FINAL

Risk Management Decision Framework for BC Contaminated Sites

Phase 2 – Guiding Principles for Applying Risk-based Standards to Ecological Receptors

For Review

Prepared for:

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May 2016 (revised August 2016)

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Project No. CSAP-15-03

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USE AND LIMITATIONS OF THIS REPORT

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ACKNOWLEDGEMENTS

Research and Development funding for this work was provided by the Contaminated Sites Approved Professionals (CSAP) Society.

This Phase 2 report was prepared by Patrick Allard and Cheryl Mackintosh of Azimuth Consulting Group Partnership (Azimuth). Beth Power (Azimuth), provided advice and peer review. Angela Crampton (Azimuth) assisted with project coordination and provided valuable technical input during Phase 1 of the project.

A core team of CSAP approved professionals was part of a Technical Working Group (TWG) that participated in a workshop and reviewed previous drafts of the Phase 2 material presented herein. Members of the Phase 2 TWG included: Mike Rankin, Trish Miller, Sam Reimer, Michael McLeay, David Williams (representing CSAP), and Reidar Zapf-Gilje. A representative from MOE (Heather Osachoff) participated in the TWG and gathered input from other MOE staff. Tara Kennedy and Scott Steer were part of the Phase 1 TWG. The contributions of all of these individuals are gratefully acknowledged.

1. INTRODUCTION

1.1. Background and Needs

Risk assessment practitioners, including qualified professionals (QPs) and approved professionals (APs), recognize the need for a clearer decision-making process with respect to the management and remediation of contaminated sites. Where Contaminated Sites Regulation (CSR) numeric standards are being applied for remediation, decisions can be made using current guidance and policy (i.e., numerical-based approach). Where risk-based standards are being applied, especially for ecological risks, there is greater uncertainty in outcomes for all involved (e.g., property owners, QPs, standards and risk APs, Ministry of Environment [MOE] Land Remediation Section staff, affected parties). In contrast to human health risk assessment (HHRA; CSR Section 18.1), there are no clear, functional criteria established in regulation to determine if risk-based standards are met or not in ecological risk assessment (ERA; CSR Section 18.6). A more formalized process is needed to link risk assessment (RA) with risk management (RM) and define guidelines around risk acceptability. This process needs to be clear, fair and scientifically defensible, resulting in more consistent practice while still allowing flexibility and professional judgement.

In 2014-2015, Azimuth Consulting Group Partnership (Azimuth) led a technical working group[1] (TWG) comprised of risk APs to begin addressing some of these RA/RM challenges. Phase 1 of the RA/RM process was funded by the Contaminated Sites Approved Professional (CSAP) Society (through the Technical Review Committee [TRC]) and resulted in two deliverables:

1. A draft flowchart and explanatory text for a contaminated site going through the CSR process, with emphasis on decision-making related to applying risk-based standards; and,
2. An annotated compilation of available CSR policies and guidance related to acceptability of ecological risk, considered a "pre-cursor" to the future development of guiding principles.

The main goal of this report is to present the methods and key deliverables for Phase 2 of the RA/RM process, which is specifically aimed at developing guiding principles for APs to apply in review of applications that use risk-based standards for ecological receptors.

[1] Members of the Phase 1 TWG included: Tara Kennedy, Trish Miller, Sam Reimer, Scott Steer, David Williams (representing CSAP), and Reidar Zapf-Gilje. A representative from MOE (Heather Osachoff) participated in the TWG and gathered input from other MOE staff.

1.2. Objectives and Approach

Specific objectives of this document are to:

- Provide a flow chart and supporting tools to harmonize decision-making among APs (and, by extrapolation, QPs) regarding the interpretation of risk-based standards in ERA; and,
- Eventually, support development of CSAP practice guidelines and possibly CSR technical guidance.

To achieve these objectives, the following approach was adopted:

- We built on final deliverables from Phase 1 submitted to CSAP in June 2015 (see **Section 1.1**);
- We conducted a series of internal Azimuth research and development (R&D) working sessions in summer and fall 2015 to develop an internal working version (v1.0) of Phase 2 guiding principles for applying risk-based standards to ecological receptors;
- In early January 2016, v1.0 was distributed to members of the Phase 2 TWG[2] and we organized a first workshop on January 27, 2016 to gather comments and identify initial gaps/revisions;
- Based on feedback obtained from the TWG, v2.0 was developed;
- A second workshop was held with the TWG on April 14, 2016 to review v2.0 and identify outstanding issues that required revisions; and,
- We prepared v3.0 for submission to CSAP's TRC along with supporting documentation.

1.3. Report Structure

This report is organized as follows:

- **Section 2**: core deliverables that will support decision-making by APs;
- **Section 3**: references cited;
- **Appendix A**: updated version of the Phase 1 annotated compilation of CSR policy and guidance on risk-based standards for ecological receptors;
- **Appendix B**: a list of action items taken from **Appendix A** which appear to warrant further discussions between CSAP risk APs and MOE;

[2] Members of the Phase 2 TWG included: Mike Rankin, Trish Miller, Sam Reimer, Michael McLeay, David Williams (representing CSAP), and Reidar Zapf-Gilje. Heather Osachoff (MOE) also continued her participation and gathered input from other MOE staff.

- **Appendix C**: agenda for the first TWG workshop (January 27, 2016) and detailed comments provided by the TWG on v1.0 of the guiding principles;
- **Appendix D**: summary of decisions and actions made during the first TWG workshop (January 27, 2016) to guide preparation of v2.0; and,
- **Appendix E**: TWG pre-meeting comments as well as a summary of decisions made during the second TWG workshop (April 14, 2016) to support this final document (v3.0).

2. GUIDING PRINCIPLES FOR APPLYING RISK-BASED STANDARDS TO ECOLOGICAL RECEPTORS

2.1. Overview

Decisions for managing risks at contaminated sites regulated under the CSR in British Columbia (BC) are ultimately governed by whether human health and ecological risks meet CSR risk-based standards. The objective of this deliverable is to provide a decision-making tool for APs when interpreting risk-based standards for ERAs submitted under Protocol 6. The tool lays down the foundation for evaluating the completeness and technical adequacy of an ERA using existing guidance documents and practice guidelines. It then provides a conceptual depiction of risk and uncertainty accompanied by a set of narratives to guide the AP (and QP) in determining whether risk-based standards have been met. The tool is meant to facilitate decision-making while still allowing flexibility and professional judgment when evaluating risk predictions and their implications for issuing regulatory instruments under the CSR.

This section is organized as follows:

- Background for development of the guiding principles, including an annotated compilation of CSR policy and guidance, and a summary of the roles of QPs and APs as risk assessors under the CSAP review process; and,
- Decision-making tool and narratives to support APs in their review of ERAs, including the application of risk-based standards.

2.2. Background

2.2.1 Annotated Compilation of CSR Policy and Guidance

The first step in developing guiding principles for interpreting risk-based standards for ecological receptors was a compilation of existing CSR policy statements and definitions related to risk-based standards, narrative protection goals or statements of acceptability, acceptable effects levels (AELs), and risk calculations. This information, which is provided in **Appendix A** (updated from Phase 1), is not new; it reflects what is currently available to risk assessors and risk managers to guide their professional judgment on the acceptability of risk. **Appendix A** is annotated to draw attention to particularly relevant notions and also identify limitations and/or challenges in using available policy and guidance.

From **Appendix A**, we made a list of action items which appear to warrant further discussions between CSAP Risk APs and MOE. This tracking list is provided in **Appendix B**.

2.2.2 Roles of Risk Assessors as QPs and APs

The CSR definitions of APs and QPs are provided in **Appendix A**. This section further clarifies their roles in the context of the CSAP review process. For instance, the role of QPs is to prepare ERAs that describe

risks, uncertainties, and reach conclusions on whether risk estimates meet risk-based standards for each receptor group or assessment endpoint. Over the course of the ERA, QPs can obtain feedback from MOE and/or APs (arm's length). This can be an iterative process where incremental ERA studies are conducted until a sound remediation decision can be made. If an ERA is submitted under Protocol 6, the role of APs is to "mimic" or emulate the MOE decision-making process and determine whether the ERA's conclusions (and associated documentation) are administratively complete, technically sound, and meeting risk-based standards in which case issuance of a CSR instrument can be recommended to MOE.

2.3. Decision-making Tool and Supporting Narratives

2.3.1 Risk AP Review Process for ERAs Submitted Under Protocol 6

Figure 1 is a flowchart showing the risk AP review process for ERAs submitted in support of risk-based instruments (e.g., certificates of compliance [CofCs] and approvals in principle [AiPs]), with emphasis on decision-making related to applying risk-based standards for ecological receptors per CSR Section 18.6. This flowchart sets the stage for understanding key decision nodes and provides linkages to relevant narratives meant to support interpretation of risk-based standards for ecological receptors. **Figure 1** along with **Tables 1 and 2** serve as a decision-making tool for APs (and QPs) to standardize practice to a greater extent and provide a more transparent basis for conducting reviews of ERAs submitted under Protocol 6. This tool may also provide a useful basis for submission of ERAs to MOE.

Descriptions of each step are provided below; numbering corresponds to box numbers in **Figure 1**.

- **Box 1**. QP Submission of ERA to AP – This step is the starting point of the AP review process under Protocol 6 for Contaminated Sites, which begins in **Box 2a**.
- **Box 2a**. AP Review of ERA Completeness and Technical Adequacy – This step is an initial check by the AP to confirm that the ERA is complete and technically. It involves two main steps:

  (1) Confirming that the protection goals, AELs and assessment endpoints used in the ERA are adequate, given the goalposts provided in **Table 1** of this document (see **Section 2.3.2**).

  (2) Confirming that the ERA is complete, according to the CSAP Risk Assessment Practice Guidelines Checklist. This Checklist references all relevant CSR policies, protocols ("P"), procedures, administrative and technical guidance ("AG" and "TG"), and technical bulletins ("TB") (e.g., P1, P20, Procedure 10, Tier 1 ERA Policy Decision Summary, AG10, AG14, TG4, TG6, TG7 and TG15), which also must be adhered to for a complete and adequate submission.

  If the ERA submission is deemed complete and adequate, the review can proceed to **Box 2b**. However, if the submission is considered incomplete or inadequate, the review proceeds to **Box 3** or **Box 4**.

- **Box 2b**. AP Review of ERA Conclusions and Application of Risk-based Standards – In this step, the AP reviews the conclusions of the ERA for each assessment endpoint (as submitted by the QP and based on the AP's professional judgment) and determines whether risk-based standards are met. **Box 2b** illustrates how different ERA outcomes, in terms of risk and uncertainty, might conceptually be interpreted. This figure, along with the narratives provided in **Table 2** (see **Section 2.3.3**), are the core tools that define risk-based standards in these guiding principles. Essentially, the degree of risk and associated uncertainty (specifically the potential for underestimating risks), define whether risk-based standards for a particular assessment endpoint are met. There are three potential outcomes:

  (1) Meets risk-based standards (area shown in green on the **Box 2b** figure) – This outcome is associated with risks in the negligible and low categories, and situations where there is a low to moderate potential for underestimating risks. The review process proceeds to **Box 5** in this case.

  (2) Does not meet risk-based standards (area shown in dark grey on the **Box 2b** figure) – This outcome is associated with risks in the moderate and high categories and any level of uncertainty (defined as the potential for underestimating risks). The review process proceeds to **Box 6** in this case.

  (3) May meet risk-based standards (area shown in light grey on the **Box 2b** figure) – This outcome is associated with low risks with a high potential for underestimating risks. It may also be associated with negligible risks with a high potential for underestimating risks. If the ERA findings fall into this category, the QP should provide a strong rationale for categorizing risks as low (i.e., provide confidence that risks are not moderate) and for enabling sound management decisions despite the high uncertainty. The ERA review process may proceed to **Box 5** (if the AP agrees that risks are "low") or to **Box 6** (if uncertainty is considered too high to proceed).

- **Box 3**. QP Revisions and Further AP Review – When the initial ERA submission is deemed incomplete or inadequate (**Box 2a**), the QP may make revisions to the ERA and re-submit for further AP review (arm's length) under Protocol 6 (i.e., return to **Box 2a**).

- **Box 4**. AP Rejects Submission – An AP may reject the ERA submission when there are significant deficiencies in the ERA, and/or the QP does not address the deficiencies.

- **Box 5**. AP Recommendation and Review of CSR Instruments and Documents – In cases where ERA conclusions meet risk-based standards, the AP reviews CSR documents (e.g., Summary of Site Conditions) and makes a recommendation to MOE to issue a CSR instrument (e.g., Certificate of Compliance, Approval in Principle, Performance Verification Plan, Operations and Maintenance plan, Contingency Plan).

- **Box 6**. ERA Does Not Support Instrument Under Protocol 6; QP to Evaluate Other Options – In cases where ERA conclusions do not meet risk-based standards, issuance of a CSR instrument under Protocol 6 is not supported. The QP may evaluate other options (e.g., remediation, EMA Section 56) outside of the AP review process.

2.3.2 Protection Goals, Acceptable Effects Levels (AELs) and Assessment Endpoints

Problem formulation is arguably the most important stage of an ERA as it provides the foundation upon which risks and uncertainties are characterized and, eventually, upon which risk management decisions are made. Accordingly, the AP review process needs to revisit the "goal posts" that set the stage for evaluating an ERA submission under Protocol 6. For this purpose, **Table 1** compiles the protection goals (overarching statements for CSR sites), AELs (ranges of acceptable effect sizes, depending on land use) and assessment endpoints which can be found in various CSR documents (e.g., TG7, P1, Tier 1 ERA Policy Decision Summary, Omnibus Update protocol papers[3]), as well as other relevant sources of ERA technical guidance (e.g., Barnthouse et al. 2008, Environment Canada 2012, SAB 2008, 2010, Suter et al. 2000, 2005).

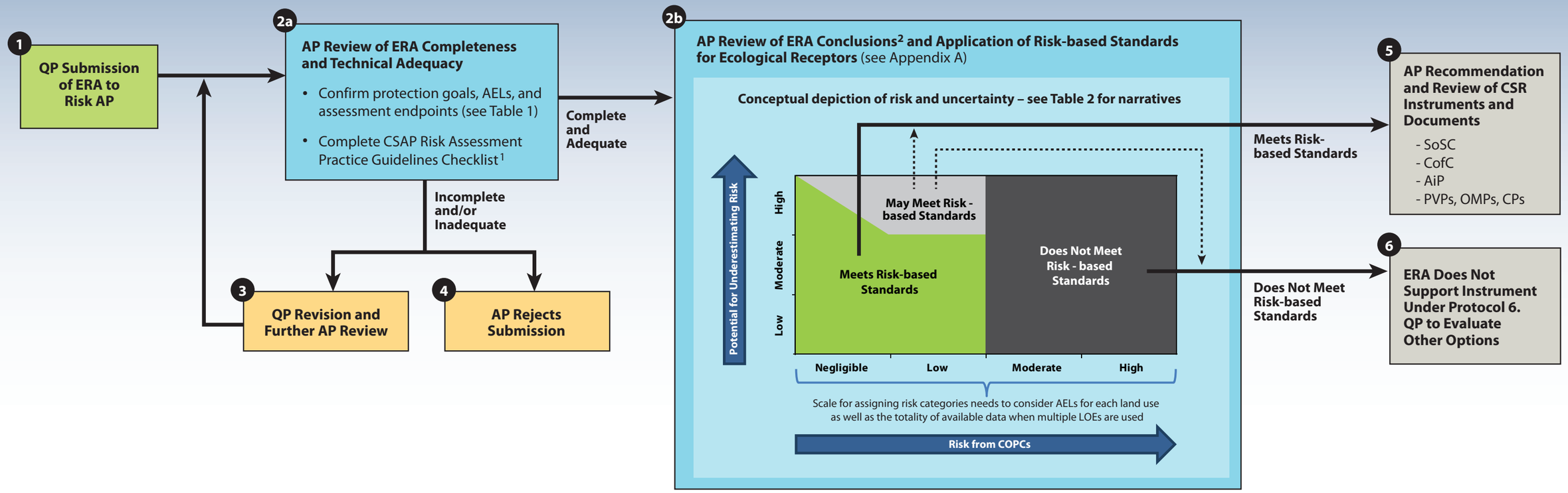
2.3.3 Risk and Uncertainty

As described in **Section 2.3.1**, **Figure 1 (Box 2b)** provides a conceptual illustration of how risk-based standards can be interpreted based on the degree of risk and uncertainty associated with an ERA's assessment endpoint(s). **Table 2** provides supporting narratives, including examples, for different categories of risk and uncertainty. The risk narratives are modified from the DERA guidance document (SAB 2008), while the uncertainty narratives are new and focus on the implications of uncertainty for risk management decision-making. While uncertainty and its various components are defined in **Table 2**, for the purposes of this document, uncertainty is defined based on the potential for underestimating risks (i.e., Type II error – predicting negligible/low risks when they are in fact moderate/high). This approach is considered particularly relevant for AP reviews under Protocol 6.

