

# 2021 COMMENT REPORT

As part of implementing Stage 13 changes, and to incorporate modifications made during previous amendments, the Ministry of Environment and Climate Change Strategy have revised ten Director's protocols. The ministry requested stakeholder feedback on the revisions, and comprehensive lists of the responses to each of the stakeholder comments, organized chronologically by protocol, are presented in the Comment Report.

Stage 13 Amendments  
to the Contaminated  
Sites Regulation –  
Revised Director's  
Protocols

# Summary

Legislation of contaminated sites in British Columbia is largely under Part 4 of the *Environmental Management Act* (EMA). Supporting provisions are in the Contaminated Sites Regulation (CSR), with further provisions detailed in Director's Protocols. Section 64 of EMA allows the Director of Waste Management to establish protocols over detailed procedural and technical matters related to contaminated sites. Director's protocols must be consistent with EMA and the CSR, and they are legally binding. They are instruments that were created to support compliance with EMA and the CSR, and contravention of the requirements of a protocol is an offence under section 120 of EMA.

In accordance with the established administrative process, any new or amended protocol must undergo a legal review and include consultation. A thorough legal review of the proposed protocol revisions took place in the fall of 2020. To meet the consultation requirements and to ensure that the proposed revisions made to each protocol were scrutinized fully by both internal and external stakeholders, a request for comment was initiated by the Ministry of Environment and Climate Change Strategy (the ministry) on November 27, 2020. A Site Remediation News update was posted to all subscribers reminding them that changes to EMA (Bill 17) and Stage 13 CSR amendments would come into effect on February 1, 2021. Although these amendments focussed on changes to the contaminated sites identification process, as part of implementing the changes, and to incorporate modifications made during previous amendments, ten protocols had been revised and were posted for comment. The ministry requested stakeholder feedback on the ten draft protocols and set 5 pm on January 11, 2021 as the comment submission deadline.

The draft protocols that were updated and posted for comment are:

- Protocol 1: Detailed Risk Assessment
- Protocol 4: Establishing Local Background Concentrations in Soil
- Protocol 6: Applications with Approved Professional Recommendations and Preapprovals
- Protocol 9: Establishing Local Background Concentrations in Groundwater
- Protocol 11: Upper Cap Concentrations for Substances Listed in the Contaminated Sites Regulation
- Protocol 12: Site Risk Classification, Reclassification and Reporting
- Protocol 13: Screening Level Risk Assessment
- Protocol 16: Determining the Presence and Mobility of Non-Aqueous Phase Liquids and Odorous Substances
- Protocol 17: Site Remediation Forms
- Protocol 28: 2016 Standard Derivation Methods

Adhering with the consultation process requirements, the ministry granted a 45-day request for comment period. The stakeholder feedback was to be submitted to the ministry on a template feedback form that was provided with the request for comment.

The ministry received approximately 700 stakeholder comments. Feedback on each of the revised protocols was collected, sorted and compiled for review and discussion by the respective ministry protocol teams. Every single comment was considered and addressed individually. Where warranted, changes were made to the protocols to reflect the feedback that was received. Comprehensive lists of the responses to each of the stakeholder comments, organized chronologically by protocol, are presented in the following appendices.

*The information provided in this report does not replace the legislative requirements in the Environmental Management Act or its regulations. If there are differences between this document and the Act, Regulation, or Protocols, the Act, Regulation and Protocols apply.*

## Appendix 1. Protocol 1: Detailed Risk Assessment.

Protocol #	Section #	New Section number	Comment/Recommendation	Ministry Response
1	1 - Acceptable Risk	1.0	Definition of acceptable risk should refer to the Contaminated Sites Regulation (Contaminated Sites Regulation (CSR)) risk-based standards (Contaminated Sites Regulation (CSR)) sections as per defn' of unacceptable risk for HH. Definition of acceptable risk for ecoRA should be based on CSAP/Azimuth document titled Risk Management Decision Framework for BC Contaminated Site, Phase 2 - Guidance Principles for Applying Risk-Based Standards to Ecological Receptors ( <a href="https://csapsociety.bc.ca/wp-content/uploads/Azimuth-RA-RM-Report-Final-version-May-submitted-to-CSAP-rev-August-2016.pdf">https://csapsociety.bc.ca/wp-content/uploads/Azimuth-RA-RM-Report-Final-version-May-submitted-to-CSAP-rev-August-2016.pdf</a> ) (Azimuth 2016)	The definition of "unacceptable risk" includes specific details on acceptable risk thresholds for human and ecological receptors. At this time, the ministry does not feel it necessary to repeat these items in the definition of "acceptable risk". Ultimately, the director determines if risks are acceptable. The Contaminated Sites Approved Professionals (CSAP) guidance has been noted for additional future consideration.
1	1 - Acceptable Risk	1.0	This definition of "acceptable risk" is different compare to what is in the new Protocol 13.	The definition of "acceptable risk" in Protocol 13 is specific to Screening Level Risk Assessment and the definition of this term in Protocol 1 is specific to Detailed Risk Assessment.
1	1 - Acceptable risk	1.0	The definition of acceptable risk should be expanded to include the definitions provided in the Contaminated Sites Regulation (Contaminated Sites Regulation (CSR)) for human health. For ecoRA, the definition should refer to the CSAP document titled Risk Management Decision Framework for BC Contaminated Site, Phase 2 - Guidance Principles for Applying Risk-Based Standards to Ecological Receptors	The definition of "unacceptable risk" includes specific details on acceptable risk thresholds for human and ecological receptors. At this time, the ministry does not feel it necessary to repeat these items in the definition of "acceptable risk." Ultimately, the director determines if risks are acceptable. The Contaminated Sites Approved Professionals (CSAP) guidance has been noted for additional future consideration.
1	1 - Bioaccumulation	1.0	The following definition of bioaccumulation does not appear to be consistent with well accepted definitions in the literature and regulatory guidance: <i>"bioaccumulation" means the progressive increase in the amount of a substance in an organism, or part of an organism, which occurs because the substance's rate of intake by an organism exceeds the rate at which the</i>	Thank you for your comment, it has been noted for future consideration.

		<p><i>organism is able to degrade or eliminate the substance.</i></p> <ul style="list-style-type: none"> <li>• Practically all substances that can cross biological membranes will undergo bioaccumulation to a certain degree and by definition bioaccumulation factors are determined as the steady state relationship between exposure concentration and body burden. At steady state, chemical uptake is equal to chemical elimination resulting in a stable concentration (i.e., the condition of intake exceeding elimination is not maintained). The process of bioaccumulation (which most chemicals undertake) on its own is not cause for concern, rather meaningful or significant bioaccumulation is (as defined using log K<sub>ow</sub>, BCFs and BAFs or other evidence).</li> <li>• We suggest the following definition largely based on Gobas et al (2009) and ECHA 2017: <i>"Bioaccumulation is a process in which the chemical concentration in an organism achieves a level that exceeds that in the respiratory medium (e.g., water for a fish or air for a mammal), the diet, or both. It refers to uptake from all environmental sources including water, food and sediment." The extent to which chemicals bioaccumulate is expressed by several quantities, including the bioconcentration factor (BCF), bioaccumulation factor (BAF), biomagnification factor (BMF), and trophic or food web magnification factor (TMF)."</i></li> </ul> <p>Relevant bioaccumulation references:</p> <p>Gobas FA, de Wolf W, Burkhard LP, Verbruggen E, Plotzke K. Revisiting bioaccumulation criteria for POPs and PBT assessments. Integr Environ Assess Manag. 2009 Oct;5(4):624-37. doi: 10.1897/IEAM_2008-089.1. Epub 2009 Jun 24. PMID: 19552497</p> <p>ECHA. 2017. Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.7c: Endpoint specific guidance, Version 3.0. ECHA-17-G-11-EN. June 2017. <a href="https://www.echa.europa.eu/documents/10162/13632/information_requirements_r7c_en.pdf">https://www.echa.europa.eu/documents/10162/13632/information_requirements_r7c_en.pdf</a></p>	
--	--	--	--

1	1 - Bioaccumulation Factor	1.0	Does the Ministry have preferred sources for Bioaccumulation Factors? Suggest providing clear guidance on what is meant by “best” when referring to “available science”. Use of such terminology is ambiguous as the ‘available science’ at any given time is not labeled in such a fashion.	The ministry acknowledges that the use of best available science is not specific, however it allows the inclusion of new scientific information to be applied as it becomes available. The ministry's Risk Assessment web pages contain further resources. The inclusion of bioconcentration factor resources has been noted for future consideration.
1	1 - Bioaccumulative Substance	1.0	Regarding the definition of "bioaccumulative substance", there is no differentiation between bioaccumulation and biomagnification, but it is an important distinction. Typically $\log K_{ow} > 4.5$ is used to define biomagnification. Bioaccumulative substance defined differently than CEPA (Canadian Environmental Protection Act). Shouldn't these definitions be consistent with the federal definition? With respect to the definition of "biomagnification", having used the $\log K_{ow}$ criteria under bioaccumulation confuses these two processes.	The Canadian Environmental Protection Act (CEPA) thresholds are insufficiently protective and do not include important bioaccumulative substances (was enacted in 1999). The current state of science is better demonstrated by screening approaches presented by other jurisdictions such as US EPA, European Union, Australia and Canadian Council of Ministers or the Environment (CCME) National Classification, which the current Protocol 1 definition is based on. Bioaccumulative substances, as defined in Protocol 1, may include substances that biomagnify.
1	1 - Bioaccumulative Substance	1.0	<b>Bioaccumulative Substances</b> - Is there a scientific basis for this definition? In particular the new BCF value of 2000, which previously was 5000?	The Canadian Environmental Protection Act (CEPA) thresholds are insufficiently protective and do not include important bioaccumulative substances (was enacted in 1999). The current state of science is better demonstrated by screening approaches presented by other jurisdictions such as US EPA, EU, Australia and Canadian Council of Ministers or the Environment (CCME) National Classification, which the current Protocol 1 definition is based on.

1	1 - Bioaccumulative Substance	1.0	<p>Based on the rationale above (i.e., that bioaccumulation on its own is not necessarily cause for concern), we also suggest the following revision to the definition of bioaccumulative substance:</p> <p><i>"bioaccumulative substance" means a substance in which:</i></p> <p><i>(a) the logarithm (base 10) of the octanol-water partition coefficient (log Kow) is greater than or equal to 4.5, or the Bioaccumulation Factor is greater than or equal to 2000, or the Bioconcentration Factor is greater to or equal to 2000; or</i></p> <p><i>(b) the substance is determined by best professional judgment of the qualified professional preparing a report to potentially cause bioaccumulation be a bioaccumulative substance based on relevant scientific information.</i></p>	The ministry agrees with this comment and a revision to the definition was made.
1 a n d 1 3	1 - Bioaccumulative Substance	1.0	<p>definition of bioaccumulative substance:</p> <p>"(b) the substance is determined by best professional judgment of the qualified professional biologist preparing the SLRA report to have the potential to bioaccumulate based on relevant scientific information."</p> <p>1) It has been our experience that professional judgement often identifies substances as bioaccumulative in direct contradiction to recent decision by Health Canada and Environment Canada. It is our recommendation that decisions regarding the bioaccumulative potential of a given substance be consistent with decisions by Environment Canada and Health Canada.</p> <p>2) Should this clause be retained, the wording of the clause in Protocol 13 should be consistent with Protocol 1 such that a qualified professional is not limited to qualified professional biologists.</p>	<p>A substance should be conservatively considered to bioaccumulate where best available science and professional judgement suggest it is possible, regardless of whether that substance is missing from previously published documents.</p> <p>The CEPA threshold are insufficiently protective and do not include important bioaccumulative substances (was enacted in 1999). The current state of science is better demonstrated by screening approaches presented by other jurisdictions such as US EPA, EU, Australia and CCME National Classification, which the current Protocol 1 definition is based on.</p> <p>"Biologist" has been removed from the definition in Protocol 13.</p>

1	1 - Food Chain Modelling	1.0	Page 4, indicates that food chain modeling will be only for biocon/bioacc/biomag substances. The definitions for these terms elsewhere in the glossary are oriented to organic substances. Is it ENV intent that the many metals will not need to be evaluated in ERA food chains? We did not have time to conduct a helpful review of the glossary for biocon/accm and biomag but flag to ENV that these definitions may be too narrow.	The definition of bioaccumulative substance includes the 'or' statement between part (a) and (b) to account for metals, or substances with bioaccumulation or bioconcentration factors, regardless of the log Kow. The ministry does not intend to exclude metals as bioaccumulative substances but rather to provide guidance around how to identify which metals are considered as such. The definition of food chain modelling describes the quantitative estimation of a dose through the diet. The ministry concurs that food chain modelling is not limited to bioaccumulative substances. A revision was made to clarify this point.
1	1 - Bioaccumulative Substance	1.0	Please provide the scientific supporting rationale for the Log Kow and BAF or BCF thresholds (4.5 and 2000, respectively) provided as definition of a substance being bioaccumulative.	The CEPA threshold are insufficiently protective and do not include important bioaccumulative substances (was enacted in 1999). The current state of science is better demonstrated by screening approaches presented by other jurisdictions such as US EPA, EU, Australia and CCME National Classification, which the current Protocol 1 definition is based on.
1	1 - Bioconcentration	1.0	To the definition of bioconcentration, we suggest adding: <i>"Bioconcentration is measured in a laboratory experiment in which the test organisms are exposed to a chemical in the water but not in the diet."</i> (Gobas et al. 2009)	The ministry acknowledges that there are many definitions and multiple interpretations of the term bioconcentration. The definition of bioconcentration presently included in Protocol 1 accounts for exposure within any aquatic medium including the water column and porewater and reflects the understanding that bioconcentration can occur in laboratory and natural settings.



1 a n d 1 3	1 - Bioconcentr ation	1.0	"bioconcentration means the process leading to a higher concentration of a substance in an organism compared to the concentration of the substance in the <u>aquatic environmental media</u> to which the organism is exposed."Recommend changing "aquatic environmental media" to "water column" since bioconcentration does not reflect sediment exposure.	The ministry acknowledges that there are many definitions and multiple interpretations of the term bioconcentration. The definition of bioconcentration presently included in Protocol 1 accounts for exposure within any aquatic medium including the water column and porewater and reflects the understanding that bioconcentration can occur in laboratory and natural settings.
1	1 - Biomagnifica tion	1.0	"biomagnification means the incremental process within a food chain by which progressively higher contaminant concentrations are attained in organisms located at respective higher trophic levels in the food web."  This appears to be the definition for trophic magnification not biomagnification. Biomagnification reflects the concentration in the diet (as the only exposure pathway) relative to the organism.	The ministry acknowledges that there are many definitions and multiple interpretations of terms surrounding biomagnification and bioaccumulation in general. The definition of biomagnification presently included in Protocol 1 is similar to the one included in Federal Contaminated Sites Action Program (FCSAP) guidance and is consistent with definitions provided by the US EPA. An edit has been made for clarification.
1	1 - Contaminant of Concern	1.0	I suggest you define " appropriate screening benchmark", which I assume also includes background concentration, but can it include benchmarks from other jurisdictions when one does not exist within BC Regulations, or when BC regulations do not include a given exposure pathway?	Screening benchmark is defined within Section 1.0. The ministry will consider guidelines and standards from other jurisdictions for use as screening benchmarks where one is not currently available in BC.
1	1 - COPC	1.0	The use of COPC is adding an extra level of potential confusion when we also use PCOC. If we are taking PCOCs out of a DSI could we then in risk assessment still call them PCOCs and label them as under evaluation for potential risk.	To avoid confusion, the ministry prefers that potential contaminants of concern (PCOC) only be used when referring to substances which are potentially present, but not confirmed to be present, on a site based on historical uses or other sources of contamination. Once a substance is confirmed to be at a site, it is considered a contaminant of concern (COC). Contaminants of potential concern (COPC) are used in risk assessment to indicate that the substance is confirmed to be

				present and may result in unacceptable risk.
1	1 - Ecosystem Services	1.0	What is the rationale for limiting this definition to human benefits only and not also considering general biological needs for maintaining healthy ecosystem services?	The ministry's definition of ecosystem services is not intended to lessen the importance of ecosystem function as a key consideration in detailed risk assessment (DRA). The ministry acknowledges that additional work is needed to develop the requirements associated with ecosystem services in a DRA. Your comment has been noted and may be considered in future revisions.
1	1 - Effect concentration	1.0	<p>In addition to effect concentration on x% of organisms (ECx), the following definition (or similar) should be included:</p> <p><i>"Inhibition concentration of x% to a particular endpoint (ICx)", the concentration of a substance causing a specified percent reduction in an endpoint."</i></p> <ul style="list-style-type: none"> <li>• many toxicity tests determine the ICx rather than the ECx and the ICx can also be used to assess protection levels.</li> </ul>	The current definition of effect concentration on x% of organisms (ECx) includes when the effect is an inhibition endpoint.
1	1 - Engineering Control	1.0	Definition for engineering control: ... soil or sediment caps? (reads: soil, sediment caps)	Thank you for your comment, this edit had been made.
1	1 - HHRA	1.0	Definition for human health risk assessment seems odd, especially the use of the words appraisal and impacts? Suggest: quantitative evaluation of the nature and probability of adverse health effects in humans who may be exposed to chemicals in contaminated environmental media, now or in the future (based off of USEPA defn').	The definition has been revised.
1	1 - intrinsic control	1.0	Please provide an example of "an inherent feature which modifies (i) the physical, chemical or biological behaviour or properties of a substance, or (ii) the environmental media in which a substance is contained."	"... An inherent feature which modifies (i) the physical chemical, or biological behavior or properties of a substance, or (ii) the environmental media in which a substance is contained" is meant to describe an existing naturally-occurring feature which may alter the fate and transport of a substance. Examples may include, but are

				not limited to, permafrost, geological features (causing oxidation or reduction), and seasonal changes in hydrology.
1	1 - Receiving Environment	1.0	The definition herein refers to “artificial watercourses or impoundments”, a term not defined in the Protocol. However, the term “maintained watercourse” is defined in the Protocol. Suggest revising the “receiving environment” definition to use the defined “maintained watercourse” definition rather than the undefined “artificial watercourse” reference.	Thank you for your comment. The full text of the definition for receiving environment includes the text "excluding artificial watercourses and impoundments that are maintained."
1	1 - Risk-based standards	1.0	For the following definition: “risk-based standards” means the standards prescribed in Contaminated Sites Regulation (Contaminated Sites Regulation (CSR)) sections 18 and 18.1  Consider adding the qualifier that these standards are for human health risks and not for ecological receptors.	Although Contaminated Sites Regulation (CSR) s. 18 does not specify numerical risk levels for ecological receptors, the content does apply to both human and ecological risk assessment. Via Protocol 1, the ministry is hereby clarifying risk based standards for ecological receptors.
1	1 - Screening Benchmark	1.0	Screening Benchmark - The definition for Screening Benchmark is vague. Can ENV clarify whether its expectation is use of the Contaminated Sites Regulation (CSR) receptor-specific standards as screening benchmarks, when such standards are available for the receptor group (humans, soil invertebrates & plants, aquatic life).	Yes, Contaminated Sites Regulation (CSR) receptor-specific standards should be used when available unless alternate rationale is provided. As well, the ministry's expectations are provided in Protocol 1 regarding the use of guidelines.
1	1 - Screening Benchmark	1.0	Definition of screening benchmark is awkward. Suggest: Regulatory standards, guidelines or background/reference site concentrations used to screen for COPCs in a risk assessment.	Thank you for your comment. This definition was revised for clarification.
1	1 - Sediment Porewater	1.0	Please provide the scientific rationale for limiting the definition to just the uppermost 1 metre of sediment. Is this related to an assumed typical biologically active zone, or some other science?	The definition for sediment porewater is intended to define the zone within which interstitial water is considered porewater compared to that which is considered groundwater. At the majority of sites, one metre will conservatively encompass the biologically active zone, but it is not necessarily equivalent to the biologically active zone.

