minor errors or omissions • TRVs are not supported by a rationale for their selection • TRVs are not provided with a valid citation • Risk estimates are calculated incorrectly • A worked example for all types of calculations performed to produce risk estimates is not provided

This protocol provides criteria and examples relevant to determining if a risk assessment report is incomplete or contains errors of sufficient magnitude to require the return of the report for correction and/or resubmission. Note that the authority of the director to return a submission based on completeness or errors is not limited by the content of this protocol.

Detailed risk assessment reports found to be incomplete or which are found to contain a major error will be returned for resubmission in accordance with ministry policy, the EMA, and CSR requirements. The director may return any risk assessment containing multiple minor errors that in combination would potentially act to substantively change the conclusions of the risk assessment.

6.0 Risk Management

6.1 Risk Controls and Performance Verification Plans

Risk controls ensure that risk-based standards are met and continue to be met at a site. The maintenance of risk mitigation measures and specific risk controls are supported by Performance Verifications Plans (PVPs).

Section 53 (3)(c) of EMA and CSR section 18 and 18.1 require a plan for containing, controlling and monitoring any substances remaining on the site in excess of standards as a pre-condition to issuance of a Certificate of Compliance or the director's acceptance of risk-based standards. CSR section 49 (2) requires information on the quality and performance of remediation measures on completion of

remediation. CSR section 47 also require applicants for Approval in Principle to provide a proposed remediation plan and additional information necessary for the director to determine whether remediation standards are likely to be complied with. A PVP must be included in applications for contaminated sites legal instruments supported by a detailed risk assessment that rely on engineered or institutional risk controls to meet risk-based standards. Note: If engineered risk controls are used to ensure risk-based standards are met and continue to be met, the PVP must contain contingency actions. A PVP that supports a risk assessment report should be submitted with the application for contaminated sites services.

6.2 Decision Process

Risk management decisions for contaminated sites are made based on the outcome of human health and ecological heath risk assessments. In some cases, stakeholder concerns and ecosystem services may be considered at a contaminated site to assist in decision making for risk management. QPs recommend to the ministry whether risks are acceptable on a contaminated site. The director's decision on whether risks are acceptable is a pivotal point in contaminated sites remediation. The finalization of risk conclusions may be an iterative process between the applicant and the reviewer (Approved Professional, ministry reviewer, and/or the director) with the results supporting risk management decisions.

EMA section 60 reserves the right for the director to take further action including issuance of remediation orders in certain situations, including if activities occur on a site that may change its condition or use, a responsible person fails to exercise due care in managing contamination, or information becomes available leading to a reasonable inference that the site poses a threat to human health or the environment. For example, subsequent monitoring could indicate discrepancies in assumptions used in the risk assessment or risk assessment assumptions and recommendations could prove to be incorrect. Adequate risk characterization and uncertainty analysis assists with mitigating the potential for a site to trigger follow up action by the ministry.

Revision history

Approved Date	Effective Date	Document Version	Notes
	January 1998	1	Title: "Recommended Guidance and Checklist for Tier 1 Ecological Risk Assessment of Contaminated Sites in British Columbia"
February 1, 2021	February 1, 2021	2	Major revisions to support CSR Stage 13 amendment
May 13, 2021	May 13, 2021	3	Revisions to reflect application of the *Professional Governance Act*
February 1, 2023	February 1, 2023	3.1	Updated qualified professional definition
March 23, 2023	March 1, 2023	4	Minor revisions to align with CSR Stage 14 amendment

Appendix 1

Professional Statement and Signature of Qualified Professional Completing the Detailed Risk Assessment Report

Professional statement and signature:

I declare that I am a qualified professional with the required knowledge, skills and experience to provide expert information, advice and/or recommendations in relation to the specific work described above.

As a qualified professional, I confirm the:

1. Risk Assessment referred to above has been conducted in accordance with the *Environmental Management Act*, Contaminated Sites Regulation, director approved protocols, procedures, guidance and standard professional practice; and
2. Information used in the performance of the risk assessment and the conclusions of the risk assessment reported herein are true based on my knowledge as of the date completed.

_____	_____	_____
Print Name	Signature	Date completed

<Apply applicable Professional Society stamp>

< If multiple signatories, add additional statements and signature blocks on new pages as required.>

Note
The ministry considers all risk assessor signatories to be jointly and equally responsible for all aspects of a detailed risk assessment report submitted in support of an application for an Approval in Principle or a Certificate of Compliance under the *Environmental Management Act* and Contaminated Sites Regulation.

Appendix 2

Professional Statement and Signature of Qualified Professional Completing the Habitat Assessment

Professional statement and signature:

I declare that I am a qualified professional with the required knowledge, skills and experience to provide expert information, advice and/or recommendations in relation to the specific work described above.

As a qualified professional, I confirm:

1. I have demonstrable experience in, and my area of practice includes, the assessment of ecological habitat evaluated in this risk assessment.
2. The habitat assessment done as part of the detailed risk assessment was completed and the report was prepared in accordance with Protocol 1, and any other protocols relevant to the habitat assessment, and are true and accurate based on current knowledge as of the date completed.

_____	_____	_____
Print Name	Signature	Date completed

<Apply applicable Professional Society stamp>

< If multiple signatories, add additional statements and signature blocks on new pages as required.>