Based on the risk and uncertainty findings in the ERA, the AP (and QP) can interpret whether risk-based standards are met or not, and determine whether the issuance of a regulatory instrument should be recommended.

[3] We note that information on draft/proposed AELs from CSR Omnibus Update protocol papers is provided in the table; however, these values are not in effect until signed into force by the BC Minister of Environment. Given the anticipated Omnibus Update, the TWG supported including these values in this document, recognizing that they may need to be revised in the future.

Figure 1: Decision-making tool for interpreting risk-based standards for ERAs submitted under Protocol 6 for Contaminated Sites.



Footnotes:

[1] Checklist includes references to all relevant CSR policies, protocols, procedures, administrative or technical guidance, and technical bulletins.

[2] This applies to each assessment endpoint identified in the ERA.

Acronyms:

AEL – Adverse Effects Level
AiP – Approval in Principle
AP – Approved Professional
CSR – Contaminated Sites Regulation
CofC – Certificate of Compliance
COPC – Contaminant of Potential Concern
CP – Contingency Plan
CSAP – Contaminated Sites Approved Professionals
ERA – Ecological Risk Assessment
LOE – Line of Evidence
OMP – Operations and Maintenance Plan
PVP – Performance Verification Plan
QP – Qualified Professional
SoSC – Summary of Site Conditions

DRAFT

Table 1: Compilation of narratives to support the problem formulation stage of an ERA: protection goals, acceptable effect levels (AELs), and assessment endpoints for ecological receptors at contaminated sites.

Topic	Description		Reference
Generic CSR protection goal for ecological receptors	The primary goal of ERA 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.		Technical Guidance 7
AELs for each land use represented by EC_x[1]	Agricultural (AL)	$EC_{10\text{-}20}$ (Protocol 1, Tier 1); EC_{25} (Omnibus Update)	Protocol 1, Tier 1 ERA Policy Decision Summary, Omnibus Update[2]
	Urban park (PL)	$EC_{10\text{-}20}$ (Protocol 1, Tier 1); EC_{25} (Omnibus Update)	
	Wildland (WL)	$EC_{10\text{-}20}$ (estimated from PL); EC_{15} "Natural" (Omnibus Update); EC_{25} "Reverted" (Omnibus Update)	
	Residential (RL)	EC_{20} (Protocol 1, Tier 1); EC_{25} "Low Density" (Omnibus Update); EC_{50} "High Density" (Omnibus Update)	
	Commercial (CL)	EC_{50}	
	Industrial (IL)	EC_{50}	
	Aquatic life (AW)	EC_{20}	
Assessment endpoints	An assessment endpoint is an explicit expression of the environmental value to be protected. An assessment endpoint is operationally defined by an ecological entity (e.g., organism, local breeding population, specific community) and its attributes (e.g., growth, abundance, function). The spatial area for which the risk is estimated should also be defined. Implementation of the ERA should be sufficient to characterize risks at spatial scales that are: (1) ecologically meaningful; and (2) able to support remediation at a practical level of resolution. An ERA may have one assessment endpoint per receptor group (particularly if the assessment endpoints are broadly worded) or multiple assessment endpoints per receptor group (if assessment endpoints are more specific).		Suter et al. (2000), Suter et al. (2005), SAB (2008), Environment Canada (2012)
	Common species are typically assessed at the community[3,4] or population[5,6] level; however, protection at the level of the individual organism can be warranted for listed species[7]. Furthermore, assessment of habitat considered critical to support listed species may also be needed. CSR documents do not appear to operationalize the listed species protection goal as a lower ECx value. Although reducing the "x" may be an option for the risk assessor, perhaps a more important consideration is the use of endpoints that are representative of individual organisms (not based on community- or population-level metrics).		Technical Guidance 7, SAB (2008), Barnthouse et al. (2008)

[1] DERA (SAB 2008) defines an EC_x as an effect concentration, with percent effect of X. Note that this definition overlaps with the definition of an ICx (inhibitory concentration resulting in X percent effect in a given endpoint) which is commonly used in toxicological literature.

[2] Based on CSR Omnibus Update protocol papers; EC_x values are proposed/draft and not in effect until signed into force by the Minister of Environment.

[3] Community structure may be assessed by considering common metrics (e.g., abundance, faunal composition, species richness, diversity, trophic structure, and size structure) or by using other relevant investigative tools.

[4] Community ecological function may be assessed by considering microbial nutrient cycling, biomass, production or other relevant investigative tools.

[5] The assessment population consist of a group of conspecific organisms occupying a defined area. It is operationally defined as the local population, which consists of all organisms exposed to, or indirectly affected by, contaminants at the site.

[6] Population viability is defined as the ability of a population to sustain itself over the long term. The types of ecological effect endpoints that typically need to be addressed at the population level for common species include acute (e.g., toxicity and lethality) and chronic processes (e.g., reproductive, growth and maintenance, and critical developmental).

[7] Listed species usually consist of the following: red- or blue-listed by the BC Conservation Data Centre, or classified through the Committee on the Status of Endangered Wildlife in Canada (COSEWIC) and the Species at Risk Act (SARA) as "endangered" or "threatened". The types of ecological effects endpoints that can be used for evaluating organism-level effects to listed species maybe similar to those used for common species. In addition, cancer can be an appropriate chronic effect endpoint and can be considered, if data are available and adequate for assessment.

Table 2: Risk and uncertainty narratives to support the interpretation of risk-based standards for ecological receptors. A detailed rationale needs to be provided by the QP and linked to topics described in **Table 1** and the decision-making tool depicted in **Figure 1**.

Risk[1] Characterization
Four risk categories are identified following an evaluation of the totality of available data[2] for each assessment endpoint under a specified land use: • Negligible risk – Applies when requirements of Protocol 13 SLRA (e.g., lack of exposure pathways) are met, or when evidence from all LOEs for an assessment endpoint shows that effect sizes are lower than the AEL for the applicable land use (or appropriate reference[3]) and that HQs, if used for specific LOEs, are less than one (or appropriate reference). • Low risk – Applies when some or all LOEs may indicate adverse effects (e.g., effect sizes greater than the AEL for the applicable land use [or appropriate reference], HQs greater than one [or appropriate reference]), but where the integration of multiple LOEs using WOE indicates that, overall, there are limited ecological consequences to the assessment endpoint. For instance: o The magnitude of effects relative to the applicable land use is considered low based on the type of effect (e.g., growth reduction rather than mortality to organisms, limited impairment to community structure), the effect size (e.g., relatively small difference from AEL), and the spatial and temporal extent of effects (e.g., localized rather than widespread impacts); and, o While some adverse effects are possible, they are considered unlikely based on the WOE. • Moderate risk – Applies when some or all LOEs may indicate adverse effects (e.g., effect sizes greater than the AEL for the applicable land use [or appropriate reference], HQs greater than one [or appropriate reference]) and the integration of multiple LOEs using WOE indicates that, overall, there are substantial ecological consequences to the assessment endpoint. For instance: o The magnitude of effects relative to the applicable land use is considered of greater ecological relevance based on the type of effect (e.g., some reproductive impairment or mortality to organisms, or impairment of community structure), the effect size (e.g., moderate difference from AEL), and the spatial and temporal extent of effects (e.g., some widespread impacts, larger proportion of local populations being affected for common species, or individual organisms being affected for listed species); and, o Adverse effects are likely to occur based on the WOE. • High[4] risk – Applies when some or all LOEs may indicate adverse effects (e.g., effect sizes greater than the AEL for the applicable land use [or relevant appropriate], HQs greater than one [or relevant appropriate]) and the integration of multiple LOEs using WOE indicates that, overall, there are severe ecological consequences to the assessment endpoint:

[1] Risk refers to the magnitude and, where relevant, the probability or likelihood of adverse ecological effects associated with contaminants of potential concern; magnitude refers to the type of effects (e.g., growth impairment, mortality), the effect size, and the spatial and temporal extent of effects; probability or likelihood commonly refer to a way of expressing knowledge or belief that an event or outcome will occur or has occurred (modified from SAB 2008 and Environment Canada 2012).

[2] These definitions apply to ERAs with single or multiple LOEs.

[3] A location, group of locations, or experimental treatment designed to reflect the ambient physical and chemical conditions of a contaminated medium or location in the absence of the contaminants of potential concern related to the site being evaluated in the ERA (Environment Canada 2012) and consistent with naturally occurring background concentrations (see CSR Protocol 4).

[4] The term "high risk" used in this table reflects the magnitude of potential risks to ecological receptors as characterized in a risk assessment. It should not be interpreted as being consistent with the definition of "high risk site condition" per CSR Procedure 8, which means a condition at a site defined under a director's protocol and includes the presence of mobile nonaqueous phase liquids and the potential for high risk exposure to contaminants to occur.

- The magnitude of effects relative to the applicable land use is considered high based on the type of effect (e.g., severe reproductive impairment or mortality to organisms, or impairment of a community's ecological function), the effect size (e.g., large difference from AEL), and the spatial and temporal extent of effects (e.g., widespread impacts, large proportion of local populations being affected for common species, or several organisms being affected for listed species); and,
- Adverse effects are very likely to occur based on the WOE.

Uncertainty Characterization[5] and Implications for Decision-making[6]

Uncertainty is categorized relative to the potential for it to result in changes to the predicted risk category. This can include a directional element to account for the influence of known bias (e.g., to discern between cases where much of the uncertainty is due to known conservatism versus cases without known bias). The implications of uncertainty for decision-making are determined for each assessment endpoint by considering the best estimate of risk and associated uncertainty (in terms of both range and bias). Three categories are identified based on the potential for underestimating risk (i.e., making a Type II error):

- Low potential – Applies when the actual risk category is unlikely to be higher than the current prediction.
- Moderate potential – Applies when the actual risk category could be higher than the current prediction (e.g., + one risk category).
- High potential – Applies when the actual risk category could be much higher than the current prediction (e.g., + two risk categories).

[5] Uncertainty generally refers to imperfect knowledge regarding a given parameter, process, or condition. In ERA, uncertainty is often related to the degree of confidence in the estimate of magnitude and, where relevant, the probability or likelihood of adverse effects, and their cause(s). Uncertainties come in many forms, including natural variability, measurement or parameter error, structural or model uncertainty, and ignorance (modified from SAB 2008 and Environment Canada 2012).

[6] In the face of uncertainty, an ERA should provide a statement regarding the possibility of making Type I errors (false positives) versus Type II errors (false negatives).

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Appendix A

Annotated Compilation of CSR Policy and Guidance on Risk-based Standards for Ecological Receptors

Appendix A is a pre-cursor to **Figure 1** and **Tables 1 and 2** which are presented in **Section 2** of this report. This appendix compiles available statements from CSR policies, protocols, and technical guidance related to the acceptability of ecological risks. This information is not new; it reflects what is currently available to practitioners, reviewers and risk to guide their professional judgment on whether risk-based standards are met or not. **Appendix A** is annotated to draw attention to particularly relevant notions and also identify limitations and/or challenges in using available policy and guidance to interpret whether ecological risks meet risk-based standards within the CSR process.

In annotating this table, members of the TWG for this project also identified various topics that might warrant further discussions with MOE to ensure a clear understanding and application of its policies for the protection and assessment of ecological receptors. These action items are presented in **Appendix B**.

Appendix A. Annotated compilation of CSR policy and guidance on risk-based standards for ecological receptors (May 2016).

No.	CSR POLICY AND GUIDANCE	SOURCE	NOTES AND IMPLICATIONS
Section A: Policy Statements and Definitions Related to Risk-based Standards			
A1	"56 (1) A person conducting or otherwise providing for remediation of a site must give preference to remediation alternatives that provide permanent solutions to the maximum extent practicable, taking into account the following factors: (a) any potential for adverse effects on human health or for pollution of the environment; (b) the technical feasibility and risks associated with alternative remediation options; (c) remediation costs associated with alternative remediation options and the potential economic benefits, costs and effects of the remediation options; (d) other prescribed factors. (2) When issuing an approval in principle or a certificate of compliance, a director must consider whether permanent solutions have been given preference to the maximum extent practicable as determined in accordance with any guidelines set out in the regulations."	Environmental Management Act http://www.bclaws.ca/Recon/document/ID/freeside/03053_00 *published March 25 2015*	*These definitions provide valuable context for the application of risk-based standards.* *Section 56 (2) requires the director to give preference to permanent solutions as much as possible. It is challenging to define permanence under this provision – The Ministry of Environment (MOE) may consider that a "remediation concentration goal" is the metric (see draft Protocol 5 [still in the works] and Procedure 8).The point here is not the definition of permanence but that the context of Section 56 lends greater import to the need for clear, defensible rationale for non-permanent solutions.* *In ERA, the development of "remediation concentration goals" can be challenging for various reasons:* • *Many ERAs rely on weight of evidence (WOE) approaches that integrate multiple lines of evidence (LOEs), which make it difficult to determine a "safe" concentration target; rather, the WOE usually serves to identify portions of site or particular media that result in levels of effects that might "meet" or "do not meet" risk-based standards (based on overall exposure).* • *Wildlife ERAs often estimate exposure based on habitat features of a site (e.g., chemical exposure weighted by foraging suitability of different habitat polygons for each receptor); therefore, a "safe" dose depends on receptor, habitat type and media concentration.* • *Many ERAs assess risks of contaminant mixtures; a chemical-specific "safe" concentration is difficult to identify, unless causality is well established; toxicity may also be altered over time (e.g., PHC biodegradation).*
A2	"1 (2) For the purposes of this Act, a detrimental environmental impact occurs when a change in the quality of air, land or water substantially reduces the usefulness of the environment or its capacity to support life."	Environmental Management Act http://www.bclaws.ca/Recon/document/ID/freeside/03053_00 *published March 25 2015*	
A3	"pollution means the presence in the environment of substances or contaminants that substantially alter or impair the usefulness of the environment"	Environmental Management Act http://www.bclaws.ca/Recon/document/ID/freeside/03053_00 *published March 25 2015*	