1	1 - Sensitive habitat	1.0	This is a better definition of "sensitive habitat" than is currently in Procedure 8, which is all-encompassing. Can this be used for determining the appropriate sediment standard?	The sensitive habitat definition part d) states that sensitive sediment is defined in the Regulation. The definition of "sensitive sediment use" in the Regulation has not been revised and should be used to determine which sediment standards are appropriate for a site or receiving environment.
1	1 - Terrestrial Habitat	1.0	In the definition of "terrestrial habitat", there is no minimum area of land associated with item (a) (" <i>the agricultural, wildlands, or urban park land use classification applies</i> "). Was this the intent? It seems overly restrictive...why not 50 m <sup>2</sup> as with residential land use?	Yes, this is the intent of item (a) in this definition. The land uses described in item (a) have been identified by the ministry as potential habitat.
1	1 - Terrestrial Habitat	1.0	Definition for terrestrial habitat should include footnote or other reference to defn's for sensitive habitat and undeveloped land. Suggest making link to Protocol 13?	Thank you for your comment. The ministry feels this is unnecessary at this time.
1	1 - Terrestrial Habitat	1.0	<b>Terrestrial habitat</b> - Note, there is an inconsistency with Protocol 13, which uses "Potential Terrestrial Habitat" in its definitions. "Potential" should be added and is likely more accurate given more detailed evaluation of habitat on a receptor by receptor basis is permitted.	Thank you for your comment, this discrepancy has been addressed.
1	1 - Unacceptable Risk	1.0	<b>Unacceptable Risk</b> - Should part (b) of the definition include mention of unacceptable cancer risk, i.e. ILCR > 10 <sup>-5</sup> ?	Unacceptable cancer risks include scenarios where the human lifetime cancer risk is greater than or equal to 10 <sup>-5</sup> . This is captured by part (a) of the definition.
1	1 - Undeveloped Land	1.0	With respect to the reference made to 'associated roadside or highway margins', please provide clarity on how one would define the margin given that vegetation is allowed within the margin? Often such margins provide productive habitat, e.g., raptors often take advantage of such highway margins for foraging.	Thank you for your comment, it has been noted for future consideration. Margins are defined by the specific road type and associated right-of-way. It is agreed that some lands may not be identified as potential terrestrial habitat whilst being used by wildlife species and qualified professionals are required to use best professional judgment for evaluating these sites.

1	1 and 4.2	1.0	The definition of a bioaccumulative substance, which determines the need for an evaluation of food chain impacts, is not conservative enough. Several metals and organic substances would not meet these criteria (e.g., methyl mercury and several pesticides) and would therefore not require this evaluation despite ample evidence that food chain impacts have occurred from these substances. A lower log Kow (3.5) and a list of select metals is recommended.	The definition of bioaccumulative substance includes the 'or' statement between part (a) and (b) to account for substances with bioaccumulation or bioconcentration factors, regardless of the log Kow. The ministry does not intend to exclude metals as bioaccumulative substances but rather to provide guidance around how to identify which metals are considered as such.
1	2	2.0	Para 2, 2. ... and provides information (provides is missing an s)	Thank you for your comment, this edit had been made.
1	2	2.0	Para 3, first and second line - ...and contents of ecological risk assessments and human health risk assessments	Thank you for your comment, this edit had been made.
1	2.1	2.1	Last para is awkward. Suggest Further, or in addition instead of Also,... and receiving site used in this para could be confused with receiving environment. Suggest adding further clarification.	Thank you for your comment, this edit had been made. As this sentence refers to soil relocation agreements, the term receiving site is appropriate.
1	2.1	2.1	States: "Except where a Screening Level Risk Assessment has been completed in accordance with Protocol 13,"Screening Level Risk Assessment" (Protocol 13), an applicant for an Approval in Principle or Certificate of Compliance that is based on the site being remediated in accordance with risk-based standards must provide the director with a detailed risk assessment report."  This statement restricts the application of detailed risk assessment to only an Approval in Principle or Certificate of Compliance – this problematic since this conflicts with provisions in the environmental management act and regulations set therein. Conducting a risk assessment does not always end with an Approval in Principle or a Certificate of Compliance.	Language in this section does not limit the use of a detailed risk assessment to Approvals in Principle (AiP) and Certificate of Compliance (CoC) submissions. Rather it states that if a site is remediated using risk-based standards with the objective of obtaining an AiP or CoC, that a detailed risk assessment, conducted in compliance with Protocol 1, is required. Protocol 1 is intended to support any type of detailed risk assessment (DRA) conducted under Part 4 of the Environmental Management Act.
1	2.1	2.1	The new Protocol 1 applies to the preparation and contents of ecological and human health risk assessments as part of a detailed Risk Assessment. A reference is provided for a detailed ecological risk assessment as Protocol 20. Suggest providing a reference for a detailed human health risk assessment.	The ministry agrees that additional guidance for human health risk assessment would be useful and this will be noted for future consideration. Additional guidance is provided on the Risk Assessment web pages.

1	2.1	2.1	First para - should refer to definitions for acceptable/unacceptable risk for consistency - for example, for ERAs it indicates that the director requires evidence that any significant... should it not indicate that requires evidence that risks are below the protection levels in Section 4.2, Table 1 and make linkages to Azimuth 2016 (see comment 1 above)	Thank you for your comment. Revisions to this section have been made for clarity.
1	2.2	2.2	At the end of the paragraph, there is a statement "Remediation Orders may also be used". Suggesting elaborating on this statement and/or providing a reference. This will assist owners and responsible parties.	Thank you for comment. Your request has been noted for future consideration; however, the <i>Environmental Management Act</i> is clear in this regard so it seems unnecessary at this time.
1	2.2 - Para 2	2.2	Suggest striking out "any significant". Use of this phrase suggests that not all potential risks require consideration.	This section in Protocol 1 has been revised for clarification.
1	2.3	2.3	It is indicated that SLRA and DRA cannot be used in the same submission. This is inconsistent with practice to date, where the SLRA pathway elimination (e.g., no operable pathways to soil contamination > 1 m bgs for HH and terrestrial eco, except deep rooting veg) is used in a DRA. The current approach (where a DRA can build on screening completed using policy implicated in Protocol 13) is reasonable and consistent with protection goals and should be allowed going forward.	The ministry considers Screening Level Risk Assessment (SLRA) and detailed risk assessment (DRA) to be discrete tools that cannot be used in combination in the same submission. It is, however, acceptable to eliminate inoperable pathways from further consideration in the Problem Formulation of DRA if acceptable rationale can be provided.
1	2.3	2.3	<p>The middle (third) sentence in Section 2.3 states "<i>For example, risk assessors cannot eliminate exposure pathways in SLRA and then initiate a DRA for remaining complete exposure pathways.</i>" The second paragraph in Section 4.4 of SLRA states "<i>Sites that have an unacceptable risk for one or more exposure pathways are considered to fail the SLRA. Further remediation – or completion of a detailed risk assessment – is necessary for these sites to address the failed exposure pathways.</i>"</p> <p>SLRA refers to completion of a detailed risk assessment to address the failed exposure pathways - this contradicts Section 2.3 of draft Protocol 1, which indicates that risk assessors cannot initiate a DRA for remaining complete exposure pathways.</p> <p><b>Recommendation:</b> Reconcile Protocol 13 and</p>	Thank you for your comment. This issue has been clarified in Protocol 13.

			draft Protocol 1 regarding failed exposure pathways.	
1	2.3	2.3	SLRA and DRA acronyms should be defined on first use in earlier sections; acronyms used in some sections and not in others throughout document. This applies to all acronyms in all sections (e.g., WGQ in section 3.2).	Thank you for your comment. Revisions have been made.
1	2.3 - Text box	2.3	Suggest revising the statements in the box for the following: (a) replacing the phrase "Risk Assessment" with "Risk Management" as a remedial strategy (b) define "permanently"; does this mean remediation to numerical standards? (c) risk management can be a permanent solution in some instances (d)	The ministry defines risk assessment as a type of remedial strategy and the text box accurately reflects this. It is up to the QP to make an argument for what is considered a permanent solution which respect to <i>Environmental Management Act</i> s. 56.
1	2.3 - Text box	2.3	Text box is inconsistent with current practice in BC and ENV issuance of CofCs over the last several years	The current position of the ministry is that risk assessment at contaminated sites in BC is intended to address residual contamination. In stating this position, the ministry is reaffirming what has always been written in <i>Environmental Management Act</i> , s. 56, which states, "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," considering factors including human health, pollution, feasibility, and remedial costs. The ministry has established a position on this matter and the protocol reflects this.
1	2.3 - Text box	2.3	This text box indicates that risk assessment is not a permanent solution and is somehow inferior to remediation approaches that remove contamination from a Site. If this is the view of ENV, I suggest that ENV develop a technical protocol on how to select and evaluate remediation technologies for a Site that clarifies the values ENV would like to see used to evaluate candidate remediation technologies for a Site. Having this text box in this Protocol is not helpful as i) it sends a confusing message regarding the acceptability of risk assessment as a remediation approach, and ii) the decision to	The current position of the ministry is that risk assessment at contaminated sites in BC is intended to address residual contamination. In stating this position, the ministry is reaffirming what has always been written in <i>Environmental Management Act</i> , s. 56, which states, "A person conducting or otherwise providing for remediation of a site must give preference to remediation

			use risk assessment is made long before the risk assessment is conducted (it's too late). If ENV want to control or direct the conditions under which risk assessment is used, a separate protocol outlining factors for consideration in selecting a remediation technology is needed.	alternatives that provide permanent solutions to the maximum extent practicable," considering factors including human health, pollution, feasibility, and remedial costs. The ministry has established a position on this matter and the protocol reflects this.
1	2.3 and other refs to SLRA	2.3	The text indicates that SLRA and DRA are discrete tools and cannot both be used in the same submission in a contaminated sites application under the Contaminated Sites Regulation (CSR). The current practice is that pathways are eliminated using SLRA as part of the DRA's problem formulation. The final deliverable is a DRA. This text, as written, could be interpreted by an auditor that one is making a major error by relying on SLRA in the PF to rule out pathways. In addition, P1 already references that various components of SLRA (e.g. beneficial use, terrestrial habitat etc.) can/should be used as part of a DRA. If ENV is intending that a single instrument cannot combine areas where the recommendation is based only on the P13 checklists with areas that progress to DRA, then this may be as simple as clarifying that this guidance does not limit the use of SLRA concepts in a properly constructed PF.	The ministry considers screening level risk assessment (SLRA) and detailed risk assessment (DRA) to be discrete tools that cannot be used in combination in the same submission. It is, however, acceptable to eliminate inoperable pathways from further consideration in the Problem Formulation of a DRA if acceptable rationale can be provided. The completion of DRA requires that all exposure pathways be considered, regardless of whether a SLRA has been previously completed. Nonetheless, there are some basic principles of risk assessment which may be employed in both SLRA and DRA. These include the use of beneficial use exclusions and habitat assessment.
1	2.4	2.4	Are ENV's requirements for demonstrating groundwater contaminant plume stability that are described in Section 6.0 of Protocol 13 also expected for detailed risk assessment? E.g. 2 year data requirement. If "yes" can this be clarified by adding mention of this to Protocol 1.	The ministry expects the plume stability assessment described in the newly released (January 2021) Technical Guidance 8 to be applied prior to conducting a detailed risk assessment (DRA).
1	2.4	2.4	By requiring that every plume be fully delineated and stable and or decreasing, you remove the possibility of modelling to receptors and delay the of closing sites. Detailed risk assessment should be able to be conducted with the use of modelling for delineation purposes. On Site truthing models can be used to ensure desired conservatism.	The ministry expects the plume stability assessment described in the newly released (January 2021) Technical Guidance 8 to be applied prior to conducting a detailed risk assessment (DRA). Modelling is permitted as a line of evidence within the plume stability assessment.



1	2.4	2.4	Suggest revising the title and other statements to reflect Risk Management as a remedial strategy and Risk Assessment is a tool to assess the level of risks.	Thank you for your comment. Please note that where risks are found to be acceptable, the ministry considers risk assessment in and of itself to be a remedial strategy. Risk Management has been addressed in Section 5.0 of the Protocol. Your comment may be considered in a future revision to improve clarity.
1	2.4	2.4	Regarding point 3, it is often appropriate to bring in experts to improve on risk assessments. We are not experts in all things that could apply to a risk assessment. I wouldn't want to discourage this approach?	This statement does not prevent the inclusion of experts to evaluate components within a risk assessment (e.g. Species at Risk biologist, geotechnical engineer, etc.). The qualified professional (QP) is responsible for all aspects of the risk assessment. This includes the selection of experts, and the use of their data, assessment and/or opinion within the risk assessment.
1	2.4 - Bullet 2	2.4	Is it not already a requirement for a DSI to be deemed complete, that it asserts that PCOCs have been delineated horizontally and vertically? Same for the notation with respect to plume stability – are these not existing requirements of a complete DSI? If so, it's not clear why this bullet suggests these are in addition to DSI general requirements.	Yes, this is not new ministry policy. The requirement to delineate all contaminants of concern (COCs) as part of the site investigation stage is being highlighted in this bullet as mandatory prior to risk assessment.
1	2.4 - 1. and 3.	2.4	Suggest elaborating the reference to the QP as QP (standards) and QP (risk assessors).	Qualified professionals are defined as accredited in BC under a professional association's code of ethics, and who is practicing in a particular area of expertise. Due to the range in contamination and site types (e.g. multi-level vapour intrusion vs. benthic invertebrate community), the risk assessor at different sites may have expertise in very different fields. It is within their practice and professional code of ethics that this should be determined.

1	2.4 - Text box	2.4	Text box does not seem to be consistent with current practice. Implies that risk assessments in the aquatic receiving envt needs approval of the director to use risk based standards, which is not current practice.	<p>This comment is assumed to refer in actuality to the text box in Section 3.2. The ministry is stating that BC Water Quality Guidelines apply in the aquatic receiving environment. Additional risk-based standards may be used for the aquatic receiving environment, if acceptable to the director or a statutory decision maker.</p> <p>Most often, off-site migration of contamination that reaches the aquatic receiving environment is pollution under the <i>Environmental Management Act</i>. Therefore, there is a duty to remediate this contamination and the director has a role in reviewing and accepting any proposed risk-based standards.</p>
1	3.1	3.1	First para - should refer to definitions for acceptable/unacceptable risk for consistency - for example, for ERAs it indicates that the director requires evidence that any significant... should it not indicate that requires evidence that risks are below the protection levels in Section 4.2, Table 1 - also suggest making linkages to Azimuth 2016.	Thank you for your comment. Revisions to this section have been made for clarity.
1	3.1	3.1	Please provide a clear definition of the term 'significant' as it is used in this section. It is unclear how the implications would differ if the term were removed.	Thank you for your comment. Revisions to this section have been made for clarity.
1	3.2 page 10	3.2	"For sediment and sediment porewater, the <u>detailed risk assessment (should this be detailed site investigation?)</u> report must either demonstrate that concentrations of contaminants do not exceed applicable numerical standards as set out in Table 2 of Technical Guidance 15, version 2.0..."	Thank you for your comment. Revisions to this section have been made for clarity.
1	4 (all)	4.0	This section needs to be re-organized. Section 4.1 could be a stand-alone section as it primarily ties to regulatory documents. Section 4.2 has too many sub-sections as currently organized. Section 4.2 could be restricted to Problem Formulation, including Conceptual Site Model, which is a part of problem formulation, Section 4.3 could be Exposure Assessment, Section 4.4 Toxicity/Effects Assessment, etc. This would allow currently un-numbered	Thank you for your comment. The ministry agrees that organizational changes would improve this document. Minor changes have been made at this time and further organizational changes are noted for future consideration.

			<p>sections to be more easily put into the table of contents and would increase readability.</p> <p><b>Recommendation:</b> Reorganize Section 4 of the current draft of Protocol 1.</p>	
Dis	4.1	4	<p>Paragraph 2 of this section refers to using sampling methodologies following BC's field sampling manual. This section should also acknowledge that where samples or data have been collected for a different purpose following different methods (e.g., monitoring data collected for mines, and following ENV's Water and Air Baseline Monitoring Guidance Document for Mine Proponents and Operators), those data may be acceptable for use in a risk assessment if the risk assessor can demonstrate applicability and interpret the data in the context of the risk assessment.</p> <p>Paragraph 4 of this section – <i>"For deterministic human health risk assessment, QPs must consider the following Health Canada documents:"</i> (multiple documents listed) Does this supersede the HH TRV hierarchy listed in Tech Guidance 7 which indicates that US EPA IRIS TRVs take precedence over Health Canada TRVs? Ideally this should be clarified.</p>	<p>If deviating from the BC Field Sampling Manual, the qualified professional must demonstrate that the proposed methods are equivalent to those in the BC Field Sampling Manual. These proposed methods must be approved by the director. The ministry has noted your comment and may consider it in future revisions.</p> <p>Technical Guidance 7 components have been moved into Protocol 1 and the new RA webpage. For human health toxicity reference value (TRV) selection see Section 4.4.1. Additional guidance is available on the ministry's Risk Assessment web pages.</p>
1	4.1	4	<p>Section 4.1, para 2 refers to using sampling methodologies following BC's field sampling manual. This section should also acknowledge that where samples or data have been collected for a different purpose following different methods (e.g., monitoring data collected for mines, and following ENV's Water and Air Baseline Monitoring Guidance Document for Mine Proponents and Operators), those data may be acceptable for use in a risk assessment if the risk assessor can demonstrate applicability and interpret the data in the context of the risk assessment. If the protocol does not permit use of other methods (with substantiation), would this preclude risk assessments using data collected for other purposes or early data prior to the recent revisions to the BC Field sampling manual?</p>	<p>If deviating from the BC Field Sampling Manual, the ministry needs to approve the proposed methods. The ministry has noted your comment and may consider it in future revisions.</p>

1	4.1	4	<p>HC documents include Interim Guidance: HHRA for short-term exposure to carcinogens at contaminated sites (2013). This document/approach was not used by ENV in the derivation of the numerical standards and use of the approach in an RA will result in unacceptable risks at concentrations less than the numerical standards (e.g., PAHs). A consistent approach to the derivation of the numerical standards and requirements for RA is essential. It is noted also that the CCME has not used this approach in the derivation of the guidelines for HH.</p>	<p>The Contaminated Sites Regulation (CSR) generic numerical standards derived by the ministry as per Protocol 28 are reflective of the ministry's position on matters in 2015/2016 and the decisions made regarding setting provincially-applicable numerical CSR standards. There is no limitation on the usage of different protection levels at a contaminated site as better information becomes available. Specifically, Protocol 1 does not limit the derivation of the most appropriate risk based standards for a specific site. It is possible that best available science will result in risk based standards that are lower than generic numerical CSR standards.</p> <p>The ministry's intent is to not restrict exposure estimation to methods, values, or data that continuously evolve. Protocol 1 Section 4 states that qualified professional must consider this Health Canada document. If a qualified professional deems this guidance as inappropriate for a particular site and scenario, adequate scientific rationale must be provided for the use of alternate methods. As this topic may require further guidance from the ministry, it has been noted for future consideration.</p>
---	-----	---	---	--

1	4.1 and elsewhere in doc	4	<p>This document references the following Interim Guidance: HHRA for short-term exposure to carcinogens at contaminated sites (2013). This document/approach was not used by ENV in the derivation of the numerical standards and use of the approach in an RA can result in unacceptable risks at concentrations less than the numerical standards. A consistent approach to the derivation of the numerical standards and requirements for RA is essential. It is noted also that the CCME has not used this approach in the derivation of the guidelines for HH. It would be beneficial for ENV to clarify that detailed HHRA does not need to follow this approach when calculating HH risks.</p>	<p>The Contaminated Sites Regulation (CSR) generic numerical standards derived by the ministry as per Protocol 28 are reflective of the ministry's position on matters in 2015/2016 and the decisions made regarding setting provincially-applicable numerical CSR standards. There is no limitation on the usage of different protection levels at a contaminated site as better information becomes available. Specifically, Protocol 1 does not limit the derivation of the most appropriate risk based standards for a specific site. It is possible that best available science will result in risk based standards that are lower than generic numerical CSR standards. The ministry's intent is to not restrict exposure estimation to methods, values, or data that continuously evolve. Protocol 1 Section 4 states that qualified professional must consider this Health Canada document. If a qualified professional deems this guidance as inappropriate for a particular site and scenario, adequate scientific rationale must be provided for the use of alternate methods. As this topic may require further guidance from the ministry, it has been noted for future consideration.</p>
1	4.1	4	<p>Regarding the second paragraph of this section, further clarification is requested with respect to chemical contamination and number and location of samples required to ensure a high level of confidence and responsibility.</p>	<p>A qualified professional must have a high level of confidence in the data quantity and quality used to support a risk assessment. The ministry intends this phrase ("ensure a high level of confidence") to reflect that sufficient work has been done to make decisions on/about a site, rather than doing minimal or the minimum amount of effort. As a starting</p>

				point, ministry technical guidance and web pages must be used but industry best practices are a factor as well.
1	4.1	4	The phrase 'ensure a high level of confidence' is vague without clarifying specifics with respect the suggested varying levels of confidence. Traditionally in the field of risk assessment, the degree of certainty/uncertainty is an inherent aspect of the reporting such that the risk assessor (QP) would provide commentary on what they deem to be the most relevant aspects of the risk assessment and the certainty associated. Typically decisions made would err on the side of conservatism such that resulting risk estimates would potentially over-estimate risk - regardless these should be decisions/assumptions should be included in the reporting.	A qualified professional must have a high level of confidence in the data quantity and quality used to support a risk assessment. The ministry intends this phrase ("ensure a high level of confidence") to reflect that sufficient work has been done to make decisions on/about a site, rather than doing minimal or the minimum amount of effort. As a starting point, ministry technical guidance and webpages must be used but industry best practices are a factor as well.
1	4.1 Inhalation exposure pathway	4	What is a "worst case condition"? Is it the highest concentration estimated or measured? Please provide additional clarification.	The worst case conditions referenced in this paragraph should be determined based on Technical Guidance 4.
	4.2	4	The use of the word <i>must</i> infer inflexibility. How does a weight-of-evidence approach fit into this organization?	Ministry protocols outline requirements for practitioners and the term <i>must</i> indicates the mandatory nature of these requirements. The use of weight-of-evidence in risk assessment is described in Section 4.4.7 of Protocol 1.
1	4.2 - Food chain modelling	4	The Protocol states the following, "A food chain model must be completed at large or complex contaminated sites where habitat is present unless it can be show that concentrations in lower trophic levels are insignificant or other rationale can be provided." If no bioaccumulative substances are identified as COPCs, is that rationale sufficient?	Generally, if no bioaccumulative substances are identified as contaminants of potential concern (COPC), then food chain modeling is not required; however, exceptions exist. If it is unclear when food chain modelling should be conducted at a particular site, seek guidance from the director.

1	4.2.1	4.1.3	<p>Text indicates food chain modeling should be a common activity. Guidance is: <i>When a complete exposure pathway exists between a receptor and bioaccumulative substance, the potential for food chain impacts must be evaluated and quantified. Even when a substance is not considered to biomagnify to higher trophic levels, food chain impacts from lower trophic level organisms must be evaluated. Detailed rationale must be provided if food chain impacts are not quantitatively evaluated. .... A food chain model must be completed at large or complex contaminated sites where habitat is present unless it can be show that concentrations in lower trophic levels are insignificant or other rationale can be provided.</i> All of the above text suggests that a wildlife FCM will become mandatory whenever log Kow &gt;4.5, or there is a reported BAF or BCF &gt; 2000 except if “concentrations are insignificant” or “site is not large or complex”. Agree in principle that food chain modelling can be valuable in a DRA, but this current text would benefit from more clarity. ENV should specify which substances need to have food chain models based on Kow and needs to be clear if they are declaring that the common practice of excluding metals from modeling if they do not exceed soil standards is unacceptable. A general comment is that there is a tendency to assume that food chain models are straightforward (including for amphibians). In fact, food chain models are highly problematic and can easily lead to incorrect conclusions.</p>	<p>It is the ministry's expectation that food chain modelling (or actual sampling and analysis) be done where bioaccumulative substances are present as contaminants of potential concern (i.e. where concentrations exceed the applicable screening benchmark) with a complete exposure pathway and where habitat is identified, unless sufficient rationale can be provided to exclude food chain modelling. Exposures from multiple media and pathways must be evaluated as cumulative exposures, if applicable.</p> <p>It is not the intent of the ministry to exclude metals from food chain modelling. If it is unclear when food chain modelling should be conducted at a particular site, seek guidance from the director. The request for further guidance on this matter has been noted for future consideration.</p>
1	4.2.1 - Food chain models	4.1.3	<p>Under the heading Food Chain Models (p 16), the protocol does not define "large or complex" in the context of contaminated sites, which is appropriate. The text suggests that food chain modeling is not required if there is no habitat; however, this may (1) preclude future scenarios of site restoration or regrowth of vegetation at sites and/or (2) trigger site owners to remove habitat on contaminated sites. For consideration.</p>	<p>The request for further guidance on this matter has been noted for future consideration.</p>

1	4.2.3 - Food Chain Modelling	4.1.3	<p>Food chain models are noted to be completed for large and complex contaminated sites. What is the definition of a "large and complex contaminated site"? Food chain models are typically not validated or calibrated tools but can be helpful to estimate exposure to higher trophic level receptors. Keeping their limitations in mind, they should be used when peer reviewed scientific literature indicates there could be a significant exposure pathway to higher trophic level receptors. Use of the lowest TRV and most conservative estimates of exposure could easily result in unreliable estimates of risk. Making recommendations for remediation using an unvalidated model primed with conservative assumptions is not scientifically defensible and may result in legal challenges.</p>	<p>The ministry's intent is for food chain modelling be used to estimate exposures and provide risk estimates for wildlife using realistic but somewhat conservative estimations of species parameters. Food chain modelling is typically not conducted for all species and is intended to capture potential risks to the most likely and most highly exposed species. If a qualified professional deems food chain modelling to not be appropriate for a site due to uncertainties surrounding input parameters etc., tissue sampling may be an option in some cases. Full rationale must be provided in the risk assessment report to justify the exclusion of food chain modelling.</p>
1	4.2.3 - Food Chain Modelling	4.1.3	<p>The last paragraph in Section 4.2.3 under the heading "Food Chain Models" states "A <i>detailed food chain model or other exposure model may be used...</i>", but does not indicate a requirement to undertake food chain modelling, except "<i>...at large or complex contaminated sites where habitat is present unless it can be shown that concentrations in lower trophic levels are insignificant or other rationale can be provided.</i>" In Section 1.0, for food chain modelling, the definition states: "<b><i>food chain modelling</i></b>" means the quantitative estimation of the dose of contaminant received due to bioconcentration, bioaccumulation and biomagnification by each member of a food chain". Quantifying dose for each member of a food chain is often impractical and ecological risk assessment guidance (e.g., DERA, Sections 4.3.3 and 4.3.5 - "Food chain models are frequently used for estimating COPC exposure for wildlife ROPC") focuses on higher trophic wildlife species that consume other species. There is no indication in Section 4.2.3 that food chain modeling is expected to include "<i>each member of a food chain</i>".</p> <p><b>Recommendation:</b> ENV should define what is meant by "<i>at large or complex contaminated</i></p>	<p>The food chain modelling definition was revised for clarification.</p>



			<i>sites</i> ", for example, by referring to their definitions of terrestrial habitat based on land use. It needs to be clear when " <i>A food chain model must be completed...</i> " and when " <i>each member of a food chain</i> " must be included in a food chain model. Or indicate in Section 4.2.3 that this is left to the professional judgement of the risk assessment QPs.	
1 & 1 3	4.2 and 3.2/Figure 1, respectively	4.1.3	Draft Protocol 13 indicates that deep-rooted trees at a Commercial, Industrial or High-density Residential Land Use are not a precluding condition. Does deep-rooting vegetation exposure to subsurface contamination need to be evaluated at a Commercial, Industrial or High-density Residential Land Use in a SLRA or DRA? Contamination may not be present in the top 1 m of soil, resulting in a "N" in Question TS-2, potentially resulting in a No Unacceptable Risk in the SLRA, while there may still be subsurface contamination and exposure to deep-rooting vegetation. We recommend explicitly stating that deep-rooting vegetation exposure to subsurface contamination does not need to be evaluated at a Commercial, Industrial or High-density Residential Land Use since populations of these receptors are unlikely to occur.	The ministry expects that all exposure pathways be considered in a detailed risk assessment (DRA), including the evaluation of deep-rooting vegetation in a commercial, industrial, or high-density residential setting. A qualified professional may provide rationale that the pathways to deep-rooting vegetation are inoperable in a DRA; however, the ministry believes that a universal "rule" for deep-rooting vegetation is not appropriate in DRA at this time.
1	4.2.3 - Field Study	4.1.4	Clarification should be added regarding the requirements for ecological field surveys. It does not seem appropriate to complete a field survey at the level specified for small sites with limited ecological habitat, but that still require a Detailed Ecological Risk Assessment. Many larger sites also do not need surveys beyond the site visits and information listed in Protocol 13 to identify potential receptors and to (conservatively) characterize ecological risks.	If 'potential terrestrial habitat' or aquatic receiving environment is present as defined in Protocol 1, a field study is required. The level of detail required in this field study should be commensurate with the complexity of the site. In some cases, where species at risk were identified at the site in the absence of habitat (as defined by the ministry), a field study will also be required. If habitat is not identified at the site, but future site use will include habitat, this should be evaluated by a qualified professional. The ministry's position enables continued improvement of the standard of practice to protect species at risk.
1	5.1	6.1	may be supported by PVPs (rarely developed, except in the case of complex sites)	The ministry has established its position on Performance Verification Plans (PVPs).

				Further details are included on the ministry's website on PVPs.
1	5.1	6.1	indicates an application for a AiP or CofC will generally be considered incomplete if it does not include a PVP... this is inconsistent with current practice and what ENV has accepted in recent years, as well as guidance which indicates that a PVP is only required in cases where further clarification of the risk controls included in Sch B of the CofC is required or in the case of engineered controls where monitoring and contingency is required.	The ministry has established its position on Performance Verification Plan (PVP). It is correct that an Approval in Principle or Certificate of Compliance (CoC) will be considered incomplete if a PVP is absent where required. Further details are included on the ministry's website on PVPs.
1	5.1	6.1	<p>The first sentence in Section 5.1 (page 23) states "Section 53(3)(c) of EMA and Contaminated Sites Regulation (CSR) sections 18 and 18.1 require a plan for containing, controlling and monitoring any substances remaining on the site as a pre-condition to issuance of a Certificate of Compliance or the director's acceptance of risk-based standards."</p> <p>Recommendation: Clarify this statement - it would be clearer if the words "in excess of numerical standards", or similar, were inserted after the words "substances remaining on the site".</p>	The statement has been revised and now reads "Section 53(3)(c) of EMA and Contaminated Sites Regulation (CSR) sections 18 and 18.1 require a plan for containing, controlling and monitoring any substances remaining on the site in excess of standards as a pre-condition to issuance of a Certificate of Compliance or the director's acceptance of risk-based standards."
1	5.2	6.2	Reference to an iterative process wrt risk conclusions - it is unclear how this would happen with P6 submissions?	The text has been revised to clarify. It now reads, "the finalization of risk conclusions may be an iterative process between the applicant and reviewer (Approved Professional, ministry reviewer, and/or director) with the results supporting risk management decisions.
1	5.2	6.2	<p>The last sentence in the paragraph at the top of page 24 states "<i>The finalization of risk conclusions may be an iterative process between the applicant and ministry with the results supporting risk management decisions.</i>" There is no indication of what an "iterative process" would look like for submissions made under Protocol 6, or whether it is even feasible.</p> <p><b>Recommendation:</b> Provide some details and expectations by which ENV would facilitate an iterative process for Protocol 6 submissions, or be clear that this is not intended for risk assessments prepared in support of recommendations made by risk assessment approved professionals under Protocol 6.</p>	The text has been revised to clarify this statement. The ministry expects that there will be several rounds of communication (questions and clarifications) between a qualified professional and a reviewer (Approved Professional, ministry reviewer, and/or director) prior to finalizing risk conclusions.