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A4	"remediation" means action to eliminate, limit, correct, counteract, mitigate or remove any contaminant or the adverse effects on the environment or human health of any contaminant, and includes, but is not limited to, the following: (a) preliminary site investigations, detailed site investigations, analysis and interpretation, including tests, sampling, surveys, data evaluation, risk assessment and environmental impact assessment; (b) evaluation of alternative methods of remediation; (c) preparation of a remediation plan, including a plan for any consequential or associated removal of soil or soil relocation from the site; (d) implementation of a remediation plan; (e) monitoring, verification and confirmation of whether the remediation complies with the remediation plan, applicable standards and requirements imposed by a director; (f) other activities prescribed by the minister.	Environmental Management Act http://www.bclaws.ca/Recon/document/ID/freeside/03053_00 *published March 25 2015*	
A5	Application of risk-based standards for remediation CSR Section 18 (6) A person who applies the risk-based standards of this section must also prepare an environmental risk assessment report which identifies (a) the potential onsite and offsite environmental risks of any substances causing contamination before and after remediation, and (b) procedures, including monitoring, designed to mitigate any significant potential risks identified in paragraph (a). CSR Section 18 (7) A director may impose requirements on a responsible person to prevent or mitigate risks identified (a) in the environmental risk assessment report required under subsection (6), or (b) by the director using other available data.	Contaminated Sites Regulation http://www.bclaws.ca/civix/document/LOC/complete/statreg/--%20E%20--/Environmental%20Management%20Act%20[SBC%202003]%20c.%2053/05_Regulations/21_375_96%20-%20Contaminated%20Sites%20Regulation/375_96_01.xml#section18 *includes amendments to January 31 2014*	*CSR language for applying risk-based standards to ecological receptors. This mentions the need to "mitigate any significant potential risks".*
A6	"ecological risk assessment" means a qualitative or quantitative appraisal of the actual or potential impacts of contaminants on biota other than humans. "risk assessment" [RA] means the systematic process of identifying and evaluating substances, persons potentially affected, and exposures to the substances in order to estimate cancer risks or hazard indices in accordance with a director's protocol. [Source – Section 1, Contaminated Sites Regulation] "risk-based standards" means the standards prescribed in sections 18 and 18.1 of the Regulation. "risk management" [RM] means actions, including monitoring, designed to prevent or mitigate risks to human health or the environment caused by contamination at a site. [Source – Section 1, Contaminated Sites Regulation]. Risk management may include institutional controls and engineering controls.	Procedure 8 – Definitions and Acronyms for Contaminated Sites http://www2.gov.bc.ca/gov/DownloadAsset?assetId=93799F13FEF0485A9055A55731476A66&filename=procedure-08-2014.pdf *valid November 20, 2015*	
A7	"remediation plan" [RP] means a written document which may include, but is not necessarily limited to, plans and other information respecting (a) overall site location and delineated horizontal and vertical locations of contamination presented in maps, cross-sections and other graphic representations, (b) remediation alternatives which were considered for managing contamination from or at a site, and evaluation methods used to assess the factors under section 56 of the Act, (c) remediation methods selected to ensure compliance with the numerical standards, or the risk based standards	Procedure 8 – Definitions and Acronyms for Contaminated Sites http://www2.gov.bc.ca/gov/DownloadAsset?assetId=93799F13FEF0485A9055A55731476A66&filename=procedure-08-2014.pdf, *November 20, 2015*	*Shows how risk-based standards are considered in remediation and remediation planning.*

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	prescribed in this regulation, and the conditions imposed by a director under section 53 of the Act or in a remediation order, (d) identification and classification in accordance with the numerical standards of the substances in any soil, surface water, groundwater, sediment or vapour to remain in place, (d.1) identification and classification in accordance with the numerical standards of the substances in any soil or sediment to be relocated, (e) risk assessment calculations and methodology to demonstrate compliance with risk-based remediation standards if remediation is assessed relative to the risk-based remediation standards, (f) a schedule with estimated dates for implementing remediation, (g) identification and discussion of the effects of known regulatory requirements on remediation, including any authorizations which will be required to implement remediation, (h) proposed confirmatory sampling, analysis, testing or monitoring during and after treatment, management or removal of contamination, (i) proposed measures and controls to ensure security, including covenants under section 219 of the Land Title Act, restrictive covenants and financial security in accordance with section 48 of this regulation, for ongoing management of any contamination if it will be managed at the site, and (j) any public consultation or review of remediation which has occurred or which is proposed during remediation."		
A8	"remediation concentration goal" means a concentration of a substance in soil, water, sediment or vapour which must be met in order for a site to be considered to meet the remediation standards of the Contaminated Sites Regulation and includes: (a) a numerical standard (b) a site-specific numerical standard, (c) a background concentration for the site , and (d) a site-specific risk-based concentration. "	Procedure 8 – Definitions and Acronyms for Contaminated Sites http://www2.gov.bc.ca/gov/DownloadAsset?assetId=93799F13FEF0485A9055A55731476A66&filename=procedure-08-2014.pdf, *November 20, 2015*	*A site-specific risk-based concentration that "meets" remediation standards is difficult to establish when there is no clear definition of what meets or does not meet risk-based standards for ecological receptors.*
Section B: Narrative Protection Goals or Statements on Ecological Risks			
B1	"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 in British Columbia." "Despite the primary focus on assessing effects and impacts at the community, population or species level in ecological risk assessment, in some circumstances assessment at the individual organism level may be required. For example, some applicable legislation (e.g., Canadian Federal Species at Risk Act and B.C. Wildlife Act) requires protection at the level of the individual organism for rare and endangered species. In addition, assessment of habitat considered critical to support rare and endangered species or individuals may be needed." "Contaminated sites that meet [Protocol 13] SLRA benchmark screening criteria are considered to satisfy Contaminated Sites Regulation (CSR) risk-based standards. No further risk assessment or remediation is required at such sites as long as site conditions do not change. Ongoing environmental monitoring, to ensure maintenance of site conditions, may be necessary at SLRA assessed sites." "The use of specified effects levels such as: Effective Dose, Lethal Dose, Effective Concentration or Lethal Concentration, for x percent of exposed organisms (i.e. EDx, LDx, ECx or LCx values, respectively) for the estimation of risks to ecological receptors at the population/species level is generally preferred. Ecological risks are acceptable if the effects	Technical Guidance 7– Supplemental Guidance for Risk Assessments http://www2.gov.bc.ca/assets/gov/environment/air-land-water/site-remediation/docs/technical-guidance/tg07.pdf *Version 4 November 2015*	*These definitions provides important context for overarching protection goals and assessment endpoints.* *Note that the federal Species at Risk Act (SARA) protects organisms of listed species from "harm" and protects "critical habitat" of listed species from destruction, this includes habitat of provincially listed species that occur on federal lands.*

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	levels at the site are less than or equal to the specified effects level for the particular land use applicable at the site." "EcoTRVs are acceptable for use as ecologically relevant benchmarks in ecological risk assessment with the caveat that ecological risk assessments are designed to protect species at the population, rather than at the individual organism level. The types of ecological effect endpoints that typically need to be addressed at the population level for non-endangered species include acute (e.g., toxicity and lethality) and chronic processes (e.g., reproductive, growth and maintenance, and critical developmental)."		
B2	DERA's operational guidance for the use of different narrative descriptors of risk "Negligible risks: Implies that adverse effects, based on the totality of available data, are very unlikely to be present, and that the risk assessor has high confidence that adverse effects will not be present in the future. This term should only be used in situations where multiple lines of evidence demonstrate a lack of adverse effects, and where each line of evidence (or the overall risk estimate) has relatively low uncertainty. Risk management or remediation is not necessary. Hazard quotients, if used as a line of evidence, tend to be less than one, although screening hazard quotients greater than one can still be associated with negligible risk in a WOE. Low risks: Implies that adverse effects are likely not present based on the totality of data available. Low risk differs from the term negligible risk in that the former designation is more appropriate for situations where the conclusion is based on the balance of probabilities. Adverse effects are unlikely to be present, although some data may indicate limited adverse effects, or the uncertainty is such that one cannot definitively exclude potential adverse effects in the future. Risk management or remediation is not necessary. Moderate (or intermediate) risks: Implies that some degree of adverse effects are likely, based on the totality of data available. Risk estimates suggest that risk management or remediation is necessary, unless further refinement of the risk estimate is conducted. High (or severe) risks: Implies that adverse effects are likely (and of relatively high magnitude) based on the totality of data. Risk estimates suggest that risk management or remediation is necessary, and that this conclusion is unlikely to change even if further refinement of the risk estimate is conducted."	(see DERA 2008, Section 6.5): http://www.sabcs.chem.uvic.ca/DERA2008.pdf *published September 2008*	*DERA provides useful narratives for framing decisions about what meets risk-based standards and acceptable levels of uncertainty. Other important topics or concepts that require consideration include:* • *Clarification of receptor groups and endpoints (e.g., lethal, sublethal) being protected under different land uses.* • *Explicit protection goals (e.g., definition and attributes of populations, definition and attributes of community structure and ecological function) to clarify what we are trying to protect – although we recognize the need for being site-specific and allowing professional judgment, we believe that it's important to provide guidance beyond the use arbitrary decision points to draw the boundaries of meeting risk-based standards.* • *Ensure that the concept of causality contributes to describing risk.* • *Outline spatial and temporal scales of interest when defining assessment endpoints, which get reflected in the risk categories and risk predictions.* • *Highlight challenges with applying ECx to categorize risks.* • *Specifically address the topic of HQs (HQ<1 acceptable, but HQ>1 cannot be placed into risk categories based on magnitude alone – understanding of underlying dose-response is needed).* • *Provide distinction between predictions of effect vs. predictions of uncertainty when determining what meets risk-based standards and next steps for risk management.* • *Clarify that risk categorization (e.g., negligible risk) does not necessarily require multiple LOEs if a single LOE provides sufficient evidence to rule out contaminants/pathways.*
B3	"potential terrestrial habitat" means land that satisfies any of the following conditions: a) urban park land use classification applies; b) contains over 50 m2 (where residential land use applies at the site) or over 1,000 m2 (where commercial or industrial land use applies at the site) of contiguous undeveloped land; or c) lies within 300 m (where	Protocol 13 – Screening Level Risk Assessment http://www2.gov.bc.ca/gov/DownloadAs	*These definitions provide useful context for defining risk-based standards (e.g., spatial extent, receptor sensitivity).*

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	residential, commercial or industrial land use applies at the site) of sensitive habitat. "sensitive habitat" includes: a) national, provincial, regional or municipal parks; b) sensitive ecosystems; c) areas supporting sensitive species; and d) wetlands or riparian assessment areas as defined in section 1 of the Riparian Areas Regulation "undeveloped land" means any bare or vegetated soil, excluding gravelled walkways, roadways, parking areas, and soil or vegetation in planters (i.e. landscaped soil confined by a container or lying on top of a structure)."	set?assetId=E4D4EAE2AD5F4EA7886A017D379256EC&filename=protocol_13.pdf *effective August 1 2008*	
B4	Narrative protection goals for soil • Industrial Land: Support a reasonable level of ecological function; maintenance of managed areas such as flower beds and grass (at least able to grow unsupplemented grass); Due to the lack of data regarding dermal contact with contaminated soil by other organisms, it is assumed that the level of protection provided for soil dependent species will also be generally adequate for the protection of livestock and wildlife • Commercial Land: Support a reasonable level of ecological function; should be able to grow basic ornamentals/grass; Due to the lack of data regarding dermal contact with contaminated soil by other organisms, it is assumed that the level of protection provided for soil dependent species will also be generally adequate for the protection of livestock and wildlife • Residential Land: Should be able to grow ornamentals and native flora; Due to the lack of data regarding dermal contact with contaminated soil by other organisms, it is assumed that the level of protection provided for soil dependent species will also be generally adequate for the protection of livestock and wildlife • Urban Park Land: Should be able to grow ornamentals and native flora; Due to the lack of data regarding dermal contact with contaminated soil by other organisms, it is assumed that the level of protection provided for soil dependent species will also be generally adequate for the protection of livestock and wildlife • Agricultural Land: Should be able to growth of crops; Should be able to raise livestock; Protect microbial nutrient cycling essential for the health of soil invertebrates and plant growth (crops); no indirect phytoxicity related toxicity occurs in livestock; No direct soil related toxicity occurs in livestock	(summarized from:) Overview of CSST Procedures for the Derivation of Soil Quality Matrix Standards for Contaminated Sites http://www2.gov.bc.ca/gov/DownloadAsset?assetId=A11BB9CF961D40EA806FC003BBFA9FC5&filename=overview_of_csst_procedures-derivation_of_soil_quality_matrix_standards_cs.pdf *published January 31 1996* and CSST Policy Decision Summary http://www2.gov.bc.ca/gov/DownloadAsset?assetId=EF02110C5970415192983BED8F6A8B7E&filename=csst_policy_decision.pdf *published January 24 1996*	*These protection goals are very broad and do not address all receptors of concern usually included in an ERA, even for IL/CL.* *We also note that there is somewhat of a disconnect between the ECx protection goal values for different land uses and the CSST approach for deriving the soil standards. Schedule 5 soil standards are less conservative (e.g., EC_{50} sublethal or lethality endpoints to plants and invertebrates) than protection goals specified in ERA guidance (e.g., TRVs). This topic should be followed-up with MOE.*
B5	Tier 1 ERA Policy, Issue 2: Rules for Selecting Species of Potential Concern: "The rules were developed in accordance with BCE's policy to provide greater protection of ecological resources on urban parks and agricultural lands than on industrial and commercial sites, with residential areas somewhere in between the two extremes. Thus, the rules were developed to: 1) Ignore migratory species that may spend only a small portion of their time on an industrial, commercial, or residential site. Urban Parks and Agricultural lands may be expected to provide necessary habitat for migrants (feeding, resting). 2) Small streams are not considered critical habitat for waterfowl (ducks, geese, swans) as they cannot support a large enough number of individuals to affect the productivity of the overall population. 3) Only threatened or endangered raptors are considered for industrial, commercial, or residential sites. Raptors require a large foraging area and it is anticipated that most of these sites will be small, capable of providing only a fraction of the total dietary intake for these species. Furthermore, it is not BCE's intent that these types of sites should support a diverse enough plant and animal community to be attractive to raptors. 4) Galliforms (e.g., pheasant and quail), cavity-dwellers (e.g., flickers and woodpeckers), and hummingbirds are not considered for industrial and commercial sites. Residential sites consider cavity-dwellers while urban parks and agricultural lands consider nearly all birds. Most industrial and commercial sites are in urban areas where galliforms are not expected to occur, nor does BCE intend that they should have habitat suitable to support these birds. Cavity-dwellers generally eat foliar invertebrates which require maintenance of diverse plant communities. Again, it is not BCE's intent that industrial or commercial areas provide this type of habitat. Hummingbirds are nectar feeders and there is no information about the potential for accumulation of contaminants in nectar. It is known that metals do not	Tier 1 Ecological Risk Assessment Policy Decision Summary http://www2.gov.bc.ca/gov/DownloadAsset?assetId=F048A972850140D680E7B916D79D27C4&filename=tier_1_ecological_risk_assessment_policy_decision_summary.pdf *undated*	*These rules (developed in 1998 as part of a protocol [mandatory]) identify scenarios where risks to certain receptors would not be required to be assessed (implies that risk-based standards for those receptors are met). However, excluding these receptors might be considered gaps in a risk assessment under more recent ERA guidance/policy.*