1	5.2	6.2	<p>Top of page 24, second full sentence - the protocol indicates that "<i>The finalization of risk conclusions may be an iterative process between the applicant and ministry with the results supporting risk management decisions</i>". This is a welcome statement - please consider adding another sentence about the PROCESS of how that engagement would occur (i.e., when, who, how). Also, how would it work in the case of Protocol 6 where ENV is not at the table.</p>	<p>The text has been revised to clarify this statement. The ministry expects that there will be several rounds of communication (questions and clarifications) between a qualified professional and a reviewer (Approved Professional, ministry reviewer, and/or director) prior to finalizing risk conclusions.</p>
1	5.2	4.7	<p>Guidance states statistical analyses of the levels of contamination in environmental media and associated impacts are critical for decision-making purposes. Ecosystem services may be taken into account at a contaminated site to assist with decision making. Yes, but this type of high level guidance needs amplification. Is the intent that the RA needs to convey more statistics than the DSI? What does a "statistical analyses of contamination and impacts" mean? Spatial kreiging of HQs? An overlap of the distributions of exposure and effects? Suggest that high level guidance benefits from listing a few e.g.s along with a repeated theme that the level of interpretative effort needs to be tied back to the complexity of the RA, and that this decision is always a professional judgement.</p>	<p>It is not the ministry's intention to require specific statistical analyses for risk assessment. Rather, the ministry accepts the use of statistics in risk assessment where appropriate at the site. Alternatively, statistics may be unnecessary where conservative assumptions (e.g., maximums) are appropriately used. Examples of statistical analyses may include, but are not limited to, the use of 95% Upper Confidence Limit of the Mean (UCLM), 90th percentiles, t-tests, Analysis of Variance (ANOVA), and regression analysis. Generally speaking, the complexity of statistics is likely to be commensurate with the complexity of the site.</p>
1	5.2	6.2	<p>Near the top of page 24, the last sentence in the second paragraph begins with the term "Ecosystem services". The definition in Section 1.0 is "<b><i>ecosystem services</i></b>" means the processes and conditions by which humans benefit from the natural or engineered ecosystems around us." This term is unclear in the context of ecological risk assessment at contaminated sites - when would benefits to humans outweigh risks to ecological receptors from contaminants, and who decides?</p> <p><b>Recommendation:</b> Provide a few examples and some guidelines to illustrate how "ecosystem services" would be taken into account.</p>	<p>The ministry agrees that additional guidance is required for the inclusion of ecosystem services into risk assessment. This will be considered in future revisions.</p>
1	5.2 and 6.3	6.2	<p>Both titled decision process? Remove title for 6.3 as it refers to previous section?</p>	<p>Thank you for your comment, revisions have been made for clarification.</p>

1	6.1	5.1	Point #2 is welcome and very clear. There may be exceptions, such as (1) where a DSI is unable to achieve delineation (Pre-approval not to delineate...), (2) flow-through sites (property may not need delineation if not a responsible person), (3) background release (may not need to be sought if previous decision on broader area). TB2 has a footnote #3 which may provide useful language for reference here.	Thank you for your comment. You are correct that there may be exceptions. Protocol 1 is intended to outline the broad requirements for detailed risk assessment which will apply at most sites. "Exceptions to the rule" can be made via a Protocol 6 application or in some cases, can be justified with other documentation.
1	6.2	5.1	Table 2 lists errors and omissions but this section does not provide any direction or requirement for what must be done under Protocol 1 to (presumably) avoid these errors and omissions. Also, we anticipate that errors/omission would not only be limited only to those listed in Table 2.  Suggest removing Section 6.2 from Protocol 1, except for the second paragraph – “The detailed risk assessment report must be sufficiently comprehensive and sufficiently recent to reflect current site contaminants, conditions, receptors, exposures, and risks and present information on future site conditions and risk.” This text could be included under Section 6.1.	Table 2 is intended to act as an aid to practitioners in that it highlights common errors in risk assessment prior to ministry or Approved Professional review, hopefully saving time and money for all parties involved. In the past, the ministry has received feedback that such a table is useful. Your comment has been noted and will be considered for future revisions.
1	4.2.1	4.1.2	Beneficial use approach is inconsistent with Section 2.3, which indicates that SLRA cannot be used in DRA. As per previous comment, suggest re-considering the exclusivity of SLRA and DRA.	Thank you for your comment, it has been noted for future consideration.
1	4.2.1	4.1	Please provide a link to the "Technical Guidance for Risk Assessors" website	The Guidance for Risk Assessment web page is now available
1	4.2.1	4.1	The first para on page 14 indicates that <i>"Additional context can be found on the "Technical Guidance for Risk Assessors" website."</i> It sounds like ENV is going to prepare a new website with additional content - CSAP would like to have the opportunity to contribute to and/or review that content.	The Guidance for Risk Assessment web page is now available
1	4.2.1	4.1.3	Drinking water: para 2 should indicate if both current and future DW exposure pathway is considered incomplete...	Thank you for your comment. The text has been revised for clarification.
1	4.2.1	4.1.3	Pathways only refers to eco	Thank you for your comment. Some revisions have been made.
1	4.2.1	4.1.3	Suggest recommending multi-route exposure evaluation of DW, in particular for volatiles. HC benzene derivation could be cited.	Thank you for your comment. Text has been revised for clarification.

1	4.2.1 - Bioaccumulative Substances	4.1.3	<p>Under the heading "Bioaccumulative Substances" (bottom of page 12), it is stated "<i>When a complete exposure pathway exists between a receptor and bioaccumulative substance the potential for food chain impacts must be evaluated.</i>" Presumably this only refers to bioaccumulative substances which exceed applicable numerical standards (i.e., are contaminants).</p> <p><b>Recommendation:</b> On page 12, make it clear that food chain impacts do not need to be evaluated for bioaccumulative substances if numerical standards are not exceeded.</p>	Generally, if no bioaccumulative substances are identified as contaminants of potential concern (COPCs), then food chain modeling is not required; however, exceptions exist. If it is unclear when food chain modelling should be conducted at a particular site, seek guidance from the director.
1	4.2.1 - Bioaccumulative Substances	4.1.3	<p>Can more detailed information please be provided in this section on the <b>function</b> of the Bioaccumulative Substances definition within detailed risk assessment? Is its purpose only whether one needs to evaluate higher trophic level ingestion risks, e.g. hawk consuming small mammals? Or is it ENV's intention that common substances not meeting the definition of bioaccumulative substances (e.g. most metals) do not require lower trophic level food ingestion dose/risk modelling, e.g. wildlife consumption of invertebrates and plants?</p>	Generally, if no bioaccumulative substances are identified as contaminants of potential concern (COPCs), then food chain modeling is not required; however, exceptions exist. The ministry does not intend to exclude metals as bioaccumulative substances but rather to provide guidance around how to identify which metals are considered as such. If it is unclear when food chain modelling should be conducted at a particular site, seek guidance from the director.
1	4.2.1 - Contaminants of Potential Concern	4.1.1	<p>Can ENV clarify if or how <i>Technical Guidance 2 Statistical Criteria for Classifying a Volume of Contaminated Material</i> (Max &lt; 2X Std., 95% UCLM &lt; Std, 90th &lt; Std.) can be used within a Problem Formulation's COPC Screening section. <b>In particular if such statistics were not used in the supporting Detailed Site Investigation.</b></p>	The ministry's current position is that a substance is retained as a contaminant of concern (COC) for contaminants of potential concern (COPC) screening in detailed risk assessment (DRA) if the maximum concentration exceeds the applicable Contaminated Sites Regulation (CSR) standard. Statistics referenced in Technical Guidance 2 are intended to apply to sites meeting numerical standards only. This is not to say that statistics cannot be used in DRA; however, the expectation is that they are used carefully and with supporting rationale following COPC screening in the Problem Formulation.

1	4.2.1 - Contaminants of Potential Concern	4.1.1	Can statistics be used within the Problem Formulation's COPC screening section as rationale for not carrying a COPC (Max > Screening Benchmark per definition) through to the risk assessment. Or is ENV's expectation that contaminants with maximum > receptor-specific Screening Benchmark will be carried forward for exposure pathway evaluation, and quantitative estimate of risks (e.g. human health HQ/ILCR)?	The ministry's current position is that a substance is retained for contaminants of potential concern (COPC) screening in detailed risk assessment (DRA) if the maximum concentration exceeds the applicable Contaminated Sites Regulation (CSR) standard. Statistics (such as the 95% Upper Confidence Limit of the Mean) or spatial distributions may be considered later in the Problem Formulation to argue that exposure pathways are insignificant.
1	4.2.1 - COPC Screening	4.1.1	COPC - suggest that further explanation of COPCs be provided. For example, all COCs identified in DSI should be carried forward as preliminary COPCs. This is important as they are remediated to risk-based standards and thus are at a min preliminary COPCs. A secondary screening approach should be detailed, as per CSAP COPC screening guidance.	Noted. Some additional clarification has been added to Section 4.1.1
1	4.2.1 - Receptor Identification	4.1.5	There is only mention of receptors 'known or reasonably inferred to be present' at a site, but no mention of potential future receptors that are not currently present. Is the intention to also consider potential future receptors? If so, how would one go about rationalizing the potential for future presence of 'any sensitive life stages, vulnerable individuals' (even with current human site users, there's no guarantee that they would disclose such personal health conditions).	Thank you for your comment. Revisions to this section have been made for clarity.
1	4.2.1 - Selection of Ecological Receptors	4.1.5	Under the heading "Selection of Ecological Receptors" (page 14), the final sentence indicates that " <i>a Registered Professional Biologist must decide on potential species to include in the risk assessment</i> ". In our experience, this decision is best made by BOTH an RPBio and the risk assessor (or one person if they have both attributes). The RPBio can develop the long list, but the risk assessor understands the decision criteria for selecting receptors and has the site context in mind - both are needed to develop the optimal receptor list.	The word "decide" has been changed to "identify and assess" (i.e., a qualified professional must identify and assess potential species to include in the risk assessment").

1	4.2.1 - Selection of Ecological Receptors	4.1.5	Under the heading "Selection of Ecological Receptors" (top of page 14), the text starts with content related to cultural significance. While this is an important aspect for selecting receptors, it seems out of place in an introductory paragraph - suggest reorganizing this section to be clearer. One possible solution is to introduce the section with a statement that there are a number of aspects that require consideration when selecting ecological receptors (refer to ENV new website for RA and FCSAP/CCME guidance) but in particular, the following considerations are required - and then go onto the specific topics that ENV wants to emphasize based on the draft, including cultural significance.	Thank you for your comment. The ministry agrees that organizational changes would improve this document. Minor changes have been made at this time and further organizational changes are noted for future consideration.
1	4.2.1 - Selection of Ecological Receptors	4.1.5	Under the heading "Selection of Human Health Receptors" (middle of page 14), it is stated <i>"When selecting human health receptors, QPs must follow recommendations in Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0 (2012), except where the QP completing the assessment considers it inappropriate."</i> PQRA Part I (e.g., Tables 2 and 3) includes a construction/utility worker receptor. In Technical Guidance 7 (Version 5, November 2017), the text box at the top of page 2 indicates that only occupational exposures >90 days need to be evaluated for utility, trench, and construction workers.  <b>Recommendation:</b> If Technical Guidance 7 is intended to be retired (which seems probable given the extent to which draft Protocol 1 captures items currently in TG7), include the text box at the top of page 2 of Technical Guidance 7 in draft Protocol 1.	Technical Guidance 7 components been moved into Protocol 1 and the new RA webpage. Protocol 1 contains a section titled Human Health - Pathways to subsurface media that addresses this point.
1	4.2.1 - Selection of Ecological Receptors	4.1.5	Under "Selection of Ecological Receptors", the determination of suitable terrestrial habitat seems to now require use of the Protocol 13 forms/procedures. Can you please confirm that all detailed terrestrial ERAs must now use these specific forms/procedures, or can an R.P.Bio. reasonable use their professional judgement in the context of the Contaminated Sites Regulation (CSR) requirements, including Protocol 20? While use of the Protocol 13 process makes sense in the context of SLRA that do not need to be conducted by a risk assessment QP, use of these procedures/forms in every detailed terrestrial ERA will not add	It is agreed that the Protocol 13 forms are simple. Currently, the habitat assessment forms from Protocol 13 are required as a minimum in detailed risk assessment. More sophisticated habitat assessments are valuable for some sites. These comments are noted for consideration in future revisions.

			scientific value and make the process of regulatory review more cumbersome than is needed on the vast majority of sites. Please consider changing or clarifying this requirement to allow QPs flexibility in reporting/presentation of how detailed terrestrial ERAs meet the necessary requirements for habitat assessments/receptor selection.	
1	4.2.1 - Selection of Ecological Receptors	4.1.5	Selection of ecological receptors and ref. to P13 for habitat assessment procedure inconsistent with Section 2.3 (indicated SLRA cannot be used in DRA). Reconsider.	<p>The ministry maintains that SLRA and DRA are discrete tools and cannot be used in the same submission. The completion of DRA requires that all exposure pathways be considered, regardless of whether a SLRA has been previously completed.</p> <p>Nonetheless, there are some basic principles of risk assessment which may be employed in both SLRA and DRA. These include the use of beneficial use exclusions and habitat assessment.</p>
1	4.2.1 - Selection of Ecological Receptors Deep Rooting Vegetation	4.1.5	Within Detailed ERA, for commercial, high density residential, and industrial sites can deep rooting vegetation be excluded as receptors of concern? Protocol 13 (Section 3.2 Precluding Conditions) appears to have adopted such a policy. Hence is it also applicable to DERA?	The ministry expects that all exposure pathways be considered in a detailed risk assessment (DRA), including the evaluation of deep-rooting vegetation in a commercial, industrial, or high-density residential setting. A qualified professional may provide rationale that the pathways to deep-rooting vegetation are inoperable in a DRA; however, the ministry believes that a universal "rule" for deep-rooting vegetation is not appropriate in DRA at this time.
1	4.2.1 - Selection of Ecological Receptors Professional Statements	4.1.5	The present wording of Section 4.2.1 and the Professional Statements pages introduces a new requirement to DERA that only R.P.Bio.s with <b>experience in habitat assessment</b> can perform a simple evaluation of "Potential Terrestrial Habitat". Can ENV clarify if that is correct, or can any R.P.Bio. regardless of experience in wildlife habitat be able to answer whether a site is potential terrestrial habitat? Answering that question is often a relatively simple evaluation of area of undeveloped land.	The ministry expects that a qualified professional with relevant experience in habitat assessment perform evaluations of potential terrestrial habitat. This expectation echos the requirements set out by the <i>Professional Governance Act</i> which states under s. 57(2)(b) that practitioners "practice only



				in those fields where training and ability make the registrant professionally competent."
	4.2.1 - Selection of Human Health Receptors	4.1.5	<p>Under the heading "Selection of Human Health Receptors" (middle of page 14), it is stated "<i>In human health receptor selection, QPs must include all relevant receptors and most sensitive life stages.</i>" On Page 1 of Technical Guidance 7 (Version 5, November 2017), sensitive receptors that are listed include the following:</p> <p><i>"b) hypersensitive individuals (e.g. pregnant women, PICA children, etc.),</i></p> <p><i>c) vulnerable individuals known to suffer compromised health impacts (e.g., chemical hypersensitivity, impaired pulmonary function, immunodeficiency, etc.)"</i></p> <p>Unless an institutional facility (e.g., hospital, long-term care home) was present, it would be very difficult to identify the presence or probable presence of such sensitive receptors. In practice, very few HHRAs address such receptors in CSAP submissions or in direct submissions made to ENV. The wording on page 14 of the current draft Protocol 1 seems adequate.</p> <p><b>Recommendation:</b> If Technical Guidance 7 is retired, do not port over the wording with respect to sensitive receptors and enshrine it in Protocol 1.</p>	Thank you for your comment. It has been noted for future consideration.
1	4.2.1, 4.2.2, 4.2.3, 6.1	4	References are made to a "Technical Guidance for Risk Assessors" website for additional context and/or guidance. A source or link to this website was not provided and I am not familiar with this source. Is this intended to be a replacement for TG7?	Yes, the Guidance for risk assessment web page is intended to replace Technical Guidance 7.
1	4.2.3 - Field Study	4.1.4	Under the heading "Field Study" (page 16), the final paragraph discusses soil sampling - this topic is out of context for this section for two reasons: (1) the rest of the field study text seems to be related to ecological characterization which is often carried out by different practitioners than soil characterization and (2) soil characterization is part of exposure assessment, typically conducted prior to ecological field studies through site investigation and sometimes supplemented at finer scales of resolution. For these reasons, suggest (1) that the guidance in the last paragraph be moved to another section within 4.2.1, perhaps "Exposure Parameters and	Thank you for your comment. The ministry agrees that organizational changes would improve this document. Minor changes have been made at this time and further organizational changes are noted for future consideration.

			Scenarios" (page 13) - this clarification of top 1 m is very welcome policy and (2) that the title "Field Study" be revised to reflect ecological - perhaps "Ecological Field Study".	
1	4.2.2	4.2	a link to the ministry's website "Technical Guidance for Risk Assessors" should be included	The Risk Assessment website will be available in the near future.
1	4.2.2	4.2	Usually the final CSM does not include incomplete exposure pathways – these must be discussed in the PF but are not carried through to the CSM.	In the interest of transparency in risk assessment, it is the ministry's expectation that both complete and incomplete exposure pathways be presented in a visual conceptual site model, in addition to justification in the text.
1	4.2.3	4.3.1	Exposure Parameters and Scenarios - Para 1 - indicates P28 as default source of HH risk exposure parameters and scenarios. This is inconsistent with earlier sections that specify HC guidance should be used for deterministic RA. Further P28 doesn't cover all exposure pathways (e.g., soil only include ingestion, not dermal contact or inhalation of soil particulate) and includes many assumptions that are inconsistent with Health Canada guidance.	In the interest of clarification, Protocol 1 describes the requirements of detailed risk assessment in the context of the Contaminated Sites Regulation (CSR), and Protocol 28 describes the derivation of numerical standards in the CSR. In any jurisdiction, risk assessment is inherently related to standards derivation and it is only natural that risk assessment begins with the same assumptions used in standards derivation. Therefore, it is the ministry's expectation that Protocol 28 exposure parameters and scenarios be considered in DRA prior to adoption of those outlined in Health Canada guidance. The ministry emphasizes that each site is unique and that there may be cases where it is necessary to use exposure parameters and scenarios which are more appropriate and conservative than those included in Protocol 28. Where an exposure pathway has not been considered in Protocol 28, the practitioner is referred to Health Canada. Additional resources for evaluating exposure scenarios not in Protocol 28 or Health Canada

				will be available on the risk assessment website. Text has been added to Protocol 1 to clarify this.
1	4.2.3	4.3.1	Exposure Parameters and Scenarios - indicates P28 as default source of HH risk exposure parameters and scenarios. This is inconsistent with earlier sections that specify HC guidance should be used for deterministic RA. Further P28 doesn't cover all exposure pathways (e.g., soil only include ingestion, not dermal contact or inhalation of soil particulate) and includes many assumptions that are inconsistent with Health Canada guidance.	<p>In the interest of clarification, Protocol 1 describes the requirements of detailed risk assessment in the context of the Contaminated Sites Regulation (CSR), and Protocol 28 describes the derivation of numerical standards in the Contaminated Sites Regulation (CSR). In any jurisdiction, risk assessment is inherently related to standards derivation and it is only natural that risk assessment begins with the same assumptions used in standards derivation. Therefore, it is the ministry's expectation that Protocol 28 exposure parameters and scenarios be considered in DRA prior to adoption of those outlined in Health Canada guidance. The ministry emphasizes that each site is unique and that there may be cases where it is necessary to use exposure parameters and scenarios which are more appropriate and conservative than those included in Protocol 28.</p> <p>Where an exposure pathway has not been considered in Protocol 28, the practitioner is referred to Health Canada. Additional resources for evaluating exposure scenarios not in Protocol 28 or Health Canada will be available on the risk assessment website.</p> <p>Text has been added to Protocol 1 to clarify this.</p>

1	4.2.3	4.3.1	Earlier sections indicate that ecoRA only follow P20, it is indicated here that the ecological exposure assessment MUST consider FCSAP Module 3 and other agencies. Correct for consistency. It is indicated that food chain modelling must be performed for all members of a food chain - this should be focused on higher trophic organisms/wildlife receptors and should be left to BPJ.	As described in several sections of Protocol 1, ecological risk assessment must comply with Protocol 20 requirements. Ecological risk assessments must also consider the referenced Federal Contaminated Sites Action Program (FCSAP) guidance documents. If the FCSAP guidance is not appropriate for the specific site, rationale must be provided to explain the needs of the site and why this guidance is not appropriate.
1	4.2.3	4.3.1	Exposure Assessment, Overall - 1st para refs Section 4.2. This section is a sub-section of section 4.2 - should the sub-section be indicated? Generally the section layout is hard to follow - suggest using more section numbers	Thank you for your comment. The ministry agrees that organizational changes would improve this document. Minor changes have been made at this time and further organizational changes are noted for future consideration.
1	4.2.3	4.3.1	Second bullet - reasonable potential future land... what is reasonable? Further guidance should be provided.	The <i>Environmental Management Act</i> and Contaminated Sites Regulation establish the legal requirements of this mandatory consideration of reasonable current and potential future uses. The ministry expects a thorough consideration by the responsible person of this topic as it is key to appropriate contaminated site remediation as per Contaminated Sites Regulation (CSR) s. 12 and 18 and any future applications to the director. As per s. 12(5)b, land use and planning policies (official/municipal community plan) must be taken into account.
1	4.2.3	4.3.1	Soil in the top 1 metre is characterized in the DSI. Is this a suggestion that DSI characterization may not be sufficient? What is meant by a high level of confidence?	A detailed site investigation (DSI) must be sufficient to demonstrate delineation in all media. Additional soil samples may be collected to support the risk assessment if the qualified professional determines it necessary to adequately characterize potential

				exposure. A high level of confidence is at the discretion of the qualified professional. At a minimum, the ministry's technical guidance documents, webpages and protocols must be followed but industry best practices are a factor too.
1	4.2.3	4.3.1	There will be very few sites where burrowing animals were not be present.	Thank you for your comment. It has been noted for future consideration.
	4.2.3 - Field Study	4.1.4	It is stated that a detailed ecological field study of the site must be completed. Does ENV require a detailed ecological field study for all sites, including corner gas stations in urban environments? How would this be completed for a future scenario?	If a site contains 'potential terrestrial habitat' or an aquatic receiving environment as defined in Protocol 1, a field study is required. The level of detail required in this field study should be commensurate with the complexity of the site. In some cases, where species at risk are identified at the site in the absence of habitat (as defined by the ministry), a field study will also be required. If habitat is not identified at the site, but future site use will include habitat, this plan should be evaluated by a qualified professional.
1	4.2.3 - Field Study	4.1.4	Field study - DRA may be completed for sites where a field study is not required. E.g., sites with localized contamination > 1 m but < 3 m and evaluation of potential for deep rooting veg exposure. It is indicated that a field study must be completed, but this should not be a requirement and should be left to BPJ.	If a site contains 'potential terrestrial habitat' or an aquatic receiving environment as defined in Protocol 1, a field study is required. The level of detail required in this field study should be commensurate with the complexity of the site. In some cases, where species at risk are identified at the site in the absence of habitat (as defined by the ministry), a field study will also be required. If habitat is not identified at the site, but future site use will include habitat, this plan should be evaluated by a qualified professional.

1	4.2.3 - Field Study	4.1.4	Field study - Text indicates that a field study must be completed; however, there are a lot of sites where a field study is not required as suitable information can be gathered from site photos or other means. E.g., sites that are primarily developed and have limited areas with habitat. This should not be a requirement and should be left to the discretion of the risk assessor with rationale provided in the report.	If a site contains 'potential terrestrial habitat' or an aquatic receiving environment as defined in Protocol 1, a field study is required. The level of detail required in this field study should be commensurate with the complexity of the site. In some cases, where species at risk are identified at the site in the absence of habitat (as defined by the ministry), a field study will also be required. If habitat is not identified at the site, but future site use will include habitat, this plan should be evaluated by a qualified professional.
1	4.2.3 - Field Study	4.1.4	Section on Field Study, page 16. The first line implies that every site must have a detailed ecological field study - Not every ERA requires a detailed ecological field study. As an example, some ERAs may be based on only laboratory data including soil chemistry and soil toxicity tests - or literature reviews. Making a detailed field study mandatory is inconsistent with the philosophy of WOE approaches whereby the risk assessor considers candidate lines of evidence and selects those that make sense for the particular site, objective, and context.	If a site contains 'potential terrestrial habitat' or an aquatic receiving environment as defined in Protocol 1, a field study is required. The level of detail required in this field study should be commensurate with the complexity of the site. In some cases, where species at risk are identified at the site in the absence of habitat (as defined by the ministry), a field study will also be required. If habitat is not identified at the site, but future site use will include habitat, this plan should be evaluated by a qualified professional.
1	4.2.3 - Field Study	4.1.4	Other professionals, such as agrologists and foresters, are arguably more qualified to complete the work of a detailed ecological field study. Wouldn't it be better to be inclusive of these other experts?	Ecological field studies should be completed by a qualified professional with relevant experience in accordance with the <i>Professional Governance Act</i> .

1	4.2.3 - Field Study	4.1.4	Is a field study by R.P.Bio. only required for sites in which a more detailed evaluation of habitat is being performed? Is a site visit by R.P.Bio. necessary in identifying " <b>Potential</b> Terrestrial Habitat".	If a site contains 'potential terrestrial habitat' or an aquatic receiving environment as defined in Protocol 1, a field study is required. The level of detail required in this field study should be commensurate with the complexity of the site. In some cases, where species at risk are identified at the site in the absence of habitat (as defined by the ministry), a field study will also be required. If habitat is not identified at the site, but future site use will include habitat, this plan should be evaluated by a qualified professional.
1	4.2.3 – Field Study (Page 16)	4.1.4	Not every ERA requires a detailed ecological field study. As an example, some ERAs may be based on only laboratory data including soil chemistry and soil toxicity tests. Making a detailed field study mandatory is inconsistent with the philosophy of WOE approaches whereby the risk assessor considers candidate LOEs and selects those that make sense for the particular site, objective, and context.	If a site contains 'potential terrestrial habitat' or an aquatic receiving environment as defined in Protocol 1, a field study is required. The level of detail required in this field study should be commensurate with the complexity of the site. In some cases, where species at risk are identified at the site in the absence of habitat (as defined by the ministry), a field study will also be required. If habitat is not identified at the site, but future site use will include habitat, this plan should be evaluated by a qualified professional.

1	4.2.3 - Exposure Parameters and Scenarios	4.3.1	<p>Under the heading "Exposure Parameters and Scenarios" (middle of page 15), it is stated "<i>The human health exposure assessment must: 1. consider Protocol 28: "2016 Standards Derivation Methods" (Protocol 28) as the default source of human health risk exposure parameters and scenarios</i>" Table 2-2 in Protocol 28 provides land use-specific soil ingestion rates. This includes 40 mg/day for toddlers and 10 mg/day for adults at RL<sub>HD</sub> and CL land use sites. Health Canada PQRA Part I does not provide daily soil intake rates of 40 mg/day for toddlers and 10 mg/day for adults at commercial sites, and does not distinguish between low density and high density residential land uses. Table 2-3 in Protocol 28 provides default values for the exposure term (ET) based on land use. For IL land use, there is an assumption of 8 hr/24 hr, and for PL and CL land uses, there is an assumption of 12 hr/24 hr. Including 8 hr/24 hr, or 12 hr/24 hr, in the ET term results in amortizing the daily soil ingestion rate by a factor of 3 (e.g., 20 mg/day becomes 6.67 mg/day) for industrial land use, and by a factor of 2 (e.g., for PL use, 20 mg/day becomes 10 mg/day; for CL land use, 10 mg/day becomes 5 mg/day) for urban park and commercial land uses. Since the soil ingestion rate is a daily intake value and is not based on hourly exposure, this results in the numerical standard for "Intake of contaminated soil" being lower than a risk-based standard if other exposure assumptions (days per week, weeks per year, years of exposure (for carcinogens), absorption factor, body weight) remain the same. From a technical perspective, applying an adjustment of 8 hr/24 hr, or 12 hr/24 hr, is not supported by Health Canada or US EPA in their soil ingestion exposure equations.</p> <p><b>Recommendation:</b> If Protocol 28 is "<i>the default source of human health risk exposure parameters and scenarios</i>", state that ENV supports: i) use of the soil intake rates provided in Table 2-2 of Protocol 28, and, ii) an amortized soil intake rate, in risk assessments submitted in support of recommendations made by risk assessment approved professionals under Protocol 6, or as direct submission made to and reviewed by ENV.</p>	<p>It is the ministry's expectation that Protocol 28 exposure parameters and scenarios be considered in detailed risk assessment prior to adoption of those outlined in the 2012 Health Canada guidance (Guidance on Human Health Preliminary Quantitative Risk Assessment). The ministry emphasizes that each site is unique and that there may be cases where it is necessary to use exposure parameters and scenarios which are more appropriate and conservative than those included in Protocol 28. The ministry supports the use of the soil intake rates provided in Protocol 28 where appropriate for the site in question. The ministry acknowledges that additional clarification is needed on amortization in risk assessment. The exposure terms included in Table 2-3 of Protocol 28 are generalizations for the purpose of standards derivations and identification of a contaminated site, and are not necessarily appropriate for use in risk assessment. At present, the ministry recommends the 2012 Health Canada guidance conservatively be used with respect to amortization and emphasizes that this document indicates "amortization should be applied on a chemical-specific basis with appropriate rationale." Additional resources available on the ministry's risk assessment web pages. If you continue to have questions on this subject, please submit an enquiry through the ministry's Contact Us webpage.</p>
---	---	-------	--	--



1	4.2.4	4.4.2	"With respect to ecoTRVs, the QP must include the following in the report:..." Have these requirements been included in Protocol 20? If the most stringent TRV is selected, and it is a guideline or an Eco-SSL, these are amalgams of different studies with different species. In these cases, how do they expect to receive answers to the "specific effects levels"?	Thank you for your comment. The ministry will consider revising Protocol 20 in the future.
1	4.2.4	4.4.2	Guidance states that QPs must consider ECO-SSL and FSCAP guidance on TRVs. These two documents aren't fully reconcilable. ECO-SSL does a really good job of talking about how to do the QA, but emphasizes NOEALS. ECO-SSL <u>explicitly says that its TRVs should not be used for detailed RAs</u> . Conversely, Module 2 emphasizes NOEAL based TRVs are not ideal and highlights options for improvement without mandating a specific course of action. There needs to be some reconciliation in this section or at least an explicit statement that TRVs are also iterative and therefore, it is reasonable to push towards less conservative TRVs for large sites. As currently written, the guidance is not providing sufficient flexibility to create genuine de novo TRVs where the science warrants that consideration.	Thank you for your comment, this has been noted for future consideration.
	4.2.4	4.4.2	Guidance states that QPs must document in the detailed risk assessment report the use of scientifically defensible approaches and sources of information for any risk assessment using a weight of evidence approach. QPs must consider the following guidance: • Science Advisory Board for Contaminated Sites in B.C.: Guidance for Weight of Evidence Approach (2010) • Environment and Climate Change Canada's (FCSAP): Ecological Risk Assessment Guidance (2012), Chapter 5.5.. Missing the reference to EPA's 2018 Purple Book "Weight of Evidence in Ecological Assessment" which is the most recent and complete discussion of using WOE in detailed eco risk assessment.	Thank you for your comment. The ministry will review the reference provided and consider the addition of this reference in a future revision or on the new webpage supporting risk assessment.
1	4.2.4	4.4.1	HHRA - ref to site-specific TRVs should be removed? Is this referring to de novo TRVs?	Thank you for comment. The section on human health toxicity reference values (TRV) has been revised for clarity.
1	4.2.4	4.4.2	The most stringent ecological TRV "must be selected" unless it can be shown by the QP that an alternative value is more appropriate. This is very prescriptive, does not allow for the QP to make sure the TRV is reflective of the receptor, does not take into account the different protection levels for the different land uses,	The language in Protocol 1 indicates that the most stringent <i>applicable</i> ecological toxicity reference value (ecoTRV) from the preferred sources should be used. It is at the discretion of the qualified

			most TRV resources do not present the effects level of the TRV (most stringent TRV is unlikely to be a 20% or a 50% effects concentration/dose)	professional to determine when an ecoTRV is applicable.
1	4.2.4 - Ecological TRVs	4.4.2	<p>Page 19 text - <i>"In the case where no credible EcoTRV can be found, a de novo EcoTRV may be derived."</i> • Should be clarified that a QP can determine whether or not the TRVs in the prescribed sources are "credible" (if this is the intent). Suggest adding the following text: <i>"If the QP determines that a de novo TRV is technically preferred over the sources provided, a de novo TRV can be used with supporting rationale."</i></p>	The language in Protocol 1 indicates that the most stringent <i>applicable</i> ecological toxicity reference value (ecoTRV) from the preferred sources should be used. It is at the discretion of the qualified professional to determine when an ecoTRV is applicable. In addition, a qualified professional may determine that a de novo ecoTRV is more appropriate than any of the ecoTRVs in the preferred sources. In this case, a Protocol 6 application will be required for non-high risk sites.
1	4.2.4 - Ecological TRVs	4.4.2	<p>Page 18 text: Sediment – Aquatic Life – the CCME document listed in the bullet references is <i>"Scientific Criteria Documents for Deriving Soil Guidelines"</i></p> <ul style="list-style-type: none"> <li>• Should this be referring to the "Protocol for the Derivation of Canadian Sediment Quality Guidelines for the Protection of Aquatic Life"?</li> <li>• Also why isn't the Criteria for Managing Contaminated Sediment in British Columbia Technical Appendix (MacFarlane et al.) referenced since it is the source of the ecological protection goals levels for sediments listed in Table 1?</li> </ul>	Thank you for your comment. The reference to Canadian Council of Ministers of the Environment (CCME) sediment guidelines has been corrected.
1	4.2.4 – Effects Concentrations (Table 1)	4.4.6	ECx values are not the only way to measure whether levels of protection are being achieved and the terminology in Table 1 should be more general (e.g., 20% effect, 50% effect). For example, determining whether a 20% protection level has been achieved could be based on the EC20 for dilution or spiking series (where the EC20 is measured) or the IC20 for dilution or spiking series (where the IC20 is measured) or on testing of the actual level of effect in field collected samples. EC20 or IC20 values are typically only relevant when determining TRVs from laboratory spiking studies with single chemicals or for whole	Thank you for your comment, protection levels must be equivalent to or better than those shown in Table 1. Your comments have also been noted for future consideration.