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	accumulate in pollen (cf. Stanley and Linskens 1974) so it may be reasonable to suspect that nectar acts in a similar manner. Furthermore, it is assumed that hummingbirds will be sufficiently protected based on the levels of protection developed for insectivorous and herbivorous birds. 5) The absence of other species in certain areas (e.g., shorebirds) is dictated by the type of habitat available (e.g., shallow water marshes). 6) The aquatic species were chosen based upon the potential for the land use to be a breeding habitat. In the case of an industrial site, it will be unlikely that fish will breed in the area. In the agricultural site a larger number of species will use the land and adjacent water body as breeding or other habitat. The urban park scenario was also expanded to address the possibility that some common non-native species could be used."		
Section C: Acceptable Effects Levels (AELs)			
C1	"site-specific risk-based concentration" means a concentration of a substance in an environmental medium back-calculated in a risk assessment completed for a specific site, such that exposure to that substance in all environmental media for which all complete exposure pathways exist at that site would not exceed (a) for a non-threshold carcinogenic substance, a calculated human lifetime cancer risk of one in 100,000, and (b) for a threshold non-carcinogenic substance, a hazard index of one."	Procedure 8 – Definitions and Acronyms for Contaminated Sites http://www2.gov.bc.ca/gov/DownloadAsset?assetId=93799F13FEF0485A9055A55731476A66&filename=procedure-08-2014.pdf *November 20, 2015*	*This definition appears intended for HHRA, not ERA where there is no definition of what meets or does not meet risk-based standards. As mentioned previously in Section A1 of this table, the concept of "site-specific risk-based concentration" can be difficult to apply in ERA (mixture of contaminants, multi-media exposure, WOE [involving LOEs that are not concentration-based], habitat-related doses for wildlife).*
C2	"Classifying a specific volume of material: The following conditions must be met before the ministry considers that a material belongs in a specific class: - the data is demonstrably representative of one population; and, for that data set, - the upper 90th percentile of the sample concentrations is less than the criterion concentration; - the upper 95% confidence limit of the average concentration of the samples is less than the criterion concentration; and - no sample within the data set has a concentration exceeding two times the criterion concentration."	Technical Guidance 2 – Statistical Criteria for Characterizing a Volume of Contaminated Material http://www2.gov.bc.ca/gov/DownloadAsset?assetId=64F3BF9C399145979CEA26D8B324A319&filename=tg02.pdf *January 2009*	*These conditions define how COPCs are screened, and a magnitude of exceedance, and could be considered to reflect COPC exceedances in exposure media that meet risk-based standards for ERA. However, this interpretation needs to be verified with MOE – for instance, would risks to terrestrial plants or aquatic benthic invertebrates only be assessed if contaminants exceed statistics for study area, which implies that COPC exceedances could be < 2x the criterion at individual stations. Perhaps this makes sense since this is the way COPCs are often being screened/identified for the ERA. Also see Section C3.*
C3	"If a statistical approach is utilized in a Detailed Site Investigation (DSI) to conclude that a substance meets numerical standards, this conclusion (and the statistical approach upon which it is based) does not need to be re-evaluated in the risk assessment. Therefore, provided the substance is not relevant to the exposure of rare and endangered species or is a bioaccumulative substance, the substance would not be considered a COPC."	CSAP Technical Guidance for Risk Assessment COPC Screening (CSAP Technical Review #10) http://csapsociety.bc.ca/members/practice-guidelines/ *February 16, 2012*	*Related to Section C2, Appendix B of the CSAP Technical Review #10 COPC Screening made the following recommendations:* *If using a risk-based approach to remediation, there is a regulatory requirement for the risk assessment to address the contaminants identified by the DSI. If a statistical approach is used to characterize contaminants in the DSI, then consistent with that, the same statistical approach can be used for identifying COPCs the risk assessment. It is recommended that the rationale for the use of statistics (or not) be provided in the risk assessment. Note that if rare or endangered species are receptors for the Site, consideration should be given to using a more conservative screening approach.*

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			There may be situations when it is appropriate to use other criteria to identify COPCs for a quantitative risk assessment. For the recommendation above, it has been assumed that a DSI has 13 been conducted and is compliant with the standards outlined in the Contaminated Site Regulation. The quantitative risk assessment is to be conducted for the purposes of obtaining a regulatory instrument (e.g. certificate of compliance, approval in principle).
C4	"Surface water and porewater in aquatic receiving environments other than maintained watercourses should be evaluated against the Water Quality Guidelines (WQGs)." "The ministry encourages that, wherever possible, the WQGs be met in all watercourses (including maintained watercourses) at the point where surface water enters an aquatic receiving environment. Furthermore, in the case that a maintained watercourse: ceases to be maintained in accordance with a regular maintenance schedule, is abandoned, or allowed to ecologically succeed, or otherwise ceases to serve as a maintained watercourse, then the ministry considers the function of the watercourse to have reverted to an aquatic receiving environment to which the WQGs apply." "Reliance on dilution of substance concentrations within the aquatic receiving environment is not authorized under this guidance." "aquatic habitat" means habitat defined in a protocol approved by the Director or as used by "aquatic life" as defined in the Regulation. "aquatic life" means any living component of the freshwater, estuarine or marine aquatic ecosystem, including phytoplankton, zooplankton, benthos, macrophytes and fish. "aquatic life water use" [AW] means the use of water as habitat for any component of the freshwater or marine aquatic ecosystem, including phytoplankton, zooplankton, benthos, macrophytes and fish. [Source – Section 1, Contaminated Sites Regulation] "aquatic receiving environment" means any surface water, watercourse, wetland, sediment or porewater containing aquatic life. "maintained watercourse" means a constructed ditch or constructed pond that: (a) conveys irrigation water on agricultural land, or (b) conveys drains or stores storm water or surface water on agricultural, residential, commercial, or industrial land; unless the constructed ditch or constructed pond: (c) has been designated as critical habitat for aquatic species at risk under the Federal Species at Risk Act, or Effective date: January 7, 2011 Version 1.1 Page 19 of 47(d) constitutes sensitive habitat for designated endangered or threatened aquatic species under the BC Wildlife Act."	Technical Guidance 15 - Concentration Limits for the Protection of Aquatic Receiving Environments http://www2.gov.bc.ca/gov/DownloadAsset?assetId=560E775605984EC295A0B043672B2265&filename=tg15_2013.pdf *version 1 April 2013* Procedure 8– Definitions and Acronyms for Contaminated Sites http://www2.gov.bc.ca/gov/DownloadAsset?assetId=93799F13FEF0485A9055A55731476A66&filename=procedure-08-2014.pdf, *November 20, 2015*	*Provides definition of aquatic receiving environment where WQGs apply, which implies a greater level of protection than maintained watercourses.* *Reliance on dilution is not allowed, including in DERA. Recent legal advice interprets "waste" as based on initial quality in the CSR and HWR.* *With recent changes to the Federal Fisheries Act, there may now be greater incongruence between federal and provincial policy for fish and fish habitat. How are Federal commercial, aboriginal and recreational fisheries reconciled against provincial policy? Also, water quality guidelines are not administered under the CSR directly; EMA provisions would need to be invoked.*
C5	Sediment Quality Criteria for Sensitive Contaminated Sites (SedQCSCS): need to define concentrations of COPCs below which there is a relatively low probability (i.e., roughly 20%) of observing statistically significant adverse effects in standardized toxicity tests with sensitive benthic species and life stages. "To ensure the proper application of the SedQC, administrative rules have been established to guide determinations of sites as contaminated or uncontaminated. The administrative rules for sensitive contaminated sites state that:	Criteria for Managing Contaminated Sediment in BC – Technical Appendix http://www2.gov.bc.ca/gov/DownloadAsset?assetId=CA6312DE5AC64436A262D3F1B815DA38&filename=sed_criteria_tech_app.pdf	*Defines the spatial extent, vertical and horizontal (based on statistics), below which, sediment COPCs are not identified and therefore implying risk-based standards are met.* *The risk-based approach can be used to support remedial action planning for sediments at any contaminated site in*

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	1. A sensitive site is a contaminated site if any of the following conditions exist: • The 90th percentile concentration of one or more COPCs equals or exceeds their respective SedQCSCS (i.e., 9 of 10 measurements must be below the SedQC to designate a site as uncontaminated) and exceeds upper limit of background for that substance (i.e., mean + 2SD); • The concentration of one or more analytes exceeds their respective SedQCSCS by a factor of two or more in any sediment sample and exceeds upper limit of background for that substance (i.e., mean +2SD); • The 90th percentile mean SedQCSCS-quotients (SedQCSCS-Q) for the contaminant mixture equals or exceeds 1.0 (see Appendix 1 for more information on the calculation of mean SedQC-Qs); or, • The mean SedQCSCS-Q for the contaminant mixture in any sediment sample equals or exceeds 2.0. 2. The SedQCSCS are to be applied to a depth of 100 cm (i.e., 0-100 cm) in areas where the sediment bed has been demonstrated to be stable (i.e., non-erosional, not subject to navigational dredging). 3. The SedQCSCS will apply to depths of greater than 100 cm in areas where the sediment bed has been demonstrated to be unstable (i.e., erosional, subject to navigational dredging) or the stability of the bed is unknown. 4. The SedQCSCS will apply to depths of greater than 100 cm in areas where it is demonstrated that there is on-going transport of COPCs from depth into the shallower portions of the sediment bed at rates capable of contaminating sediments in the top 100 cm to levels exceeding the SedQCSCS." 5. The SedQCSCS must be used during the site investigation process to determine if a sensitive site contains contaminated sediments. 6. The SedQCSCS will apply at contaminated sites that have sediments that border or include habitat protection or conservation zones, or where biological habitat mapping [e.g., such as has been conducted by Fraser River Estuary Management Program (FREMP) or Burrard Inlet Environmental Action Plan (BIEAP)] have designated the area as a high productivity zone. Schedule 2 provides a checklist of factors to be considered in applications to the Ministry in support of the selection of SedQC values. 7. The SedQCSCS should be used to determine if remedial measures are needed at a sensitive site and to establish target cleanup goals for contaminated sediments. 8. The presence of sediments containing contaminant concentrations qualifying as Special Wastes as defined under the Special Waste Regulation, necessitates exceptions to the limits of potential remedial actions. Where Special Waste is present, remedial measures should focus on the removal of these wastes, to the extent feasible. The handling, treatment and disposal of these materials is to be conducted in accordance with the provisions of the Special Waste Regulation."	*undated*	*BC. This approach is often used where the scale, scope, and uncertainty of remedial efforts identified using the criteria-based approach can be reduced. Typically, this is done by demonstrating to the satisfaction of MOE that risks are less than or equal to those upon which the criteria are based (i.e., a 20% probability of an EC20 at sensitive sites and a 50% probability of an EC20 at typical sites). (See Table 1 for definition of ECx).* *The quotient approach is not generally used anymore and will likely be removed when TG19 is updated.* *Also, we should determine if MOE is using the narrative goals (e.g., P20 of EC20) to guide interpretation of what meets risk-based standards; in our experience, decisions are made on a station-by-station basis, not on groups of stations or area-basis (i.e., the EC20 rule is used, but not the P20 rule, and not in the case of WOE which is more challenging – see below). We also note that the sediment criteria appear to be based on invertebrate survival endpoints only; the use of various benthic endpoints in ERA should rely on professional judgment of the risk assessor.* *The Procedure 8 definition "ecologically active zone" means the top 1 metre of sediment below the sediment/surface water interface; Technical Guidance 15 indicates upper 1 meter of **stable** sediment. In an ERA, it is up to the risk assessor to define the ecologically active zone.*
C6	Sediment Quality Criteria for Typical Contaminated Sites (SedQCTCS): intended to define the concentrations of COPCs below which there is a moderate probability (i.e., about 50%) of observing statistically significant adverse effects in standardized toxicity tests with sensitive benthic species and life stages. "To ensure the proper application of the SedQC, administrative rules have been established to guide determinations of sites as contaminated or uncontaminated. The administrative rules for typical contaminated sites state that: 1. A typical site is a contaminated site if any of the following conditions exist: • The 90th percentile concentration of one or more COPCs equals or exceeds their respective SedQCTCS (i.e., 9 of 10 measurements must be below the SedQC to designate a site as uncontaminated) and exceeds upper limit of background for that substance (i.e., mean + 2SD); • The concentration of one or more analytes exceeds their respective SedQCTCS by a factor of two or more in any	Criteria for Managing Contaminated Sediment in BC – Technical Appendix http://www2.gov.bc.ca/gov/DownloadAsset?assetId=CA6312DE5AC64436A262D3F1B815DA38&filename=sed_criteria_tech_app.pdf *undated*	

No.	CSR POLICY AND GUIDANCE	SOURCE	NOTES AND IMPLICATIONS
	sediment sample and exceeds upper limit of background for that substance (i.e., mean +2SD); • The 90th percentile mean SedQCTCS-Q for the contaminant mixture equals or exceeds 1.0 (see Appendix 1 for more information on the calculation of mean SedQC-Qs); or, • The mean SedQCTCS-Q for the contaminant mixture in any sediment sample equals or exceeds 2.0. 2. The SedQCTCS are to be applied to any sediment depth." 3. The SedQCTCS must be used during the site investigation process to determine if a typical site contains contaminated sediments. 4. The SedCQTCS should be used to determine if remedial measures are needed at a typical site and to establish target clean-up goals for contaminated sediments. 5. The presence of sediments containing contaminant concentrations qualifying as Special Wastes, as defined under the Special Waste Regulation, necessitates the imposition of limitations on potential remedial actions. Where Special Waste is present, remedial measures should focus on the removal of these wastes, to the extent feasible. The handling, treatment and disposal of these materials is to be conducted in accordance with the provisions of the Special Waste Regulation."		
Section D: Acceptable Effects Levels (AELs) – different land uses in the CSR			
D1	Industrial Land: "…for environmental receptors such as plants or animals (i.e., not humans), the goal is not to protect each individual from any toxic effect, but rather to protect enough individuals so that a viable population and community of organisms can be maintained (provided other habitat factors are suitable). Therefore, a TRV is chosen from the concentration-response curve that provides reasonable protection for a specified percentage of the organisms. For terrestrial organisms on industrial sites, this is the EC50, or the concentration that affects 50% of the organisms exposed. For aquatic organisms at industrial sites, this is the EC20."	Protocol 1 – Recommended Guidance and Checklist for Tier 1 Ecological Risk Assessment of Contaminated Sites in British Columbia - Chapter 3. Industrial http://www2.gov.bc.ca/gov/topic.page?id=A8797D15BF2641048C04B5595AAD28B8	*Some of the challenges in using policy-derived AELs when determining what meets risk-based standards:* • *Avoid using AEL benchmarks to generate oversimplified dichotomous categorizations (little difference between a 19% effect rate and a 21% effect rate, and our confidence in distinguishing such differences will generally be very low)* • *The implications of a specific AEL on any given measurement endpoint for a population or community will vary widely depending on whether the measurement endpoint applies directly to a population (e.g., abundance), community (e.g., species richness), or to organisms within a population (e.g., growth or fecundity)* • *Derivation of ecologically-meaningful AELs can be complex. There is not necessarily a "one size fits all" effect size – even among common wildlife species, different life history characteristics may require different effect sizes (e.g., r vs. K reproductive strategies: a specified AEL has different implications for a mouse vs. a moose)* • *AELs apply to individual LOEs, which do not get interpreted in isolation when multiple LOEs are investigated – most aquatic ERA s rely on a WOE approach to integrate multiple LOEs such as chemistry, toxicity testing, and community surveys* • *While AELs are used to evaluate the magnitude of a*
D2	Commercial Land: "…for environmental receptors such as plants or animals (i.e., not humans), the goal is not to protect each individual from any toxic effect, but rather to protect enough individuals so that a viable population and community of organisms can be maintained (provided other habitat factors are suitable). Therefore, a TRV is chosen from the concentration-response curve that provides reasonable protection for a specified percentage of the organisms. For terrestrial organisms on commercial sites, this is the EC50, or the concentration that affects 50% of the organisms exposed. For aquatic organisms at commercial sites, this is the EC20."	Protocol 1 – Chapter 4. Commercial http://www2.gov.bc.ca/gov/topic.page?id=A8797D15BF2641048C04B5595AAD28B8	
D3	Residential Land: "…for environmental receptors such as plants or animals (i.e., not humans), the goal is not to protect each individual from any toxic effect, but rather to protect enough individuals so that a viable population and community of organisms can be maintained (provided other habitat factors are suitable). Therefore, a TRV is chosen from the concentration-response curve that provides reasonable protection for a specified percentage of the organisms. For terrestrial organisms on residential sites, this is the EC20, or the concentration that affects 20% of the organisms exposed. For aquatic organisms at residential sites, this is the EC20."	Protocol 1 – Chapter 5. Residential http://www2.gov.bc.ca/gov/topic.page?id=A8797D15BF2641048C04B5595AAD28B8	
D4	Urban Park: "…for environmental receptors such as plants or animals (i.e., not humans), the goal is not necessary to protect each individual from any toxic effect, but rather to protect enough individuals so that a viable population and community of organisms can be maintained (provided other habitat factors are suitable). Therefore, a TRV is chosen from the concentration-response curve that provides reasonable protection for a specified percentage of the organisms. For	Protocol 1 – Chapter 6. Urban Park http://www2.gov.bc.ca/gov/topic.page?id=A8797D15BF2641048C04B5595AAD28B8 *Note that for urban park land, the ECx is	