		<p>effluent testing. For the field collected samples, ICx or ECx values are not determined (because chemical spiking or sample dilutions are not conducted) but rather level of impairment to relevant endpoints is determined (e.g., survival, growth, reproduction), and then compared to the protection goals to see if they are achieved – e.g., when the response is &lt;20% the protection goal is met, when response &gt;20% the protection goal is not met (this is standard practice in testing of field collected samples for risk assessment).</p> <p>For sediments, it is unclear how 50% probability of EC20 or 20% probability of EC20 would be assessed in a typical sediment risk assessment? These metrics were developed through analysis of large databases of sediment effects data allowing for statistical analysis of the probability of observing standard effects sizes. However, typical practice in sediment risk assessment involves site-specific testing to determine the actual effect size at a given location (e.g., effect size is either &gt;20% or &lt;20% relative to control for the given sample, there is no ability to determine the probability because there is no extensive database of effects data) which feeds into a weight of evidence assessment.</p> <p>Although the protection levels listed in Table 1 are consistent with how the guidelines were developed, having protection goals for different median/ecosystems based on different metrics (i.e., effect levels versus proportion affected, versus probability of an effect level) adds some complication with consistent application of these levels in a risk assessment context. Also, some of these levels of protection will be difficult to measure with some lines of evidence. Because the definition of “unacceptable risks” for ecological receptors hinges on Table 1, we recommend that the protection levels be consistent metrics across the land uses based on the targeted acceptable effect level per land use (e.g., 20% for aquatic life and sediment receptors, 50% for commercial/industrial, 20% for residential/urban park/agriculture, 15-25% for wildlands etc.)</p>	
--	--	--	--

	4.2.4 - Table 1	4.4.6	Protection levels outlined in Table 1 are more stringent than those used to calculate numeric standards, as presented in Section 3.2 (Table 3-1) of draft Protocol 28. Is the intent to remediate sites using risk assessment to a more conservative level than numeric remediation or identification of contaminated sites? For example, in draft Protocol 1 the level of protection for Urban Park Land Use is an EC20 but the derivation of the Urban Park Land Use standard uses an EC25. Table 1 presents the protection level for ecological receptors at sites with Residential Land Use as the EC20. Draft Protocol 28 derives the numeric ecological standards for high density and low density residential using an EC50 and EC25, respectively. Will Protocol 1 be updated to include both types of Residential Land Use?	The Contaminated Sites Regulation (CSR) generic numerical standards derived by the ministry as per Protocol 28 are reflective of the ministry's position on matters in 2015/2016 and the decisions made regarding setting provincially-applicable numerical CSR standards. There is no limitation on the usage of different protection levels at a contaminated site as better information becomes available. Specifically, Protocol 1 does not limit the derivation of the most appropriate risk based standards for a specific site. It is possible that best available science will result in risk based standards that are lower than generic numerical CSR standards. Although it is also possible that site-specific information can be used to derive risk-based standards higher than generic numerical CSR standards. Please note that Protocol 1 provides direction on conducting DRA, while Protocol 28 describes how numerical standards were derived for the CSR Schedules. As such, some of the protection levels set out in Table 1 of Protocol 1 differ from those in Table 3-1 of Protocol 28. Table 1 of Protocol 1 has been updated to include a footnote for both residential land uses. Your comment has been noted for future consideration.
1	4.2.4 – Human Health TRVs	4.4.1	First paragraph – <i>“The HHRA report must identify and provide scientific justification for the most appropriate TRV. The ministry requires the consideration of human health TRV sources as listed in Protocol 28, Chapter 8 for soil, water, and vapour, with the exception of those substances for which the ministry derived drinking water standards and where drinking water TRVs are provided in Protocol 28 Appendix 8C”</i>	Technical Guidance 7 been moved into Protocol 1 and the new Guidance for Risk Assessment web page upon release of the final Protocol 1 version 2.

			Does this supersede the HH TRV hierarchy listed in Tech Guidance 7 which indicates that US EPA IRIS TRVs take precedence over Health Canada TRVs? Ideally this should be clarified.	
1	4.2.4 - Toxicity testing	4.4.4	The toxicity testing section page 19-20 should refer to the FCSAP ERA guidance module on tox test selection	"Federal Contaminated Sites Action Plan (FCSAP) Ecological Risk Assessment Guidance, Module 1: Toxicity Test Selection and Interpretation" has been included on the ministry's Risk Assessment web pages.
1	4.2.4 – Toxicity Testing	4.4.4	<p>Questions regarding the following sentence and bullets: <i>"The ministry requires the use of toxicity test methods established by the following agencies in ecological risk assessment: (multiple agencies methods listed)"</i></p> <ul style="list-style-type: none"> <li>• Can a QP select an alternative test protocol if it can be justified technically? This would be reasonable and would be consistent with other sections of Protocol 1 where BPJ can be applied by a QP (e.g., determination of bioaccumulative substance).</li> <li>• What about modifications to the standard protocols that are typically applied by testing labs to improve the likelihood of a successful test or address non-contaminant issues such as fungal growth? (are these allowed if justified technically?)</li> </ul> <p>This section (page 19-20) should also refer to the FCSAP ERA Guidance Module 1: Toxicity Test Selection and Interpretation (<a href="https://www.canada.ca/content/dam/ecccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-07650F3A68EA/ERA-20Module-201_en-20Final-R.pdf">https://www.canada.ca/content/dam/ecccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-07650F3A68EA/ERA-20Module-201_en-20Final-R.pdf</a>).</p>	<p>Please seek guidance from the ministry prior to using an alternate test protocol or a modification to the standard protocol. If further information is required, please send an enquiry through the email addresses on the ministry's Contact Us webpage.</p> <p>"Federal Contaminated Sites Action Plan (FCSAP) Ecological Risk Assessment Guidance, Module 1: Toxicity Test Selection and Interpretation" has been included on the ministry's Risk Assessment web page.</p>
1	4.2.4 - TRVs	4.4.3	Clarify if ENV approval is needed prior to developing a new TRV if the risk assessment is going through CSAP?	Ministry requirements regarding the derivation of new (de novo) toxicity reference values (TRVs) has not changed. If a de novo TRV is required, a Protocol 6 approval is required for submissions using the Contaminated Sites Approved Professionals (CSAP) process. For high risk sites, each de novo TRV used must be supported by full derivation details and

				provided for the ministry's review. If further direction is needed regarding specific TRVs or when de novo TRVs can be used, please seek advice from the ministry.
1	4.2.4 Ecological TRVs	4.4.2	Text under the heading "Ecological TRVs" (page 17-18) - The text implies that only TRVs can be used in ecological effects assessment - ecological TRVs are point estimates and are not the only approach used for Effects Assessment in ecological risk assessments. Exposure-response modeling is widely acknowledged to be preferred to assess ecological effects, and should be an option in cases where it is warranted.	Exposure-response modeling may be valued and accepted as a line of evidence. The ministry has established a position on the requirements surrounding toxicity reference values (TRVs) and hazard quotients (HQs). Please see the final posted version of Protocol 1 version 2.
1	4.2.4 Effects Concentrations	4.4.6	Table 1. outlines ENVs protection levels for ecological receptors for different land uses. However, ECx concentrations are rarely available for wildlife. Wildlife like humans typically have TRVs reported as doses, NOAEL or LOAEL doses. Could ENV clarify its preferred dose-based protection levels for wildlife? LOAEL for all wildlife, including listed species? LOAELs are likely more consistent with ECx protection levels outlined in Table 1 than NOAELs.	TRVs must be equivalent to or better than those listed in Table 1. If ECx values are unavailable, No-observed adverse effect level (NOAEL) and low-observed adverse effect level (LOAEL) values may be cautiously used in the toxicity reference value (TRV) derivation process. For species at risk, a separate protection level is provided in Table 1. Protection of species at risk at a LOAEL effects level is typically not adequately protective, and NOAEL effects levels are most often used.
1	4.2.4 Effects Concentrations	4.4.6	Table 1. indicates EC20 is the appropriate protection level for aquatic life. However Table 1. also indicates that for sediment there are two levels of protection, one for Sensitive sites which is a theoretical 20% probability of EC20 to amphipods, and one for Typical sites which is a theoretical 50% probability of EC20. What is ENV's default TRV for evaluating risks to the benthic invertebrate community of a Sensitive Site? The Typical standard which represents a higher probability of EC20 or the Sensitive standard?	Typical sediment standards should not be used as toxicity reference values (TRVs) in risk assessment. It would be more appropriate to choose an EC20 (the concentration causing an effect to 20% of the organisms exposed) value from a sensitive species or class of organism that is relevant to the site. The species sensitivity distribution approach is acceptable but data limitations may preclude its use for many substances.
1	4.2.4 Effects Concentrations	4.4.2	The statement: <i>"The most stringent applicable EcoTRV from the above preferred sources or supplemental sources, if applicable, must be selected"</i> . Suggest this statement be removed or modified. It indicates that all the preferred TRV sources be reviewed and the lowest TRV	This statement clarifies the ministry's position that of all <u>applicable</u> ecological toxicity reference values (EcoTRV), the most stringent must be selected. The term applicable

			selected. Note, the Eco-SSL TRVs are based on NOAELs, while the Ontario TRVs are based on LOAELs. Stating one must use the lowest value from all of the preferred sources would thus default the TRV to NOAELs, and as stated above LOAELs may be more appropriate.	allows the qualified professional to identify which EcoTRVs are most suitable for the site based on land use and other factors.
1	4.2.4 Use of de novo Derived EcoTRVs Ecological TRVs	4.4.3	Can ENV further clarify what is considered de Novo TRV derivation for ecological receptors. This needs to be very clear as it is a Protocol 6 pre-approval item. Is the only approach to selecting a TRV that does not require pre-approval, to use the end-result TRVs from those preferred sources listed in Section 4.2.4? Would selection of a single-study toxicity test endpoint, or averaging of multiple test endpoints, from the compiled tables or graphs of published data in ENVs preferred TRV source documents (e.g. USEPA Eco-SSL derivation documents, Protocol 28) be considered de-Novo derivation requiring P6 approval?	As per Protocol 1 definition, a de novo EcoTRV is an EcoTRV that has been calculated by a qualified professional using an established procedure or derivation method for the site from toxicological data. EcoTRVs that do not require preapproval are those that have been provided by preferred sources (i.e. typically regulatory agencies). Selecting data from single-study toxicity test endpoints or averaging multiple test endpoints are methods used for deriving new TRVs and would require pre-approval. However, at this time, the ministry does not consider selecting a TRV derived in a published peer-reviewed scientific journal article to be a <i>de novo</i> TRV derivation requiring preapproval. As stated above, the previous sentence excludes TRVs that are based on a single toxicity test. Selecting a single toxicity test value (e.g. from a scientific article) would be fairly poor practice and this would only be acceptable if the criteria in Protocol 1, Section 4 was met and approved by the ministry (i.e., as a Protocol 6 application for non-high risk sites). Protocols provide the requirements that must be legally followed, i.e., nothing in this response can supersede any protocol requirement.

1	4.2.4 Use of de novo Derived EcoTRVs Ecological TRVs	4.4.3	Protocol 1 states: <i>"Where uncertainty factors are used, the report must document how factors have been chosen in a manner consistent with FCSAP guidance"</i> . Note, the link provided is to CCME guidance not FCSAP guidance.	The ministry will consider reviewing the 2020 Canadian Council of Ministers of the Environment (CCME) Ecological Risk Assessment document. This link has been corrected to refer to the Federal Contaminated Sites Action Plan (FCSAP) 2012 Ecological Risk Assessment document.
1	4.2.4 - Ecological TRVs	4.4.2	General comment - TRVs are point estimates and are not the only approach used for Effects Assessment in ecological risk assessments. Exposure-response modeling is preferred, and should be an option in cases where it is warranted.	Exposure-response modeling may be valued and accepted as a line of evidence. The ministry has established a position on toxicity reference values (TRVs) and hazard quotients (HQs). Please see the final posted Protocol 1 version 2 for the latest information.
1	4.2.5	4.5	Hazard Quotients section, 2. Carcinogen: indicates that ILCRs may be required to evaluate each sensitive life stage. This is inconsistent with P28 and standard derivation and will result in unacceptable risk at concentrations less than the standards.	The Contaminated Sites Regulation (CSR) generic numerical standards derived by the ministry as per Protocol 28 are reflective of the ministry's position on matters in 2015/2016 and the decisions made regarding setting provincially-applicable numerical CSR standards. There is no limitation on the usage of different protection levels at a contaminated site as better information becomes available. Specifically, Protocol 1 does not limit the derivation of the most appropriate risk based standards for a specific site. It is possible that best available science will result in risk based standards that are lower than generic numerical CSR standards. Although it is also possible that site-specific information can be used to derive risk-based standards higher than generic numerical CSR standards. Please note that Protocol 1 provides direction on conducting detailed risk assessment, while Protocol 28 describes how numerical standards were derived for the



				<p>CSR Schedules. It is possible that a site is better evaluated using life stages not considered in Protocol 28. The ministry's intent is not to restrict the use of life stages to those only in Protocol 28. It is up to a qualified professional to determine which life stages need to be evaluated in a risk assessment in order to adequately protect all humans using the site.</p>
1	4.2.5	4.5	<p>Under the heading "Hazard Quotients", immediately below Items 1. and 2. on page 22, it is stated:</p> <p>"Where a QP preparing a DRA considers that the information specified in 1 or 2 above is either inappropriate or unfeasible, the DRA must provide an explanation of why this is true and provide justification and analysis for whether risks are acceptable or unacceptable. A clear interpretation of all cumulative risk estimates must be provided and risk estimates must be categorized as acceptable or unacceptable."</p> <p>and it is further stated:</p> <p>"The following must be included in the risk characterization section of the detailed risk assessment report for ecological receptors:</p> <ol style="list-style-type: none"> <li>1. A calculation of HQs for each COPC based on cumulative exposures from all complete exposure pathways:</li> <li>2. Where best available science indicates a common target organ or mechanisms of toxicity is shared by multiple COPCs, a cumulative hazard index for all those COPCs and pathways."</li> </ol> <p>Contaminated Sites Regulation (CSR) Section 18(6) states:</p> <p>"(6) A person who applies the risk-based standards of this section must also prepare an environmental risk assessment report which identifies</p> <ol style="list-style-type: none"> <li>(a) the potential onsite and offsite environmental risks of any substances causing contamination before and after remediation, and</li> <li>(b) procedures, including monitoring, designed to mitigate any significant potential risks identified in paragraph (a)."</li> </ol>	<p>Thank you for your comment. Points 1 and 2 under "Risk Characterization" for ecological receptors have been rewritten for clarity as a result of other feedback received. If you continue to see an issue with the section, please provide feedback for consideration in a future revision.</p> <p>It should be noted that protocols have legal authority enabled by the <i>Environmental Management Act</i> and the <i>Contaminated Sites Regulation</i>, therefore it is implied that the levels of protection in Table 1 are considered to satisfy requirements set out by <i>Environmental Management Act</i> and <i>Contaminated Sites Regulation</i>. The director decides the acceptability of risk-based standards. The ministry's position on the acceptability of eco risk based standards is described in this version of Protocol 1.</p> <p>Your comments have been noted for future consideration.</p>

			<p>Contaminated Sites Regulation (CSR) 18(6) does not provide specific risk-based standards or acceptable risk levels, including acceptable hazard quotients. It therefore remains unclear how it is determined that risk-based standards have been met for ecological receptors. At the bottom of page 20, it is stated, "Ecological receptors must be protected according to the levels of protection (ECx) identified in Table 1 below. The detailed risk assessment report must include specific details of the selected ECx levels." Therefore, in the absence of specific ecological risk-based standards, the protection levels provided in Table 1 (on page 21) of draft Protocol 21 would appear to be the default/defacto risk-based standards, if and where ECx levels of effect can be determined/quantified. Items 1. and 2. in the middle of page 22 are specific to human receptors (in particular, Item 2. "Carcinogen") and may not (commonly will not) be applicable to ecological receptors below (or even at) the highest trophic levels. Therefore, in many cases it will not be possible to satisfy the requirement "A clear interpretation of all cumulative risk estimates must be provided and risk estimates must be categorized as acceptable or unacceptable" with respect to hazard quotients (or other effects) may not be appropriate or feasible. Providing "justification and analysis for why risks are acceptable or unacceptable" is likely to fall to professional judgement in many cases.</p> <p>Recommendation: It may be more effective to limit the requirement for Items 1. and 2. in the middle of page 22 to higher trophic level organisms (e.g., birds and mammals, or those organisms known to exhibit cancer or cancer-like effects from exposure to contaminants), rather than to broadly apply "A clear interpretation of all cumulative risk estimates..." to all ecological receptors and require justification when this is not done. Under the heading "Effects Concentrations" at the bottom of page 20, it would be helpful if wording to the effect of "these levels of protection will be considered by ENV to meet Contaminated Sites Regulation (CSR) requirements for demonstrating that ecological risks are acceptable", or similar was included.</p>	
--	--	--	---	--