No.	CSR POLICY AND GUIDANCE	SOURCE	NOTES AND IMPLICATIONS
	terrestrial organisms on urban parks, this is the EC20, or the concentration that affects 10% of the organisms exposed. For aquatic organisms at urban parks, this is the EC20."	EC10 based on Tier 1 Ecological Risk Assessment Policy Decision Summary http://www2.gov.bc.ca/gov/DownloadAsset?assetId=F048A972850140D680E7B916D79D27C4&filename=tier_1_ecological_risk_assessment_policy_decision_summary.pdf *undated*	*potential impact, the determination of "risk" may require consideration of other factors such as the spatial extent of effects and the evidence for causal linkages between the effect and site-related contamination (including stressors other than site-related contaminants such as effects of human disturbance, naturally lower habitat quality).*
D5	Agricultural Land*: "…for environmental receptors such as plants or animals (i.e., not humans), the goal is not to protect each individual from any toxic effect, but rather to protect enough individuals so that a viable population and community of organisms can be maintained (provided other habitat factors are suitable). Therefore, a TRV is chosen from the concentration-response curve that provides reasonable protection for a specified percentage of the organisms. For terrestrial organisms on agricultural sites, this is the EC20, or the concentration that affects 20% of the organisms exposed. For aquatic organisms at agricultural sites, this is the EC20."	Protocol 1 – Chapter 7. Agriculture http://www2.gov.bc.ca/gov/topic.page?id=A8797D15BF2641048C04B5595AAD28B8 *Note that for agricultural land, the ECx is EC10 based on Tier 1 Ecological Risk Assessment Policy Decision Summary http://www2.gov.bc.ca/gov/DownloadAsset?assetId=F048A972850140D680E7B916D79D27C4&filename=tier_1_ecological_risk_assessment_policy_decision_summary.pdf *undated*	
D6	Aquatic Life – Tier 1 ERA Policy, Issue 4: Use of Different ECx Values Based on Land Use: As indicated for each land use, "the aquatic ECx is set at 20. This reflects a low end of the aquatic ECx value and is set this low to protect commercially important species such as Salmonids. Since migrating fish can occupy a variety of aquatic habitats bordering a variety of land uses, a constant ECx is the only means of being equally protective." (see also protection goals for sediment criteria)	Tier 1 Ecological Risk Assessment Policy Decision Summary http://www2.gov.bc.ca/gov/DownloadAsset?assetId=F048A972850140D680E7B916D79D27C4&filename=tier_1_ecological_risk_assessment_policy_decision_summary.pdf *undated*	
D7	Technical Bulletin 2, from Table 1 (common errors and omissions): "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"	Technical Bulletin 2 - Requirements for Human Health and Ecological Risk Assessment Reports http://www2.gov.bc.ca/gov/DownloadAsset?assetId=0CC02847B38445949FC2C4682A29DA21&filename=tb-02-reqs-hh-eco-ra-reports.pdf *effective date December 1 2014*	*Raises the concept of cumulative exposures and therefore risks, which need to be considered if relevant. Summing exposures is not necessarily meant for ERA unless scientific evidence supports it. As noted elsewhere, Protocol 20 considers the need to address potential toxicological interactions (e.g., synergistic or antagonistic effects) between potential contaminants of concern as optional.*
Section E: Risk Calculation			
E1	Protocol 1: Spatially Distinct Risk Quotients: "RQs should be calculated using the equation from 8.1.1 [dividing the estimated environmental concentration (EEC) by the toxicity reference value (TRV)] for each site that an environmental sample was collected, for each plant or animal species of concern. The RQs should be plotted on the site map in order to determine if there are areas where risk is high (RQ > 100), areas of low risk (RQ < 1) or areas of intermediate risk (1 < RQ < 100). If several samples were taken in close proximity to each other, use the average concentration and plot it as a single value at that location.	Protocol 1 – Recommended Guidance and Checklist for Tier 1 Ecological Risk Assessment of Contaminated Sites in British Columbia - Chapter 8. Risk Calculation http://www2.gov.bc.ca/gov/topic.page?i	*Defines the magnitude of risk quotients (RQ) that would be related to exceedance of risk-based standards.* *This does not clarify which category of RQs meets risk-based standards, and the text on not adding RQs appears consistent with Protocol 20.*

No.	CSR POLICY AND GUIDANCE	SOURCE	NOTES AND IMPLICATIONS
	The *probability* of exceeding an RQ of 1 (or 100) anywhere on the site can also be estimated from this information by: Number of RQs >1 or 100 ---------- x 100 Total number of RQs NOTE: RQs calculated for different species should NEVER be added together, as they are not equivalent values. However, the probability of exceedance will be an approximation of overall risk."	d=A8797D15BF2641048C04B5595AAD28B8	*These SQ/HQ ranges are inconsistent with current scientific practice and guidance for ERA: Allard et al. 2009 and Environment Canada's 2012 ERA guidance for federal contaminated sites*
E2	Protocol 1: Risk Characterization: "Describe the interpretation of the data and analysis. If a risk quotient suggests that there might be risk to a receptor of concern (RQ>1), but that receptor is observed on-site without obvious signs of toxicant-induced stress (or the bioassay data suggest that it can survive in 100% site soil or water), give preference to the observed effects over the RQ estimation in your conclusion of risk. Include, at a minimum, a discussion of the following questions: a) Which species are most likely to be at risk? b) For which portion of a year is risk likely to occur? c) Is the risk even over the entire area or are there "hot spots" of high risk? d) How do the pollutants move from the site of release to the plants or animals of concern (surface water run-off, groundwater movement, food chain uptake from soil, etc.)? e) What is known about the ecology or biology of a species that appears to be at risk that may mitigate this risk? f) What is known about the ecology, biology or behavior of the species that appears to be at risk that may enhance this risk? g) Are some of the life stages of the organism put at more risk than others? h) Should some of the species be of more concern because they create habitat or are a food source for a critical species of concern? i) Where are data lacking for making an adequate risk estimation?"	Protocol 1 – Recommended Guidance and Checklist for Tier 1 Ecological Risk Assessment of Contaminated Sites in British Columbia - Chapter 8. Risk Calculation http://www2.gov.bc.ca/gov/topic.page?id=A8797D15BF2641048C04B5595AAD28B8	*Provides guidance for weighing LOEs in risk characterization and de-emphasizes RQs relative to field observations or survival endpoints in bioassays.* *This guidance raises several issues (e.g., scope and power of study design for field studies to detect effects, emphasis on survival endpoints) which require clarification for defining whether risk-based standards are met; including determining whether the level of uncertainty in the ERA is acceptable for making a risk determination.*
Section F: Roles of the Qualified Professional (QP) and Approved Professional (AP)			
F1	"qualified professional" [QP] means a person who (a) is registered in British Columbia with his or her appropriate professional association, acts under that professional association's code of ethics, and is subject to disciplinary action by that professional association, and (b) through suitable education, experience, accreditation and knowledge may be reasonably relied on to provide advice within his or her area of expertise.	Procedure 8– Definitions and Acronyms for Contaminated Sites http://www2.gov.bc.ca/gov/DownloadAsset?assetId=93799F13FEF0485A9055A55731476A66&filename=procedure-08-2014.pdf *valid November 20, 2015*	*We understand that the role of the QP is to prepare ERAs that describe risks and reach conclusions on whether risk estimates meet risk-based standards. Over the course of the ERA, QPs can obtain feedback from MOE and/or APs (arm's length); this can be an iterative process where incremental remediation/ERA studies are conducted until a sound remediation decision can be made.*
F2	"Approved Professional" [AP] means a person who is named on a roster established under section 42 of the Act. [Source – Section 39, Environmental Management Act] "Approved Professional work" means work undertaken by an Approved Professional that is specified in Table 1 of the ministry's Procedures for the Roster of Approved Professionals that: - is within the scope of the applicable profession of the Approved Professional, and - is of a type required to be performed by an Approved Professional under the Environmental Management Act. "Risk-based Standards Approved Professional" means an Approved Professional who has passed an examination sponsored by the Society of Approved Professionals of British Columbia for applicants to qualify as "risk assessment specialists" and whose qualifications and experience: - represent an application of the knowledge of contaminant sources, fate, exposure and effects on biota (including humans);	Procedure 8– Definitions and Acronyms for Contaminated Sites http://www2.gov.bc.ca/gov/DownloadAsset?assetId=93799F13FEF0485A9055A55731476A66&filename=procedure-08-2014.pdf valid November 20, 2015	We understand that if an ERA is submitted under Protocol 6, the role of the AP is to "mimic" or emulate the MOE decision-making process and determine whether the ERA's conclusions (and associated documentation) are technically sound, administratively complete, and meet risk-based standards, so that issuance of a CSR instrument can be recommended to MOE.

No.	CSR POLICY AND GUIDANCE	SOURCE	NOTES AND IMPLICATIONS
	- were gained in an environment where the individual had primary responsibility for the technical and scientific aspects of the human health and/or ecological risk assessment; - show evidence that the accomplishment required a synthesis capability that only those who fully appreciate the topics of their discipline would have; and - show that appropriate regulatory requirements and guidelines for risk assessment work and the application of risk-based standards were met.		

Appendix B

Action Item Tracking List from Appendix A

Appendix B. Action items for follow-up with MOE (May 2016).

1. *With recent changes to the Federal Fisheries Act, there may now be greater incongruence between federal and provincial policy for fish and fish habitat. How are Federal commercial, aboriginal and recreational fisheries reconciled against provincial policy? Also, water quality guidelines are not administered under the CSR directly; EMA provisions would need to be invoked. Also, we should determine if MOE is using the narrative goals (e.g., P20 of EC20) to guide interpretation of what "meets risk-based standards" for sediments; in our experience, decisions are made on a station-by-station basis, not on groups of stations or area-basis (i.e., the EC20 rule is used, but not the P20 rule, and not in the case of WOE which is more challenging).*

2. *There should be consistency between the numerical standards and ERA TRVs (there is somewhat of a disconnect between the ECx protection goal values for different land uses and the CSST approach for deriving the soil standards; Schedule 5 standards are less conservative than what the ERA docs are asking for as the protection goal, because the standards used EC50 sublethal or lethality endpoints).This topic can be revisited once the Omnibus Updates have been released.*

Appendix C

Agenda for 1st Workshop (January 27, 2016) and TWG Comments on v1.0

AGENDA
Technical Working Group Workshop

Date: Wednesday January 27, 2016, 10:00 – 3:00pm
Location: Azimuth Consulting Group Office, Suite 218, 2902 West Broadway, Vancouver
Invited: David Williams (Millennium EMS Solutions Ltd.)
Heather Osachoff (MOE)
Michael McLeay (Hemmera)
Mike Rankin (AECOM)
Reidar Zapf-Gilje (GeoEnviroLogic)
Sam Reimer (SLR Consulting)
Trish Miller (Golder)
Patrick Allard (Azimuth)
Beth Power (Azimuth)
Cheryl Mackintosh (Azimuth)

Agenda:

1. Introductions & Background
- a. Introductions
- b. TWG process & expectations for group members
- c. Confidentiality of work products
- d. Review agenda & plan for meeting

2. Review of Project Objectives
- a. Deliverable/schedule
- b. Combine Phase 1 & Phase 2

3. Draft Table of Contents
- a. Part 1 – Objectives of the Technical Guidance
- b. Part 2 – Context for Developing Guiding Principles
  - i. Description of the RA/RM process – Figure 1
  - ii. Annotated compilation of CSR policy and guidance on risk-based standards for ecological receptors – Appendix A
  - iii. Roles of risk assessors as QPs and APs
- c. Part 3 – Application of Risk-based Standards to Ecological Receptors
  - i. Assessment endpoints and protection goals – Table 1
  - ii. Risk characterization (Optional) – Figure 2
    - (1) Step 1 (LOE screening)
    - (2) Step 2 (WOE attributes)
    - (3) Step 3 (ecological considerations)
  - iii. Interpretation of risks and uncertainties – Figure 3

4. Next Steps & Schedule:

Azimuth will compile a second version of the Framework (V2.0) based on workshop discussion. We would like to identify key areas of improvement, useful output formats, and future work needed.

a. By Feb 19, 2016 – Distribute V2.0 to TWG
b. By March 4, 2016 – Second workshop (optional) and receipt of TWG final comments
c. By March 31, 2016 – Submission of V3.0 to CSAP

Lunch will be provided

RISK MANAGEMENT DECISION FRAMEWORK FOR BC CONTAMINATED SITES

Phase 2 Guiding Principles for Applying Risk-based Standards to Ecological Receptors V1.1

Technical Working Group Comments – Summary and Discussion Points

This document outlines agenda items for the workshop on January 27, 2016 (see boxes below), based on collated comments provided by the TWG (see point form notes below). No changes have been made to the draft Framework (V1.1) at this time, to avoid confusion and allow further discussion of issues. A second version of the Framework (V2.0) will be developed following the workshop and circulated to the TWG for review.

1. Part 1 – Objectives of the Technical Guidance

Key message:
- *Need practical guidance for APs, which allows for professional judgement (avoid being overly prescriptive and creating new guidance).*

- I think that Step 5 in Figure 1, and the linkage to Step 6 (to the extent of determining whether risks are acceptable or unacceptable) represent the portion of the process that this project should focus on and, something in the form of Figure 3, supported by whatever definitions or descriptions are needed (including a fleshed out version of Table 1), would likely be the most useful output from the guidance for the AP.
- I agree that we shouldn't be too prescriptive in how to get there, but we could identify key considerations.
- A key desire of CSAP is to have a product that is of practical value to the AP (primarily), and also to the QP and the risk management decision maker.
    - **Discussion point**: If there's a concern about not being too prescriptive, an alternative to MOE Technical Guidance (which may be interpreted as prescriptive) would be a CSAP practice guideline.
- My feelings are that: i) we have information to support a framework in existing guidance and protocols, and ii) we need to keep it simple such that it can be interpreted with different lines of evidence. I'm seeing this as a framework that draws in existing information for the benefit of APs without drawing firm lines in the sand.
- How to develop guidance related to increasing consistency while still maintaining professional judgment is the challenge. The approach seems reasonable – the devil will be in the details.

2. Part 2 – Context for Developing Guiding Principles

Key messages:
- *Revisit Figure 1 for remediation and other links/steps*
- *Add new notes to annotated table*
- *Define role of QPs and APs*

- **Discussion point**: Definition and role of remediation (see handout re: Procedure 8)

- Figure 1. Box 6b. Change 'causing' to 'cause'.
- Figure 1. In the top righthand area of this figure, there are 3 lines that list 'CoC or IR' leading to box 7 or 8. It is not clear to me why these 3 lines have CoC or IR at this point in the Figure when box 8 contains CSR instruments, etc. And how does IR at that point in time make sense – is it common to have 'No risk Controls (Type 1A)' that are in 'CoC or IR' that then go to box 8? The IR wording seems out of place or something is missing from the explanation.
    - **Discussion point**: revisit Figure 1 steps and links
- Main Process Flow Chart (Figure 1) : Overall very good. Contrasting the main flowchart v4 (original report) and v8 (supplemental) I note the nature of the changes.
    - The conscious change from pink "risk management" steps (v4) to merging into blue "remediation decision and next steps" seems fuzzy to me (semantics?). The RA practitioner world very much makes recommendations for risk mitigation and participates in the both the decisions of how best to approach the mitigation. Many would identify this as risk management and I think BCMOE/CSAP and the risk world accept this. The view that risk assessors do not venture to risk management I think needs to be left behind. My point here is that making it all blue and calling it something else may not be the solution. Rather a mind shift to accept risk assessors in the risk management domain is ok – and probably better than handing off to remediation engineers in many instances.
    - I think the flow chart would be more effective if it showed the finish line as the largest (last) number – currently the finish line is box 9 – but Box 10 (RP) is out here and loops back into the process. The finish line is actually 2-steps: (i) CSR instrument and (ii) completion of the PVP duties, which may take several years. Showing these two items in the extreme right in their own zone may offer better optics for recognizing the regulatory finish line for all CSR practitioners.
        - **Discussion point**: Definition and role of remediation (see handout re: Procedure 8) and revisit Figure 1 steps and links

b. Annotated compilation of CSR policy and guidance on risk-based standards for ecological receptors – Appendix A

- There is a newly updated document for Procedure 8: CS e-link, 2015-12-24 (I will forward in a subsequent email). It appears you will need to double check parts from Procedure 8 against quoted definitions in Appendix A.
- Acceptable Effects Levels, <u>second box</u>, Classifying a specific volume of material, Note regarding TG2 - Statistical Criteria for Characterizing a Volume of Contaminated Material.

  "These conditions define how COPCs are screened, and a magnitude of exceedance, and could be considered to reflect acceptable exceedances for exposure in ERA. It is unclear whether these can be applied to interpretation of acceptable risks in ERA – for instance, would risks to terrestrial plants or aquatic benthic invertebrates only be assessed if contaminants exceed statistics for study area, which implies that COPC exceedances < 2x

max at individual stations are acceptable? Perhaps this makes sense since this is the way COPCs are being screened/identified for the ERA."

Suggest possible revision to above text. CSAP Technical Review #10 COPC Screening generally concluded that use of stats should be in DSI rather than COPC screening. Therefore if TG2 arguments not used in DSI contaminant would be retained for COPC screening (using CSR receptor-specific standards, surface soils, etc.) based on maximum concentration – stats might be later employed in Exposure Assessment. From CSAP Technical Review #10:

"If a statistical approach is utilized in a Detailed Site Investigation (DSI) to conclude that a substance meets numerical standards, this conclusion (and the statistical approach upon which it is based) does not need to be re-evaluated in the risk assessment. Therefore, provided the substance is not relevant to the exposure of rare and endangered species or is a bioaccumulative substance, the substance would not be considered a COPC."

- **Discussion point**: what is the scope of the annotated table re: COPC screening and acceptable risks? Maybe add to "notes and implications"?

- Acceptable Effects Levels, fourth box, Sediment quality criteria.

"The risk-based approach can be used to support remedial action planning for sediments at any contaminated site in British Columbia. This approach is often used where the scale, scope, and uncertainty of remedial efforts identified using the criteria-based approach can be reduced. Typically, this is done by demonstrating to the satisfaction of the Ministry that risks are less than or equal to those upon which the criteria are based (i.e., a 20% probability of an EC20 at sensitive sites and a 50% probability of an EC20 at typical sites). Also, we should determine if MOE is using the narrative goals (e.g., P20 of EC20) to guide interpretation of acceptable risks; in our experience, decisions are made on a station-by-station basis, not on groups of stations or area-basis (i.e., the EC20 rule is used, but not the P20 rule, and not in the case of WOE which is more challenging – see below). We also note that the sediment criteria appear to be based on invertebrate survival endpoints only. Clarification is needed to determine if survival endpoints should be afforded more emphasis than sublethal endpoints in sediment risk assessment when defining acceptable risk and/or how this gap should be addressed. Also, what about other aquatic receptors and reliance on the benthic-derived sediment criteria?."

Agree that it should be made clearer whether EC20 toxicity test results is the pass/fail for a site based on individual sample locations, or whether it is > 20/50% of site area or > 20/50% of toxicity test samples showing worse than EC20 as the pass/fail. I also believe it is the former, i.e. EC20 exceedance alone. Probability was integrated into the derivation of the standards (20% of test samples showed EC20 or worse) but I believe it is absent from the ecological protection goal? This should be resolved.

Also agree that criteria are based on amphipod EC20 lethality, and whether protection goal needs to include sublethal effects needs clarification, especially given some sediment toxicity tests report growth effects. Suspect protection goal is to include sublethal.

In addition, there should be greater clarification by MOE on how ERA can focus on more surficial sediments that represent the main biologically active zone rather than top 100 cm. Is there any consensus on what depth this is? Is Ponar method collection (often limited to 0-

10ish cm) and toxicity testing adequate assuming a non-erosional environment and no dredging plans?

- **Discussion point**: what is the scope of the annotated table re: interpretation of sediment toxicity methods and results? Maybe add to "notes and implications"?

c. Roles of risk assessors as QPs and APs

- The differentiation between the roles of QPs (risk assessment report authors) and CSAP AP Arm's Length Recommendation providers) is important for CSAP.
  - **Discussion point**: Review text for QP and AP roles (see handout re: Procedure 8 and draft proposal)

3. Part 3 – Application of Risk-based Standards to Ecological Receptors

Key messages - review content of Table 1:

- *Narrative assessment endpoints (entity, attribute, spatial extent)*
- *Values for protection goals (changing with omnibus?)*
- *Use of EC/IC/ED/ID/NOAEL/LOAEL and their relationship to the protection goals (link to TG7; check annotated table)*
- *New land uses; microbial processes versus AL only? Protection goal for listed species?*

a. Assessment endpoints and protection goals – Table 1

- The lack of clear protection goals remains a key hurdle.
- Notes 7 & 8. "It is assumed that assessing organism level attributes will be protective of population attributes", and that "the assessment population is operationally defined as the local population, which consists of all organisms exposed to, or indirectly affected by, contaminants at the site". These are very useful notes that are missing in existing MOE guidance. This helps to clarify that ERA focusses on those animals and plants exposed to the site as opposed to the larger regional Population.
- Table 1. I fully agree that at the core of the decision re whether the risk based standards are met is the a priori "assessment endpoint".
- Spatial Extent - I think an issue we need to wrestle with is the idea of whether the spatial area is ecologically relevant (stated in Footnote 1). The concept is correct – but we will be challenged with small legal parcel with even smaller earthen plots in urban concrete jungles – and likely the ecological relevance is moot. There is already the definition of the eco-habitat within the SLRA protocol (P13) which considers both size (according to land use) and whether it is contiguous. For the most part I think this works and adding anything that deviates or complicates this may not be a good idea.
- Spatial Extent – "the spatial extent of the entity is assumed to be represented by the entire property (aquatic and terrestrial habitat)s" I am not sure how this wording is intended to relate back to the population of the entity. Clearly the local population of the entity may be

distributed well beyond the "property in question" - so I am struggling with this phrase. It sounds that this may lead to dietary exposures for roaming animals being standardized to 100% from "the property" – when in fact it should be pro-rated – as it typically is now. The decision about population risk acceptability should be based on a pro-rated exposure. In addition it ought to also consider that a population of individuals may have certain members that never access the site – therefore this italicized phrase has potential to bias the decision of acceptable risk to the population (it will err towards more unacceptable outcomes). Sorry to make this more complicated.

    - **Discussion point**: See text box above.

- ECx terms and the values shown. Technical Guidance 7 (TG7) is now also using the EDx term, likely given wildlife risks are evaluated with respect to intake dose. This table may be a good opportunity to better clarify and describe the MOE ecological protection goals. Perhaps additional description could be added to Note 1. For example, for a commercial site and wildlife, if EC/ED50 is the protection goal, what would this represent? A dose synonymous with a minor effect to 50% of the population/test organisms, or a dose representing inhibition of 50% to reproduction (offspring) or growth?

    - **Discussion point**: See text box above.

- I suspect many wildlife ERAs are still using NOAEL and LOAEL, because they are available, and because MOE references them as a TRV via TG7 (USEPA eco-SSLs). Big picture question - Is MOE's preferred eco-SSL TRV the geomean NOAEL values, i.e. the default TRV that EPA used to determine the soil screening levels (without being considered de novo derivation and requiring approval per Protocol 6). If yes, i.e. if NOAELs are default TRV I can envision a scenario where wildlife risks may be overestimated, in particular relative to an EC/ED50 protection goal which is not very conservative. And given that for wildlife it is difficult to draw in other lines of evidence (no toxicity testing, lack of meaningful biological observations) most decision making weight will likely be placed on the HQ value. There is then the possibility of sites being ranked (per Figures 2 and 3) as "moderate risk" based on the NOAEL (HQ over one, perhaps $1 < HQ < 10$ range). With the resulting classification of "moderate risk" these sites would not be eligible for CoC. I'm wondering if this scenario will come up a lot and if it can be prevented, perhaps with more clarification of the protection goals and TRVs that should be used for wildlife for the different land uses. E.g. Is MOE amenable to use of the geomean of LOAELs as TRVs for all sites, or for commercial and industrial sites?

    - **Discussion point**: See text box above.

- Should high density residential be added as a land use to Table 1?
- Is soil microbial processes only a receptor/assessment endpoint for agricultural lands? If yes, perhaps indicate.
- Soil Microbial Process – I suspect this is frequently not assessed. What is the intended role of this entity in forming decisions on risk acceptability? Is it moving towards a mandatory soil bioassay for basic function – or proposed as an alternative?
- Is the protection goal for listed species EC10? Is that in any MOE documents?

    - **Discussion point**: See text box above.

b. Risk characterization (Optional) – Figure 2

Key messages: - *Does this guidance belong in this deliverable? If so, review comments below.*

- In reviewing and considering Figure 2, I found Appendix A *Compilation of CSR Policy and Guidance on Risk-Based Standards for Ecological Receptors* quite useful.
- What is also interesting is that despite Protocol 1 often getting a lot of negative criticism, Protocol 1 actually does lay out details on a similar approach, i.e. a simple weight of evidence approach to evaluate ecological risks, e.g. #1 begin with a hazard quotient screening approach based on site-wide 95% UCLM / TRV (analogous to HHRA HQ/ILCR values); #2 then proceed to considering spatially distinct risks and percent site/probability of exceeding a set HQ value (useful where 95% UCLM is biased by localized contamination and outliers); #3 integrate real site observations (for some receptor types, possibly including toxicity testing). I think that this stepwise approach, and a simple weight of evidence approach, often gets overlooked in simpler, rushed, or budget-limited detailed ERAs for sites. Reports sometimes limit themselves to just #1 (site-wide 95% UCLM HQ) and then struggle with making conclusions around whether a site meets risk-based standards if site-wide HQ is marginally over a value of one, in particular in circumstances where ~2 < HQ < 5. The struggle is in part given these ERAs lack other lines of evidence, and in part perception around HQ>1 representing not meeting CSR risk-based standards given the CSR human health risk-based standard written into the regulation, or failure to discuss uncertainties in the HQ approach/value. Therefore, overall the approach proposed (screening with an initial HQ value, and then proceeding to other lines of evidence) appears good, and is in line with existing Protocol 1.
- Figure 2 - LOE and WOE. LOE/WOE have their place – no question – particularly in more complex and larger sites. But I believe there are sites and instances where LOE/WOE are over-the-top requirements. This becomes especially troublesome to achieve practical risk-based resolutions when site investigations requires a priori LOE/WOE plans before adequate site characterization has taken place. Risk assessors (QP or AP) should have the ability where chemistry, HQs, and site recon afford a clear picture that (notwithstanding exceedances of numerical standards) predicted acceptable HQs and simple site reconn observations are sufficient to make a risk assessment "acceptable" or "not acceptable" decision – without undertaking LOE/WOE as per DERA. I am concerned that this topic and application of LOE/WOE – which is really "impact assessment" can make a mountain to of a mole hill in terms of time/effort/cost. One must understand too, that the parameters that may be sought in a LOE/WOE approach may not have had time to evolve to be meaningful at a site; and also that population influx of certain species can mask effects as well. I think in many instances, simplifying the approach, understanding the ecology of the site, elevating the effort of site reconn for ecological observations and bringing those observations to bear on the risk acceptability decision may be adequate for many low – medium risk sites of small size. The guidance on decision of risk acceptability should try to tease this out – so that risk assessors know a priori whether LOE/WOE is needed for a certain site. I don't think LOE/WOE should be a default "must do" when site chemistry, HQs and overt healthy habitat evidenced by site reconn shows an acceptable situation to an RPBio/CSAP, or

RPBio/QP. I'd encourage a modification to Figure 2 that addresses this concept. To some extent the principles in Step 3 may embody the rationale that I am encouraging. I encourage a principle whereby a rapid assessment of site HQs and reconn of habitat size and robustness/productivity can be a basis to seek pre-approval for simplified ERA without formal LOE/WOE.

- **Discussion point**: See text box above.

i. Step 1 (LOE screening)

- This appears analogous to a combination of SLRA P13 and Protocol 1 main recommended approach.
- Is LOE (lines of evidence?) the best term to use here? Would it be better to call this "Step 1 Site HQ". Followed by "This step involves screening individual receptors site-wide or AEC exposures against CSR protection goals (values in Table 1)." And then to the right side of the figure indicate "All receptors exposures < ECx", "All receptors HQs < 1.
- Should Step 1 make reference to using 95% UCLM as a default exposure concentration? (If 95% UCLM is set as default might need some conditions, e.g. might not be relevant for very large sites where contamination is focused in a smaller area (AEC), in which case 95% UCLM of AEC might be more appropriate. This topic may also need more guidance, i.e. what is the appropriate statistical exposure concentration for different ecological receptors.)
- Providing MOE agrees, could a note also be made that rounding down of the HQ values to one significant figure is permitted?

- **Discussion point**: See text box above.

ii. Step 2 (WOE attributes)

- Could Step 2 WOE perhaps mention the other lines of evidence that should be considered, perhaps similar to what is recommended in Protocol 1 (e.g. spatially distinct HQs and percent site/probability of exceeding HQ = 1; site observations, toxicity testing).