1	4.2.5	4.5	First sub section is titled Hazard Quotients, but includes a discussion of HQs and ILCRs and ecological risks. Use of HQs in eco RA has limited value and should not be a requirement, but a consideration in an WoE approach and left to BPJ.	In the interest of regulatory consistency between applications, it is the ministry's expectation that hazard quotients (HQs) be included as one line of evidence for ecological receptors. Additional lines of evidence are typically valued and needed. If a hazard quotient cannot be calculated for ecological receptors, rationale should be provided. By releasing this revised Protocol 1, the ministry is indicating its position on the requirements for hazard quotients and numerical risk estimates.
1	4.2.5	4.5	First sub section is titled Hazard Quotients, but includes a discussion of HQs and ILCRs and ecological risks. Use of HQs in eco RA has limited value and should not be a requirement, but a consideration in an WoE approach.	In the interest of regulatory consistency between applications, it is the ministry's expectation that hazard quotients (HQs) be included as one line of evidence for ecological receptors. Additional lines of evidence are typically valued and needed. If a hazard quotient cannot be calculated for ecological receptors, rationale should be provided. By releasing this revised Protocol 1, the ministry is indicating its position on the requirements for hazard quotients and numerical risk estimates.
1	4.2.5	4.5	Section 4.2.5 only describes HQs, which are really a screening tool, at least for ecological risk assessment - particularly for weight of evidence where HQs are but one measure. The last paragraph in Section 4.2.5 and the second para in Section 5.2 appear to allow for more precise estimation of risks using alternative methods, but that should be made explicit. Particularly as more sites shift to risk assessment in the future seeking COCs, it will be important to have these better tools available for use by both QPs and ENV.	In the interest of regulatory consistency between applications, it is the ministry's expectation that hazard quotients (HQs) be included as one line of evidence for ecological receptors. Additional lines of evidence are typically valued and needed. If a hazard quotient cannot be calculated for ecological receptors, rationale should be provided. By releasing this revised Protocol 1, the ministry is indicating its position on the requirements for hazard

				quotients and numerical risk estimates.
1	4.2.5	4.5	<p>Page 22, where the text talks about DERA for ecological receptors - calculation of HQs in food chain modeling will, as noted, reflect all exposure pathways. However, the use of HQs for some lines of evidence will not be able to be "cumulative exposure" so revisions are needed (connected to comments above, where the protocol seems to suggest that HQs are the same as risk characterization (not). The text here (use of "must" reads more like guidance than a protocol because of the qualifier in final paragraph which says if inappropriate or infeasible, then...) - because this is going to be a protocol, it is very important that the details are worked out (or shift the concepts in this text to guidance and/or use "should" instead of "must").</p> <p>On page 22, the first para seems to suggest that ILCRs are going to be calc in ERAs... not the case? This would be a departure from standard practice and require new guidance (i.e., too soon for a protocol)</p>	Thank you for your comment. The sentence has been revised for clarity.
1	4.2.5	4.5	<p>para 1: Hazard quotients (HQs) do not provide information on the magnitude and severity of risk. They are over/under only, because exposure-response relationships are nonlinear. For this reason, the text that reads HQs "<i>are required to provide the magnitude and severity of risk to inform risk management and decision making</i>" is incorrect and perpetuates the myth that HQs represent risk.</p>	Thank you for your comment. The sentence has been revised for clarity. The ministry agrees that hazard quotients (HQs) are not proportional to risk without the consideration of the toxicity of the particular substance and the severity of the adversity of the effect. This ministry will consider further revisions in the future.
1	4.2.5 - Hazard Quotients	4.5	<p>This section only describes HQs, which are really a screening tool. HQs are an indicator of "over/under" only do not provide information on the magnitude and severity of risk, because exposure-response relationships are typically nonlinear. Not all risk assessments use HQs. In particular, effects assessment based on toxicity testing or WOE won't use HQs (although HQs could be one line of evidence).</p> <p>The last paragraph appears to allow for more precise estimation of risks using alternative methods, but that should be made more explicit, perhaps by removing "must" from the introductory sentence and adding clarity to this paragraph.</p>	In the interest of regulatory consistency between applications, it is the ministry's expectation that hazard quotients (HQs) be included as one line of evidence for ecological receptors. Additional lines of evidence are typically valued and needed. If a hazard quotient cannot be calculated for ecological receptors, rationale should be provided. By releasing this revised Protocol 1, the ministry is indicating its position on the requirements for hazard

				quotients and numerical risk estimates.
	4.2.6	4.6	Guidance states that the uncertainty in the risk assessment must be stated as a number or in prose explicitly, including implications of the identified uncertainties. Uncertainties for the exposure and effects assessment datasets (e.g., uncertainty in TRVs) and statistical analysis, and risk characterizations must be identified. This is true, but this is the entirety of the guidance for "uncertainty assessment" being provided. Need to restate that the complexity of the uncertainty analysis is commensurate with the complexity of the RA	Thank you for your comment. A statement has been added to the section on "Uncertainty Analysis." The ministry will consider further developing the requirements surrounding uncertainty analysis in future revisions.
1	4.2.6 - Uncertainty	4.6	Consider further discussion of uncertainty in the interpretation of eco risks. See Azimuth guidance on this.	The ministry has considered your comment and will consider the addition of further discussion on uncertainty in ecological risk assessment in future revisions.
1	4.2.7	4.7	The last sentence in Section 4.2.7 (middle of page 23) states "In addition to the requirement that a QP must conduct the risk assessment and reporting, any interpretation of biological data must be completed by a Registered Professional Biologist." The term "biological data" is vague and could be interpreted very strictly, resulting in a registered professional biologist being required for every risk assessment report submitted to ENV. There are currently 7 risk assessment approved professionals (out of 24) that ENV has appointed to the roster of approved professionals who are not RP Bios. Their work commonly involves some amount of interpretation of "biological data" depending on how that term may be defined. Most stay within their areas of expertise and experience. RP Bios are not uniquely qualified for all aspects of biological data involved in human health and ecological risk assessments. Section 2.4, Item 3 already states <i>"To be considered qualified, a person and/or the team conducting risk assessment must have demonstrable experience in these fields of science."</i> (i.e., toxicology, chemistry, ecology, statistics and modelling), and Appendix 1 requires a signed professional statement. <b>Recommendation:</b> Clarify what is intended or meant by "interpretation of biological data". Reconsider the requirement for a Registered Professional Biologist to complete interpretation of biological data.	The ministry agrees that the phrase "interpretation of biological data" is somewhat vague. The statement quoted in the public comment at left has been removed.

1	4.2.7	4.7	BC does not have the policy support for the first sentence here for ERA. Determination of acceptable and unacceptable is often professional judgement. The one document that has attempted to provide guidance (due to the gap) was prepared by CSAP - <a href="https://csapsociety.bc.ca/wp-content/uploads/Azimuth-RA-RM-Report-Final-version-May-submitted-to-CSAP-rev-August-2016.pdf">https://csapsociety.bc.ca/wp-content/uploads/Azimuth-RA-RM-Report-Final-version-May-submitted-to-CSAP-rev-August-2016.pdf</a> - entitled Risk Management Framework for BC Contaminated Sites - guiding principles for apply risk based std to ecological receptors.	Protocols have legal standing developed under the authority of the <i>Environmental Management Act</i> . Thank you for providing the reference to the Contaminated Sites Approved Professionals (CSAP) Risk Management Framework for BC Contaminated Sites. It will be considered for future revisions.
1	Appendix 1 Professional Statements	Appendix 1, Professional Statements	Does ENV wish these professional statements to be within the text of a Detailed Risk Assessment report? Or does ENV prefer they are separate signed pages in an Appendix?	Either method is acceptable. The ministry's preference is for signed pages in an appendix. Please note that forms provided in Protocol 1 include signature lines and should be used.
1	Entire Document	Entire Document	As an alternative to Protocol 1; has there been consideration in taking the existing Health Canada checklist for human health risk assessments and modifying it to meet requirements for provincial detailed human health risk assessments? - Adding such a checklist for detailed human health risk assessment requirements would serve as a compliment to Protocol 20 which outlines the requirements for detailed ecological risk assessments.	Thank you for your comment, this comment has been noted for future consideration.
1	Entire Document	Entire Document	It would be helpful if there was a Table of Contents.	Thank you for your comment. The ministry agrees that organizational changes would improve this document. Minor changes have been made at this time and further organizational changes are noted for future consideration.
1	Entire Document	Entire Document	Protocol 1 seems to take information from various BC ENV documents and risk assessment guidance that need to be referenced throughout the document. The risk assessment screening and TRV selection seems to be conflict in Technical Guidance 7.	Technical Bulletin 2 and Technical Guidance 7 components been moved into Protocol 1 and the new Guidance for risk assessment web page.

1	Entire Document	Entire Document	<p>Protocol 28 contains several sections in which "must" statements are made regarding requirements for risk assessment reports and deriving risk-based standards. These "must" statements seem better suited for inclusion in Protocol 1.</p> <p>Recommendation: Move the following statements from Protocol 28 to Protocol 1 and reword as necessary (e.g., to capture references to Protocol 28, Appendix 8):</p> <p>Section 2.6: "Selecting a TRV not found in the ministry approved appendix must have a technical rationale and be justified within a risk assessment report."</p> <p>Section 3.3: "Wildlife receptors must be considered in the development of risk-based standards where appropriate in detailed risk assessment at contaminated sites."</p> <p>Section 3.3: "Selecting a TRV not found in the ministry approved appendix must have a technical rationale and be justified within a risk assessment report."</p> <p>Section 5.2.1: "Note, a detailed risk assessment must calculate risk-based standards for the protection of aquatic life to be at least as protective or more protective than a 20% effect level (i.e., <math>\leq</math> EC20)."</p> <p>Section 5.2.3.2, Item d.: "In detailed risk assessment, risk-based drinking water standards must also follow this selection of the most stringent standard as a requirement."</p>	<p>Thank you for your comment. In reference to the sections you have highlighted from Protocol 28, the following changes have been made:</p> <p>2.6 - Statement has been removed in Protocol 28, and has been adapted for inclusion in Protocol 1.</p> <p>3.3 - Reference to wildlife receptors will remain in Protocol 28 and will be further adapted for inclusion in Protocol 1.</p> <p>3.3 - Statement has been removed from Protocol 28. Protocol 1 now refers to the appendices of Protocol 28 for the development of de novo toxicity reference values (TRVs) for ecological receptors.</p> <p>5.2.1 - Statement has been removed from Protocol 28 and incorporated into Protocol 1.</p> <p>5.2.3.2 - Statement has been removed from Protocol 28 and incorporated into Protocol 1.</p>
1	Entire Document	Entire Document	<p>Reference is made in multiple locations to "Federal Contaminated Sites Action Plan (FCSAP) "Ecological Risk Assessment Guidance (2012)". Reference should be updated to the new 2020 document, or a comment made that practitioners need to be incorporating the most recent federal guidance (to the extent that it is relevant) as it becomes available.</p>	<p>The ministry will consider reviewing the 2020 Canadian Council of Ministers of the Environment (CCME) Ecological Risk Assessment document. This link has been corrected to refer to the Federal Contaminated Sites Action Plan (FCSAP) 2012 Ecological Risk Assessment document.</p>
1	Entire Document	Entire Document	<p>thank you for updating this protocol</p>	<p>Thank you for your comment.</p>
1	Entire Document	Entire Document	<p>The document could benefit from re-organization and thorough edit. It lacks flow in sections, and is difficult to follow. Further section headings should be added to avoid multiple sections with no headings. Acronyms</p>	<p>Thank you for your comment. The ministry agrees that organizational changes would improve this document. Minor changes have been made at this time and further organizational</p>

			should be defined on first use and used consistently throughout.	changes are noted for future consideration.
1	Entire Document	Entire Document	The document has an ambitious goal of covering key aspects of human and ecological risk assessment, in a short protocol so we would like to acknowledge the authors for their work. The document is uneven in places and would benefit from input from a technical editor to help flow and organization. For example, there are many headings (some with same wording) and it would help readers if the hierarchy of headings and content was clearer.	Thank you for your comment. The ministry agrees that organizational changes would improve this document. Minor changes have been made at this time and further organizational changes are noted for future consideration.
1	Entire Document	Entire Document	The revisions to Protocol 1 appear to be substantial, and likely need to be reviewed in conjunction with Protocol 20 to be fully understood. From our initial review of P1 it is unclear what revisions have been made from existing P1 and why, and we believe that professional risk assessors will be in a better position to provide substantive P1 comments. Overall, we hope that RA professionals have been able to complete a substantive review and submission for all 10 revised Protocols to BC MOECCS, which is a concern given that the time between consultation comments due (Jan 11/21) and promulgation (Feb 1/21) is so brief, and that the 45 day consultation window included the seasonal holiday vacation period.	Thank you for your comment.
1	Entire Document	Entire Document	There is much overlap with what has been included in Draft Protocol 1 and other ENV risk assessment documents, particularly Technical Guidance 7 and Technical Bulletin 2. For example, Sections 6.1 and 6.2, and Appendix 1 appear very similar to Technical Bulletin 2. Is it ENV's intent to retire TG 7 and/or TB2 once Protocol 1 is officially issued?	Technical Bulletin 2 and Technical Guidance 7 components been moved into Protocol 1 and the new Guidance for risk assessment web page.
1	Entire Document	Entire Document	There is much overlap with what has been included in Draft Protocol 1 and other ENV risk assessment documents, particularly Technical Guidance 7 and Technical Bulletin 2. For example, Sections 6.1 and 6.2, and Appendix 1 appear very similar to Technical Bulletin 2. Is it ENV's intent to retire TG 7 and/or TB2 once Protocol 1 is officially issued?	Technical Bulletin 2 and Technical Guidance 7 components been moved into Protocol 1 and the new Guidance for risk assessment web page.



## Appendix 2. Protocol 4: Establishing Local Background Concentrations in Soil.

Proto col #	Section #	Comment/Recommendation	Ministry Response
4	General	In Metro Vancouver, soil in the near shore areas often contains elevated Cl <sup>-</sup> concentration due to seawater or estuarine water intrusion. Currently, the chloride soil standard for the protection of drinking water is 100 µg/g and is applicable to all types of land uses including agricultural (AL), urban park (PL), residential (RL), commercial (CL) and industrial (IL) land uses. Based on the Metro Vancouver experience, chloride concentration in the near shore areas could be easily above the criteria for groundwater used for drinking water (100 µg/g) but may be less than the remaining standards. In near shore areas, because of the seawater and estuarine water intrusion, groundwater use for drinking water purpose is unlikely applicable. It would be beneficial if the Ministry would consider the range of chloride concentrations encountered in soil in the near shore areas and establish a pertinent chloride background concentration.	This request is currently outside of the scope of revisions to the protocol. However, the comment will be brought forward for future consideration
4	1.0	Like other protocols being updated, why aren't definitions provided within?	Terms defined in the <i>Environmental Management Act</i> (EMA) and the Contaminated Sites Regulations (CSR) do not require definition in a protocol. Terms not found there will be defined within the protocol.
4	1.0	"environmental management area" is not defined in Procedure 8.	"Environmental management area" is defined in the CSR, and therefore does not require definition in the protocol.
4	1.0	"local background concentration in soil" - refers to anthropogenic non-point sources in Procedure 8.	Procedure 8 "Definitions and Acronyms for Contaminated Sites" is being retired shortly. The term has been revised to the more generic "local background concentration" and will be incorporated into the protocol. It should be noted that a protocol has legal authority CSR so ensure the latest, in-force protocol definition is followed.
4	3.1	This section had added a section which "This protocol is also used to determine the local background concentration for use in the application of risk-based standards for remediation under Sections 18 and 18.1". Moving through the document it is clear that Regional Backgrounds cannot be used for the 0 to 1 m soil horizon (same as the old P4). As the samples used to create this database were collected in the 0 to 1 m range, it seems like it <b>should</b> be applicable to surface soils not impacted by anthropogenic sources.	Thank you for this comment, the ministry will clarify this language in the protocol. It is not the intent of the protocol to restrict sampling to only depths greater than 1 m. Note, the background concentrations estimate must match the depth and geological unit of contamination. It would be inappropriate to develop a

			local background concentration for a completely different geological unit than the unit the contamination occurred in.
4	3.1	If an elevated concentration of a substance is known to be tied to an anthropogenic source (whether it be a Schedule 2 source or a non-Schedule 2 source), can the substance be remediated to regional (or local) background concentrations or is the substance required to be remediated to applicable soil standards for the site. The statement in Section 1.0 appears to state that in cases that an anthropogenic source is established, specific local background concentrations would no be considered. However, 3.1 appears to state that a site remediated to local background concentrations <b>WOULD</b> be satisfactory	Section 3.1 of Protocol 4 "Establishing Local Background Concentrations in Soil" is clear in this respect and the legal application of background concentrations is found in the CSR, sections 11 and 17 in particular.
4	3.2	Reference to TG-17 for Background Soil Quality Database removed. Will TG-17 be retired and how will this database be accessed?	Technical Guidance 17 "Background Soil Quality Database" was migrated to a ministry web page.
4	3.2	It states that soil from a source site that exceeds a numerical standard for the receiving site but is below the local background concentration, is acceptable for deposit at the receiving site. In our experience, there is some uncertainty with respect to moving soil between the regions listed in Table 1. An example of this would be transporting soil from Region 2 containing selenium at 2 mg/kg (> CSR standard but < Region 2 P4) to a receiving site in Region 3, where the background concentration is also 4 mg/kg. In our opinion, requiring a CSRA in a scenario like this would not be in the spirit of the soil relocation regulations and would more likely result in unnecessary landfilling of clean material.	The ministry is in agreement that moving soil between regions where the regional background concentration is met in the region of the receiving site, likely will not require a Contaminated Soil Relocation Agreement, per CSR section 46.1. For site specific situations, please submit an enquiry via the ministry's Contact Us webpage.
4	4.0	Former first sentence "Substances originating from natural conditions or <b>anthropogenic non-point source contamination</b> .." is removed. Is the expectation then for the property owner to remediate to numerical, regional background or risk-assessment standards for areas like Trail and Castlegar? What if the site doesn't have local background values (Trail and Castlegar)?	In Castlegar and Trail, this protocol may not be used to develop local background concentrations for substances. The protocol is clear about the ineligibility of anthropogenic sources of contamination. Please submit an enquiry via the ministry's Contact Us webpage for any questions about a specific contaminated site.
4	4.1	Background Concentrations in Soil Database - will this still be available in TG17? TG17 was redlined/removed. If not, where will the database be accessible?	Technical Guidance 17 "Background Soil Quality Database" was migrated to a ministry web page.
4	4.1	Background Concentrations in Soil Database. Similar to the comment above for 3.2, the reference to TG17 was removed. Will this data still be available in TG17? If not in TG17, where will it be accessible?	Technical Guidance 17 "Background Soil Quality Database" was migrated to a ministry web page.