- **Discussion point**: See text box above.

iii. Step 3 (ecological considerations)

- The concept of additional considerations is good, though I found some of the examples not that self-explanatory and a touch confusing. Perhaps leave out examples and just go with the description. Or re-word and clarify examples.
- Should Step 3 also ask the risk assessor to prepare a table categorizing both risk and uncertainty into one of the four/three qualitative classifications for each receptor. That table would then feed into Figure 3 decision making on whether risk-based standards are met.

- **Discussion point**: See text box above.

c. Interpretation of risks and uncertainties – Figure 3

Key messages:

- *Objectives of Figure 3*
- *Terminology for x versus y; directional uncertainty e.g., avoid underestimating magnitude of risk/making Type 2 error*
- *Present examples/discuss options:*
  - *DERA narratives*
  - *Figure 3 (fixed magnitude scale versus change definition for each land use)*
  - *Australian ERA table*
  - *MOE example*
  - *Golder example*
- *Harmonize terminology "risk management or remediation" with Figure 1, DERA, Protocol 8*
- *Implications for QP submissions (i.e., provide table or figure that outlines predictions of magnitude and likelihood/uncertainty?)*

- In making decisions regarding acceptable risk, we will always be using professional judgment and will always need to stick our necks out a bit. Anyone can pronounce risks acceptable when it is a slam dunk. It is when all lines of evidence are not pointing in the same direction that professional judgment comes in.
  - **Discussion point**: Does Figure 3 achieve this?
- Figure 3. "Risk-based standards are met" box, the last statement reads: "Risk management or remediation is not necessary." It may not be true that the risk is low and the uncertainty is low and risk management is not necessary … it may very well be that risk management is what keeps the risk low and uncertainty low. I understand your intent with this sentence but it points to a path of 'no action' to maintain low risk, which may not be true re: risk controls (e.g., engineered), RM, etc. Perhaps this sentence could be omitted? Or updated?
  - **Discussion point:** Is risk prediction pre or post risk control?
- Figure 3. I'm not sure that I agree with the shading being labelled as "low priority", "medium priority", "high priority". It is the generalization of this classification of priority that seems ambiguous regarding the context/source of the priority (e.g., proponent vs First Nation). As well, sometimes great expense can be incurred for 'high risk, high uncertainty' risks that result in little benefit to the site as a whole so then a 'higher priority' may be the moderate risk, moderate uncertainty, or other low-hanging fruit outcomes. If you have already considered this thought then there may not be a solution that fits each situation so the generalization could stay as it is currently depicted.
  - **Discussion point:** Review priorities with group.
- Figure 3 essentially represents the pass/fail for a site for ecological receptors. Figure 3 is the judgement call made by the QP and would be reviewed by the CSAP. Overall I like the approach used by Figure 3, and its narrative descriptors of risk and uncertainty on a simple four/three-point scale, and this categorization following the encouraged WOE approach as opposed to being based on HQs alone. One could populate a single Figure 3 chart with each receptor's name placed in their appropriate region.
- Also, should the figure be drawn with a defined box around the four quadrants in the lower left quarter that represents the categorizations in which risk-based standards are met?

- Caption “Too Uncertain”. Suggest you change caption heading to “Risk-based standards are not met based on uncertainty”.
- Text under “Too Uncertain” and “Risk-based standards are not met” captions. Text reads “implies that some adverse effects are likely (possibly ranging from low to high magnitude) or (with relatively high magnitude). Just wondering if “magnitude” should be mentioned here, as what is acceptable versus unacceptable in terms of magnitude differs between the land uses (wildland versus industrial) and receptor types. And would this be confused as meaning only sites with high magnitude effects do not meet risk-based standards. E.g. an aquatic life EC20 protection goal might be exceeded (as demonstrated by toxicity testing) and the author concludes site has moderate risk and does not meet risk-based standards, though magnitude of effects some might argue are not that high relative to the conservative protection goal.
- Australia ERA Table 1 has a similar table to Figure 3 in concept that ranks risk based on likelihood and consequences. http://www.environment.gov.au/science/supervising-scientist/research/ecological-risk
- CSR 56(1) is very important to my mind – it is the core part that says “do the best you can for the sake of BC’s environment”. It dictates the considerations of what ought to be considered and what ought to be done if the risk is considered unacceptable. It would be nice if it also influenced what ought to be done if the population risk was acceptable in spite of site contamination – so that contamination could still be improved. I don’t see how this latter issue fits within Azimuth’s scope…but would support any means to strengthen the role of CSAP-Risk to tighten this part of CSR to improve the frequency of site improvements even when current risk is found acceptable. For example – perhaps the risk management decision has a guiding principle about minimally required efforts to improve upon the site conceptual eco-exposure model – notwithstanding the acceptable eco-risk.
- Remediation and Risk Reduction – partial remediation may not always translate into risk reduction (risk mitigation). Azimuth should provide direction and principles that encourage any decision respecting unacceptable risk to translate into remediation that indeed leads to risk reduction.
- Simplicity to Reconcile Assessment Endpoint Statements using Chemistry/HQ/Spatial Relevance/Population Health Endpoints/Site Reconn Status/Receptor Population Resilience AND Implications or Consequence of an “Acceptable Decision” – this is a wordy title – but the intent here is to encourage Azimuth to direct risk assessors to not only consider the routine minimal concepts above (which in this case excludes LOE/WOE to reflect a more uncertain and minimalist scenario) – but to also consider if there are any big time consequences that may arise if an “acceptable risk” is assigned and no further remediation/risk reduction required. This is bordering on subjective judgement by the QP/AP risk assessors (e.g., “if I subscribe to the finding of “acceptable risk” (especially in a marginal case) – will the resulting do no further action be a significant negative long-term consequence to the site? If the answer is yes it suggests that the scope of the risk assessment was not broad enough – and the risk assessor may want to rethink the “acceptable” decision. Principles to guide this may be useful and provide a basis to more closely exercise EMA 56(1) and 56(2).
    - **Discussion point**: Figure under development; see text box above.

Appendix D

Summary of Decisions and Actions for 1st Workshop (January 27, 2016)

RISK MANAGEMENT DECISION FRAMEWORK FOR BC CONTAMINATED SITES

Phase 2 Guiding Principles for Applying Risk-based Standards to Ecological Receptors V1.1

Technical Working Group (TWG) Workshop
January 27, 2016 at the Azimuth Office
Summary of Decisions and Actions

Attendees:

David Williams
Heather Osachoff
Michael McLeay
Mike Rankin
Reidar Zapf-Gilje
Sam Reimer
Trish Miller
Patrick Allard
Beth Power
Cheryl Mackintosh

These meeting notes are intended to document decisions taken and actions identified during the TWG workshop held at Azimuth on January 27, 2016. They are organized by topic (i.e., sections of the draft Table of Contents for the "Guiding Principles" document).

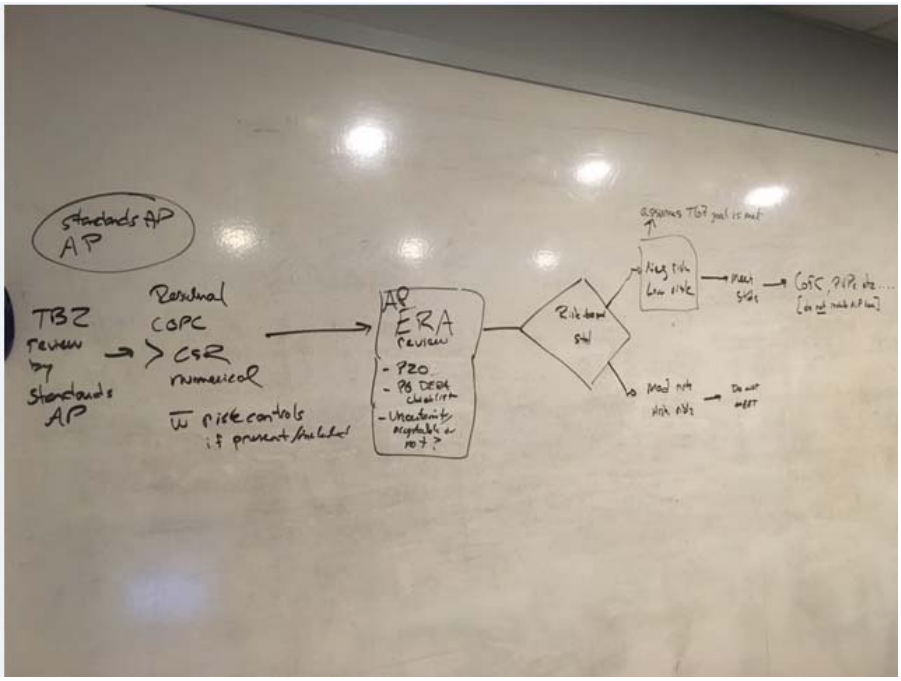
Part 1 – Objectives of the Technical Guidance

1) Decision: This Guiding Principles document will be a CSAP 'practice guidelines' document. It will target the AP reviewer, but is expected to trickle down to the QP practitioner. After version 3 submission by Azimuth to CSAP, document can be distributed to all CSAP members for input and then sent to MOE for final input (CSAP Technical Review Committee responsibility). This document could later be used by MOE as Technical Guidance or Technical Bulletin, if MOE makes a request to CSAP.

Part 2 – Context for Developing Guiding Principles

Description of RA/RM process – Figure 1

2) Decision: Figure 1 in the version 1.1 draft is useful because there isn't a flow chart for the CSR process; however, further effort to refine the figure is beyond the focus of this project (perhaps MOE wants to develop the figure further). For the CSAP practice guidance on RA/RM, Figure 1 will be cut down to only focus on the ERA decision-making steps (see below).



3) Decision: Terminology in the figure and entire document will be “meets risk based standards” or “does not meet risk based standards” (rather than risks are acceptable/unacceptable). If site does not meet, then needs to go back to proponent (remedial options analysis) or MOE (Director can consider EMA Section 56 and other factors and – then risks can be determined as acceptable or unacceptable). This is not part of the AP review process (not shown in Figure 1; figure is with risk controls in-place, as needed).

4) Action: Azimuth to cross-check above terminology with MOE/updated legislation and revise Figure 1 and Appendix A accordingly.

5) Action: In Figure 1, make footnote for AiP instrument: “moderate/high risk could be the finding, but negligible to low could be achieved with proposed control measures.”

6) Action: Add QP ERA box before Standards AP. Also add, as part of ERA review – determine if level of uncertainty in the risk prediction is acceptable or not to determine whether risk-based standards are met.

Annotated compilation of CSR policy and guidance on risk-based standards for ecological receptors – Appendix A

7) Decision: Useful as is; this document will remain an appendix (background/resource document), not part of the guidance.

8) Action: Add TG7 ERA general guidance “the primary goal of ERA… continued presence, successful re-introduction…” (if not in the table already). If risks are rated moderate or high, site does not meet goal, if risks are rated negligible/low, then site meets TG7.

9) Action: Revise/update with MOE updates (e.g., TG7, Procedure 8) and comments from TWG (also revise terminology change acceptable risks to meet risk-based standards). Azimuth to check with Heather that we have all MOE comments on Appendix A (re: comments from Peggy and/or Lizzy).

10) Action: Develop "action item list" from notes column; identify specific issues that need follow-up by CSAP/MOE (e.g., actions/white papers).

11) Action: TWG to give Appendix A another review once they receive version 2.0 (as it will have some changes to it at this point).

Roles of QPs and APs

12) Decision: Opinion that because guidance is for AP, then role of the QP should not be defined in this document (AP role is already defined in CSAP practice guidance). However, roles do need defining in regards to QP making the determination of whether risk based standards are met (and AP reviewing this). Decision was for Azimuth to prepare a second draft (V 2.0) that defines roles and incorporates existing definitions in Procedure 8 and CSAP guidance; TWG to review.

Part 3 – Application of Risk-based Standards to Ecological Receptors

Assessment endpoints and protection goals – Table 1

13) Decision: Table 1 shows AELs for individual LOEs under different land uses. Some of this information does live in other places, but is not well synthesized. Overall, there is agreement that these AELs are useful to include in the guidance as Table 1. MOE (Heather) will provide information regarding AELs for listed species. Although both TG7 and DERA indicate that the "assessment at the individual organism level may be required under certain circumstances" (e.g., listed species), Azimuth did not find any text that operationalizes this as a lower ECx value. Perhaps the intent is not necessarily to reduce the "x" but rather to apply the specified land use protection goal (EC10/20/50) using endpoints that are representative of individual organisms (not based on community- or population-level metrics). MOE to confirm.

14) Decision: Table 1 can reflect current land-use AELs (don't try to reflect the 2016 omnibus update) but make a footnote about time period in the Table (and that AELs may be changing).

15) Decision: Table 1 does not need to be broken down by receptor group (present more at the footnotes level). Make a list of topics ("principles") to include and refer to other guidance where available (SLRA – not always looking at populations for small urban sites, DERA, FCSAP). If guidance is not available for a particular topic then provide clarification in Table 1 (e.g., this is how you should define the population). After deliberation, TWG agreed that, where possible, we should rely on existing guidance; however, if there are important gaps for QP practice, then it is ok to provide direction (e.g., like the COPC screening guidance that CSAP prepared).

Risk characterization (Optional) – Figure 2

16) Decision: Keep this figure in as this information is not in any other document. Make some revisions to simplify. Rename the "steps" to clarify that you can do just the LOE HQ/ECx screen (and be done at that point). LOE screen can be one LOE or multiple (discussion about presenting these as a hierarchy – e.g., HQ first then other LOEs, but decision was just to include all LOEs together). If LOE screening is not met, then proceed to WOE; other considerations.

Interpretation of risks and uncertainties – Figure 3

17) Decision: Use table with modified DERA risk narratives as definitions of negligible, low, moderate, high risk = definition of risk-based standards. This will become Table 2 and will replace Figure 3. Low versus moderate risks is the most important boundary; wording needs careful thought. See also Note 8 above about TG7's goal for ecological risk management.

18) Decision: Uncertainty to be woven into DERA risk narrative. If uncertainty is too high then does not meet risk based standards. (Concept of does ERA have an "acceptable level of uncertainty" added to Figure 1; see above).

19) Decision: Figure 3 Option 'D' (risk vs uncertainty with relative magnitude scale – can show different AELs for each magnitude rating for different land use examples) present as an optional way of showing risk findings; will go into background/resource material (Appendix B?). If 'likelihood' is used instead of uncertainty, then change unknown to unlikely; however, in ERA for contaminated sites we are not usually really quantifying likelihood/probability.

20) Decision: Clarify that QP needs to define risk and whether meets risk based standards; guidance shows optional ways of showing this. AP reviews the evidence for QP's conclusion.

21) Action: Add clarification at the beginning of the DERA risk narratives that this is the outcome *after* implementation of risk control (because APs are reviewing applications for CoCs where those controls must already be in place).

22) Action: Add clarification that these definitions do not coincide with "high risk sites" in MOE's site classification system, which is really a priority rating (not risk rating).

23) Action: If any single ROC has moderate or high risk, then site does not meet risk based standard/get COC – add this concept somewhere.

24) Option: Could come up with scenarios – give examples of what is "low", "moderate", "high" risk.

Appendix E

Summary of Decisions and Actions and Pre-Meeting Comments for 2nd TWG Workshop (April 14, 2016)

RISK MANAGEMENT DECISION FRAMEWORK FOR BC CONTAMINATED SITES

Phase 2 Guiding Principles for Applying Risk-based Standards to Ecological Receptors V2.0

Technical Working Group (TWG) Workshop
April 14, 2016 at the Azimuth Office
Summary of Decisions and Actions, and Pre-Meeting Comments

Attendees:

David Williams
Heather Osachoff (phone)
Michael McLeay (phone)
Mike Rankin
Reidar Zapf-Gilje
Sam Reimer (phone)
Trish Miller
Patrick Allard
Beth Power
Cheryl Mackintosh

Agenda:

1) Review version 2.0 deliverables and discuss comments
   a) Figure 1
   b) Table 1
   c) Table 2
   d) (Appendix A if any comments)
2) Review running list of action items for follow-up
3) Next steps for version 3.0

These meeting notes are intended to document decisions made and actions identified during the second Phase 2 TWG workshop held at Azimuth on April 14, 2016. They are organized by topic (i.e., table and figure deliverables).

Figure 1

- Overall positive feedback and good that it focuses on what meets RB standards.
- Box 2a: Delete "level of uncertainty associated" in the third bullet; maybe delete the third bullet. Could reword 3rd bullet: "Determine whether ERA is complete and adequate to proceed." **Action: Azimuth deleted 3rd bullet.**
- Box 2b: A lot of discussion on the figure and potential scenarios.
  - Graphic is a conceptual depiction of RB categories (Table 2 narrative is too long for Figure 1). Change to a 'shades of grey' and use a straight line between meets and does not meet RB standards; maybe a zone with 'possible' category in between.

- This is guidance, so someone could provide rationale as why risks are 'low-to-moderate' but does meet RB standards. Need to justify why you think more on the low range or why you think risks are 'acceptable'. Overall, based on WOE, you would say 'low risk'.
- Why does low risk-high uncertainty category not meet RB standards? Provide rationale for why RA (QP) thinks risks are acceptable.
- Conceptual diagram needs to work for both IL and sensitive sites. TRVs could mean 0% effect for sensitive site, versus 25% or 50% effect for other land uses. Categories need to reflect specific assessment endpoints and land use. IL TRV is EC50; how can this be negligible? The risk ratings always have to be within the context of land use which affords different levels of protection. 2b x-axis label does specify that based on land use, so further clarification not needed.
- Do we need professional judgement box after 2b? No 2b incorporates professional judgement; i.e., the wording in Table 2 (definitions of RB categories) allows for judgement by the QP and incorporates some 'fuzziness'.
- Discussion on audits - can't have an ERA with "low to moderate" risk for an audit. All has to be in the green zone. If you get pulled for an audit, this becomes your risk assessment. Board is working on how we can develop a system that relies on more professional judgement rather than Audit system. Have to have a range of what is 'acceptable'.
- Should uncertainty on 2b graphic go to high? Don't even submit if you have high uncertainty. Site characterization below 2 orders of magnitude don't need to collect seasonal data. Dealt with way too high uncertainty in the 2a box.
- What about directional uncertainty i.e., if ERA used conservative assumptions. **Decision: Only uncertainty that risks are underestimated (Type 2 errors) is important (directional uncertainty) for APs.** (See further notes under Table 2). If uncertainty is high and but RA has erred on conservative side then ok; used some realistic assumptions.
- **ACTION: Replace conceptual figure; add "wedge" to risk-uncertainty plot.** There is a zone "wedge" where professional judgement has to determine whether RB standards are met. **Wedge = negligible-low risk with moderate-high uncertainty (see mock-up) "may meet risk based standards". Action: add some narrative in the text around what is required, e.g., allow professional judgment but provide strong rationale for making sound decision despite high uncertainty (not in moderate category). Make figure green for meets/dark grey for doesn't meet/light grey for wedge.**
- When QP discusses whether meets RB standards with AP, only thing that changes is your risk perception… not additional data.

- Box 6: **Action: Reword.** Delete "e.g., EMA 56" could be remediation, additional risk assessment, ect. Do whatever outside of the AP process (no e.g.,). BP comments for Box 6 reword = **"ERA Does Not Support Instrument under Protocol 6. QP to Evaluate Other Options."**
- Footnote 1, Footnote 2: **Action: Delete:** Issue with risk controls already "in place", means documented. It depends on controls. Decision: remove footnote 1 and 2 put (COC and AiP) in parenthesis.
- Title: **Action: Reword. Decision-making tool for interpreting risk-based standards for ERAs submitted under Protocol 6.** No "(COC, AiP)" in brackets. **Followed-up with Heather; correct reference is "Protocol 6 for Contaminated Sites".**

Table 1

- Protection goals list EC10-20 for AL, PL – is EC10 still being looked at by MOE for new omnibus? Protection goals not being changed? PL, RL looking at 25%? RL split, WL split. Reconciling the ECx with CSST protocol protection goals? If Tier 1 is contradictory with new omnibus, need to be aware of this; MOE reconcile. Table 1 reflect EC values for omnibus; omnibus takes precedent over Tier 1 and Protocol 1? MOE needs to reconcile. BUT today Protocol 1 and Tier 1 are still used. **Decision: Ranges of ECx protection goals are ok in Table 1 (include omnibus, Tier1, protocol 1), but must footnote that omnibus is draft/not yet in force and must change this table if the MOE policy changes in future. Update Table 1 to include ECx in new omnibus; see Remi's protocol paper, posted on-line. Azimuth checked some MOE references for ECx protection levels; these were checked with Heather:**
    - AL = EC10-25 (omnibus is EC25, Protocol 1, Tier 1 are EC10-EC20)
    - PL = EC10-25 (omnibus is EC25, Protocol 1, Tier 1 are EC10-EC20)
    - Wildlands:
        - WL = EC10-20 (estimated based on parkland… but likely superseded by below)
        - Natural Wildlands "WL_N" = EC15 (MOE update)
        - Reverted Wildlands "WL_R" = EC25 (MOE update)
    - Residential Land:
        - RL = EC20 (Protocol 1, Tier 1)
        - Low density [RL_{LDR}] = EC25 (omnibus; MOE update)
        - High density [RL_{HDR}] = EC50 (omnibus; MOE update)
    - CL = EC50
    - IL = EC50
    - AL = EC20

MOE References (accessed April 19, 2016):

Remi Odense and Glyn Fox. Feb 2016. CSR OMNIBUS UPDATING: Protocol Summary - Amendments to Schedule 5 Environmental Protection, Matrix Soil Standards. http://www2.gov.bc.ca/assets/gov/environment/air-land-water/site-remediation/docs/policies-and-standards/amendments_sch_5_eh.pdf

Remi Odense and Glyn Fox. June 2015d. CSR OMNIBUS UPDATING: Protocol Summary - Amendments to Schedule 5 Environmental Protection, Matrix Soil Standards. http://www2.gov.bc.ca/assets/gov/environment/air-land-water/site-remediation/docs/requests-for-comments/proposed_amendments_to_schedule_5_envprostd.pdf

Peter Kickham and Glyn Fox. June 2015e. CSR OMNIBUS UPDATING: Proposed High Density Residential Soil Standards. http://www2.gov.bc.ca/assets/gov/environment/air-land-water/site-remediation/docs/requests-for-comments/proposed_amendments_to_schedule_5_hdrss.pdf

Remi Odense. December 2015f. CSR Omnibus Standards Updating Supplemental Consultation Document. http://www2.gov.bc.ca/assets/gov/environment/air-land-water/site-remediation/docs/requests-for-comments/consultation_paper_two_tier_wildlands_standard.pdf

- Table 1 references - change reference to MOE or EMA Tech Guidance 7. **Action: Heather followed-up; correct way to reference documents is "Technical Guidance 7 for Contaminated Sites".**
    - (CSR?) Protocol 6
    - (CSR?) Protocol 1
    - Tier 1 ERA Decision Summary
    - (CSR?) Technical Guidance 7
    - "Omnibus Update"
- **Action: Add "spatial" area in Assessment Endpoint first box.**
- Listed species – took wording from Lizzy at MOE and reflected, but discuss further with MOE (added topic to CSAP/MOE meeting list below)
- **Action: Add footnote into Table 1 footnote 1 that ECx is really an ICx**

Table 2

- Definitions; the for instance examples are helpful even though all terms are not specifically defined. Also wisely did not include HQs>100 for high risk.
- Discussion on "Low" for instance examples. LOW = high likelihood that low level of adverse effects. **Decision: Last bullet phrase as: "While some adverse effects are possible, the WOE indicates they are unlikely".** If adverse is there – why is it acceptable? Should we use tolerable effects? LOW can be because low frequency or magnitude OR LOW based on WOE.
- **Decision: reword uncertainty. Uncertainty is defined only for underprediction of risk, put this at the top of the definition; for moderate or high remove the +/- 1 or 2 risk categories. Keep LOW = actual risk category is unlikely to be higher than current prediction. Change outside to "higher" for all definitions. Risks could be lower, but we are only worried about chances of underpredicting.**

Action item list from Appendix A

- Reviewed. The actions are not in scope of current work, not trying to resolve. But want to determine what to follow-up for another CSAP/MOE meeting.
- **Decision: Useful to follow-up with MOE about Action Items 1 and 6 (Action: Delete all other items in Appendix A; modify Appendix B [action item list] for final report)**:

1. *With recent changes to the Federal Fisheries Act, there may now be greater incongruence between federal and provincial policy for fish and fish habitat. How are Federal commercial, aboriginal and recreational fisheries reconciled against provincial policy? Also, water quality guidelines are not administered under the CSR directly; EMA provisions would need to be invoked. Also, we should determine if MOE is using the narrative goals (e.g., P20 of EC20) to guide interpretation of acceptable risks what "meets risk-based standards"; in our experience, decisions are made on a station-by-station basis, not on groups of stations or area-basis (i.e., the EC20 rule is used, but not the P20 rule, and not in the case of WOE which is more challenging).*

(Notes: This is currently being interpreted on a station by station basis – not 'acceptable' for 20% of stations to be above EC20. Is it a spatial issue? TRV is EC20, standard is 20% prob of EC20. Diff reliability in standards based on data available. No min volume to designate contamination. Tech Guidance 2 = 1 population of seds, not contamination due to 2 or 3 hits because enough samples. Could this be applied to risk. But spatial area is relevant to ROC.) **Decision: Useful to talk to MOE about this topic.**

2. *Clarification is needed to determine if survival endpoints should be afforded more emphasis than sublethal endpoints in sediment risk assessment when defining acceptable risk and/or how this gap should be addressed.*
3. *Also, what about other aquatic receptors and reliance on the benthic-derived sediment criteria?*
4. *The Procedure 8 definition "ecologically active zone" means the top 1 metre of sediment below the sediment/surface water interface. Does this also apply in cases where the stability of sediment >100 cm depth is unknown (i.e., does this part of the undated Technical Appendix for Sediment still apply)?*

(Notes: Procedure 8 says 1m; Tech Guidance 15 upper 1 m of STABLE sediment. Up to risk assessor to clarify the ecologically active zone.) **Decision: #2,3,4 don't need discussion with MOE**

5. *Re: TB2 summing of exposures. Clarification and policy of how TB2 should be followed for ERA is urgently required for APs, particularly given the consequences of not following TB2 (ACTION). As noted elsewhere, Protocol 20 considers the need to address potential toxicological interactions (e.g., synergistic or antagonistic effects) between potential contaminants of concern as optional.*

(Notes: TB2 not meant for ERA, only if there are similar modes of action of chemicals.) **Action: Meeting notes from last CSAP/MOE meeting should be added to Appendix A**

6. *There should be consistency between the numerical standards and ERA TRVs (there is somewhat of a disconnect between the ECx protection goal values for different land uses and the CSST approach for deriving the soil standards; Schedule 5 standards are less conservative than what the ERA docs are asking for as the protection goal, because the standards used EC50 sublethal or lethality endpoints).*

Decision: Useful to talk to MOE about this topic.

7. *Also not clear what is meant by EC20. Statistically significant tiny effect on plant growth to 20% of test plants, or 20% decrease in growth of the average plant (IC20). It would be nice to clarify what was meant by the protection goals, maybe with some examples for our main receptors. (Response) Table 1 (see footnote #1) includes the definition of ECx based on DERA: an ECX consists of an effect concentration, with percent effect of X. Basically under this definition ECx = ICx.*

(Notes: DERA used ECx as an ICx. So we are using ECx.) **Action: Add footnote into Table 1 footnote 1 that this is really an ICx.**

Next Steps

- **Action: Have a CSAP/MOE meeting sooner than regular Nov/Dec meeting. Target 3rd week of May. At meeting discuss this 'Practice Guidance' as well as:**
    - Action items from Appendix A (see above)
    - Listed species – review wording in Table 1 using feedback.
- Draft report to be filled in with about changes to main deliverables for final report (Azimuth). 'Thin Report' so that CSAP can pull out main things as guidance. Report needs to document how funds were spent, e.g., minutes of meetings as appendices, ect. CSAP Guidance to be pulled together by CSAP (2 or 3 pages with tables/figures?).
- Presentations/communication: clear enough that you don't need training (for APs). Possible training for QPs, e.g., professional development workshop in fall. More than half of attendees at PD training in fall are QPs. CSAP Tech review committee could put on webinar, and also =have discussion with MOE about 'gudance'.
- September MOE conference – enter this Phase 2 as a presentation/poster – needs to be entered soon.

TWG written comments received prior to Phase 2 TWG workshop held at Azimuth on April 14, 2016; organized by topic (i.e., table and figure deliverables).

1) **Figure 1 Box 2b (graph):**

   a) Perhaps this should not be a black and white (green and grey) decision that hinges on classification of risk or uncertainty by a single word.

   b) I do like the requirement for practitioners to categorize their risk and uncertainty per these words, and having the description of these words in Table 2. However, would it be better to have a gradual shading in this figure, and whether or not meets risk based standards would be discretionary and up to AP professional judgement?

   c) Also, I'm not sure one can always categorize risk as a single word. E.g. could "low-to-moderate" be a descriptor? If used, such a classification would pose problems with interpretation using this figure.

2) **Figure 1 Box 6:** Wouldn't next step possibly be QP going back and getting more data and doing more detailed ERA to lower uncertainty. With subsequent AP review of revised more detailed ERA. That should perhaps be captured in this box as well.

3) **Table 1: Question for BCMOE**.

   a) How can the protection goal be EC10 or EC20 (with Protocol 1 suggesting preference for sublethal effects) for terrestrial biota in AL, PL, WL when the basis of the CSR toxicity to soil invertebrates and plants standards are "lesser of EC50-NL or LC20" (per CSST). IE) 20% lethality or 50% sublethal effects protection goal in numeric standards is less conservative than suggested protection goal for ERA?

   b) What is the new approach/protection goal for Omnibus updates? And should the basis of the ecological standards be mentioned in this table as the protection goal for soil invertebrates and plants? Or other receptors as well, e.g. aquatic life.

4) **Table 2 Moderate and high risk wording:** Is best wording "substantial ecological consequences" here and "severe ecological consequences" below. Relates somewhat to the TRV and protection goal. EC10 level of effects perhaps not "substantial" or "severe" consequences. Should this instead say "likely adverse effects" and "very likely pronounced adverse effects". Or other wording?

5) **Table 2 High risk wording regarding HQs:** Would it be okay to perhaps add the word "significantly" here. IE) HQ significantly greater than one. While HQs not scalable, HQ=100 clearly higher risk than HQ=3, as HQ=100 tends to overide uncertainty around the HQ via uncertainty in its underlying TRV.