4	4.1	Can a link to the Background Concentrations in Soil Database be added into the document?	Technical Guidance 17 "Background Soil Quality Database" was migrated to a ministry web page.
4	4.1	last sentence -" For substances or regions not listed in Table 1" - aren't all regions listed in Table 1? What regions are missing? Should this refer to "locales" not listed in the database instead?	Thank you for this comment, the ministry will clarify this language in the protocol.
4	4.1	<p>The requirement to use median value for determination of baseline concentration of inorganic substances is inconsistent with the intent of the regulation (to exempt requirement for remediation of naturally occurring substances). Based on ENV's description of regional data set, the data set is already biased low by avoidance or exclusion of naturally mineralized areas. Using median value, or even 95th percentile value of the data set, results in a high proportion of samples having naturally occurring concentrations of substances exceeding the determined "background" concentration (approximately 50 % for median value and 5 % for 95 percentile). The exceedances then require delineation, remediation, risk assessment, or other means (TG2, Protocol 2...). To be consistent with the intent of the regulation, the maximum value of a data set defined as representing naturally occurring concentrations, plus uncertainty in quantification of that value, should be the minimum value to define as "background", and considering the limited data set, some proportion higher than that (e.g., a standard deviation on the mean greater than the maximum) would be more consistent with the intent of the regulation.</p> <p>Even the use of the term "background" is not appropriate for the intent of the regulation for inorganic substances as it is subjective and requires definition that is likely not inclusive of the full range of naturally occurring concentrations. The fact is that the planet is made of inorganic substances and natural processes result in a high degree of variability in concentrations spatially. A landowner should not be responsible for defining the extent and remediating substances that are naturally occurring.</p> <p>The guidelines for sample depth are not appropriate for most situations. Sample depth should be consistent with the range of sample depths for the site being investigated and representative of the range of geological units and conditions on the site.</p>	<p>The CSR indicates the legal application of local background concentrations with respect to being contaminated or being a contaminated site (CSR section 11) and remediation (CSR section 17), and Protocol 4 indicates the requirements (including methods and statistics) for calculating a background concentration.</p> <p>The background concentrations estimate must match the depth and geological unit of contamination. It would be inappropriate to develop a local background concentration for a completely different geological unit than the unit the contamination occurred in.</p>

4	4.1	Why is there an apparent restriction on using background estimates for surface to 1m depths i.e. they can only be used for depths greater than 1m? Suggest this restriction be taken out.	Thank you for this comment, the ministry will clarify this language in the protocol. It is not the intent of the protocol to restrict sampling to only depths greater than 1 m. Note, the background concentrations estimate must match the depth and geological unit of contamination. It would be inappropriate to develop a local background concentration for a completely different geological unit than the unit the contamination occurred in.
4	4.2.1	Specifies how to calculate a site specific local background in soils but it does not specify if this applies to only soils below 1 m or can be also used for soils in the 0 to 1 m horizon. The assumption is that it is applicable in the 0 to 1 m range and could be stated.	Thank you for this comment, the ministry will clarify this language in the protocol. It is not the intent of the protocol to restrict sampling to only depths greater than 1 m. Note, the background concentrations estimate must match the depth and geological unit of contamination. It would be inappropriate to develop a local background concentration for a completely different geological unit than the unit the contamination occurred in.
4	4.2.2	Footnote regarding hydrology is not included. Is this still a requirement?	This reference is retained in section 4.2.2
4	4.2.2	In Option 2a - geographical characteristics - Suggest that this gets re-worded to state that the single key characteristic is that you are assessing the same geological UNIT. Topography shouldn't matter either as the same geological UNIT may be near surface at one site but at depth at another site not too far away. Another consideration is why would size/area of the reference site matter if it was part of the same geological UNIT? Same comment for soil sampling depth - if it is the same geological UNIT then depth shouldn't be a significant factor.	These expectations are listed in Option 2b. The ministry is in agreement - the background concentrations estimate must match the depth and geological unit of contamination. It would be inappropriate to develop a local background concentration for a completely different geological unit than the unit the contamination occurred in.
4	4.2.2	Section (e) of minimum information needed for reference site speaks to potential contaminant sources (both natural and anthropogenic). What exactly is a 'natural' contaminant source? Isn't that essentially background?	Thank you for your comment, this has been changed in the protocol to include "areas with natural mineralization".
4	4.2.2	Option 2b - second set of bullets e) - refers to potential contaminant sources as being "natural" - what is an example of a natural contaminant source (mineral showings)? Confusing. Should "contaminant" be removed so it reads "natural source"?	Thank you for your comment, this has been changed in the protocol to include "areas with natural mineralization".

4	4.2.2	Option 2b - second set of bullets e) - refers to potential "natural" contaminant source. An example of a "natural" contaminant source should be provided or "contaminant" should be removed and indicated as "natural source" instead.	Thank you for your comment, this has been changed in the protocol to include "areas with natural mineralization".
4	4.2.2	There is a section that says " <b><i>Soil samples should be chemically analyzed for all potential contaminants of concern relevant to the site of interest</i></b> ". It is assumed that this is relevant to samples collected from the reference site which are collected for background purposes. As it must be previously determined that there are no other PCOCs at the reference site as a matter of course, then why would one have to analyze reference site samples for 'all PCOCs' that are pertinent at the site of interest. Recommend that this sentence be removed or significantly revised.	It is relevant to analyze for potential contaminants at a site as the presence of the contaminants may impact soil chemistry leading to concentrated levels of substances in soil. Soil samples used to establish background concentrations should not be impacted by anthropogenic contaminant sources, which must be demonstrated, not inferred or assumed.
4	4.2.2	Option 2b - "The reference site must closely match (i.e., be substantively similar to) the <b>contaminated</b> site in question with respect to: suggest removing "contaminated" as the site may not be contaminated if below background concentrations.	Thank you for your comment, this change has been made.
4	4.2.2	Option 2b - first set of bullets b) and c) - wouldn't it be clearer to indicate similar geomorphology / depositional environment than "soil physical characteristics"? How is hydrology defined here: surface water AND groundwater?	The ministry will retain the wording in point b) and add hydrogeology to point c).
4	4.2.2	"Soil samples should be chemically analyzed for <b>all potential</b> contaminants of concern relevant to the site of interest." What is the rationale for this? I can see where it would be relevant for a background groundwater assessment but not for a background soil assessment. If it is a metals assessment, then testing should just be for the metal of concern in background. If organics, then why not just contaminants of concern instead of all potential COC at the very most?	It is relevant to analyze for potential contaminants at a site as the presence of the contaminants may impact soil chemistry leading to concentrated levels of metals in soil. Soil samples used to establish background concentrations should not be impacted by anthropogenic contaminant sources, which must be demonstrated, not inferred or assumed.
4	4.2.2	"Soil samples should be chemically analyzed for all potential contaminants of concern relevant to the site of interest." CSAP understands the rationale for this approach in groundwater, but does not think this rationale is applicable to soil. For metals assessment, this should only be for metals of concern in background. If it is an assessment for organics, testing should only be for organic contaminants of concern at the very most.	It is relevant to analyze for potential contaminants at a site as the presence of the contaminants may impact soil chemistry leading to concentrated levels of metals in soil. Soil samples used to establish background concentrations should not be impacted by anthropogenic contaminant sources, which must be

			demonstrated, not inferred or assumed.
4	4.2.2	There is no instruction in P4 on how to calculate the local background concentrations using either Option 2a or 2b. It is assumed that it should be the 95th percentile of the data? Also, please clarify how duplicate/replicate data should be incorporated in the data (e.g., use the average of a parent sample and the duplicate?).	Thank you for advising, the protocol has been revised to include this information. It is the responsibility of the submitting professional to employ best professional judgement demonstrate that the data set and subsequent analysis is adequate.
4	4.2.2	Option 2b refers to a site's "hydrology". Generally hydrology is a branch of engineering that deals with the physical properties of surface freshwater, such as lakes and rivers, and with its chemical interactions with other substances. Hydrogeology is a subfield of geology (study of Earth) that, by definition, specifically addresses groundwater. Please confirm this only refers to surface water and does NOT include hydrogeology or specifically define what information is required (comparison of depositional environments etc.)	The ministry has added hydrogeology to point c).
4	4.2.2	"Ideally, soil samples taken from the reference site and the site of interest should be subjected to identical analyses (should this state as identical analytical methods?), using whenever possible the same analytical laboratory".	The ministry agrees and this change has been made.
4	4.2.3	bullet k) - Technical Guidance 12. It would be very helpful to include explicit direction on minimum number of samples, and a minimum standard of evaluation (i.e. median or 95th percentile) as TG12 does not provide direction on this.	Thank you for advising, the protocol has been revised to include this information. It is the responsibility of the submitting professional to employ best professional judgement demonstrate that the data set and subsequent analysis is adequate.
4	4.2.3	Point m) formal written request is not included. Please confirm this requirement has been removed.	Correct, point m) has been removed and is no longer a requirement.
4	4.3	last paragraph - does "the ministry does not recommend" mean a P4 application will be automatically rejected for an EM area? A P4 assessment on an EM area will be more robust than the methodology used to derive the regional background estimate. This shouldn't be restricted from use for EM areas.	If an applicant would like the ministry to consider establishing site-specific local background numbers in an Environmental Management (EM) area, it is recommended they submit a request to meet with the ministry to discuss first.
4	4.3	This section should be removed. While it is understood that some EM area sites do indeed cover large geographical areas, by no means do all potential EM area sites cover vast areas such as Trail. If you are chasing a suspected background substance that is not a COC associated with the EM area designation - then	Section 4.3 does not prohibit the application of site-specific background numbers in EM areas. Therefore, it is recommended the applicant submit a request to

		one should be able to proceed under the normal background process.	meet with the ministry to discuss first.
4	5	ENV has removed the approvals workbook for P4, P6 and P9 applications. Will there be a database of approved background soil concentrations for public access or will that be through the site registry? Will individual sites will need to accessed through the registry to determine if a background approval has been granted?	The ministry is considering how best to provide this information. Currently, an email request to the ministry regarding Protocol 4 approvals for an area can be used to access this information. Please see the ministry's Contact Us webpage.
4	5	Will there be a database of approved background soil concentrations for public access or will that be through the site registry? Individual sites will need to accessed through the registry to determine if a background approval has been granted?	The ministry is considering how best to provide this information. Currently, an email request to the ministry regarding Protocol 4 approvals for an area can be used to access this information. Please see the ministry's Contact Us webpage.
4	Figure 1	Contaminated fill deposit will soon be considered a Schedule 2 use. Previous feedback from ENV indicated that P4 concentrations are applicable when assessing whether fill soil is contaminated, which we agree with. However, when reviewing Figure 1, we foresee an issue with not being able to apply protocol 4 criteria for fill material. For example, following figure 1 for a site with selenium at 2 mg/kg (> CSR standard but < P4): o <b>Does the concentration of a substance in soil at the site exceed the applicable numerical standard in the CSR?</b> Yes o <b>Is the substance related to the Schedule 2 activities on the site?</b> It's not clear how to answer this question for a fill scenario in light of the amended Schedule 2.	The ministry believes this is in relation to the new CSR Schedule 2, H6 item. To clarify, the intent of Protocol 4 is for samples from native material to be included in a background application, not samples from fill. This does not exclude sites which have received fill from pursuing a background application. The ministry may consider this issue in future protocol revisions. Please note, Figure 1 was moved from the protocol to a web page. On a site-specific basis the ministry recommends submitting an enquiry through the Contact Us page.
4	Figure 1	Figure 1 and Protocol should be revised to allow for substances related to Schedule 2 activity to be allowed to be included for a Protocol 4 background determination.	Please note, Figure 1 was moved from the protocol to a web page, therefore the protocol itself should be relied upon for determining if Protocol 4 is an option at a subject site. It is possible that a background determination could be obtained if the substance is related to a Schedule 2 activity, if there is sufficient technical rationale in support. For site-specific scenarios, please submit an



			enquiry through the Contact Us webpage for assistance.
4	Figure 1	BOX - " Is the substance related to the Schedule 2 activities on the site?" - If a site is located in a region with elevated background concentrations then a background assessment should be allowed. CSR Sec. 11 (3) states that a site isn't contaminated if concentrations exceed standards but are not greater than local background. So even if a substance is related to a Sched. 2 activity, it shouldn't disqualify it from a background assessment. Background concentrations can overlap with the low end of anthropogenic concentrations but that should not disqualify use of a background assessment.	Please note, Figure 1 was moved from the protocol to a web page, therefore the protocol itself should be relied upon for determining if Protocol 4 is an option at a subject site. It is possible that a background determination could be obtained if the substance is related to a Schedule 2 activity, if there is sufficient technical rationale in support. For site-specific scenarios, please submit an enquiry through the Contact Us webpage for assistance.
4	Figure 1	BOX to the right of - " Is the substance related to the Schedule 2 activities on the site?" - If a site is located in a region with elevated background concentrations then a background assessment should be allowed. CSR Sec. 11 (3) states that a site isn't contaminated if concentrations exceed standards but are not greater than local background. So even if a substance is related to a Sched. 2 activity, it shouldn't disqualify it from a background assessment.	The body of the protocol should be relied upon for determining if P4 is an option at a subject site; Figure 1 is provided as a simplified flowchart for assistance. It is possible that a background determination could be obtained if the substance is related to a Schedule 2 activity, if there is sufficient technical rationale in support. For site-specific scenarios, please submit an enquiry through the Contact Us webpage for assistance.
4	Figure 1	If an elevated concentration of a substance is not related to a specific schedule 2 activity, can local background concentrations in soil be used? (contamination from small scale dumping, buried debris, improper fill, etc.)	The intent of Protocol 4 is to determine natural background concentrations at a site. Samples from native material would be included in a background application, and not samples from fill or debris. This does not exclude sites, which have received imported materials, from pursuing a background application. On a site-specific basis the ministry recommends submitting an enquiry through the Contact Us page.

## Appendix 3. Protocol 6: Applications with Approved Professional Recommendations and Preapprovals.

Proto col #	Section #	Comment/Recommendation	Ministry Response
6	1.0	A general reference to Procedure 8 in this section would be helpful for readers who are not intimately familiar with the full list of Protocols, Procedures and Guidance Documents.	Procedure 8 will be phased out as each protocol must have its own definitions. It should be noted that a protocol has legal authority enabled by the <i>Environmental Management Act</i> and the Contaminated Sites Regulation so ensure the latest, in-force protocol definitions are followed. In addition, the ministry is updating its website to include indications of topics in each protocol and guidance document.
6	1.0	Definition of "affected parcel" and "source site" not identical to Procedure 8, but not substantially different. In these definitions, "parcel" and "site" are seemingly interchangeable; however, they may have different legal implications. These could be harmonized.	Procedure 8 will be phased out shortly and all definitions will reside in relevant Protocols. It should be noted that a protocol has legal authority enabled by the <i>Environmental Management Act</i> and the Contaminated Sites Regulation so ensure the latest, in-force protocol definitions are followed.
6	1.0	Suggest including a sentence to state the requirement that the Approved Professional is an active member and in good standing with the CSAP Society for both Numerical Standards and Risk Based APs.	The ministry has finalized the definitions in Protocol 6. The suggested changes were not adopted at this time and may be considered in the future.
6	1.0	Suggest making the sentence for Pre-approvals generic - so that the process can be used for other requirements and not limited to Determination, Approval in Principle and Certificate of Compliance according to Section 3.2.	Preapprovals are designed in particular to support the professional reliance model for non high risk sites. Direct to ministry submissions do not require preapprovals under Protocol 6 (although they may require other protocol decisions, such as local background concentrations). However, Approved Professionals can provide other recommendations that support requirements as indicated in section 3.2.2.
6	1.0	Definition of Numeric Standards and Risk-based Standards Approved Professional seems unnecessarily detailed and could potentially become inconsistent with CSAP membership requirements (i.e., if those requirements change in future) Why not just state that these are APs as appointed to the Roster by the Director and holding appropriate class of membership in CSAP Society unless there is some intent in future to	The ministry has determined these to be the definitions best suited for the purpose of providing clarity.

		designate APs who are not described by one or both of these characteristics?	
6	1.0	Definition of "affected parcel" and "source site" not identical to Procedure 8, but not substantially different. These could be harmonized.	Procedure 8 will be phased out shortly and all definitions will reside in relevant Protocols. It should be noted that a protocol has legal authority enabled by the <i>Environmental Management Act</i> and the Contaminated Sites Regulation so ensure the latest, in-force protocol definitions are followed.
6	2	This includes a footnote that states the director may consider the recommendation of an AP for an AiP or CoC for a high-risk site if a preapproval has been obtained. It would be good if Section 4.0 also referenced the option for obtaining a preapproval for a high risk (or risk-managed high risk) site.	This is addressed on the ministry Preapprovals webpage associated with Protocol 6.
6	3.1.1	Table 1 (along with other changes to the document) now excludes AP review and recommendation of Contaminated Soil Relocation Agreements to coincide with upcoming regulatory changes in relation to soil relocation. However, it should be noted that in the new notification process, soil relocation forms may still need to be signed off by an AP or a "qualified professional".	This will be addressed during the implementation phase of the proposed regulatory amendment to support soil relocation and thus does not need to be addressed in Protocol 6 to support the Stage 13 CSR amendment.
6	3.1.1	Table 1 (along with other changes to the document) now excludes AP review of Contaminated Soil Relocation Agreements to coincide with new soil relocation rules.	Concur, although it is the currently in-force soil relocation provisions in the <i>Environmental Management Act</i> and the Contaminated Sites Regulation.
6	3.1.1 Table 1	Suggest removing "High Risk" type for Determination. This is causing confusion. If a Determination is being obtained for a Site to be not contaminated; then it certainly cannot be a high-risk Site.	It is possible for Determinations to indicate a site <i>is</i> contaminated, and in this scenario it is possible for a high risk site classification to apply.
6	3.1.2	<p>Sentence at end of section 3.1.2 "<i>Note that an Approval in Principle is typically required for scenarios involving remediation in stages.</i>" Seems out of place here - not relevant to the section heading. I assume it relates to comments made by ENV regarding seeking Site ID release under Scenario 3, 4 and 5 but this context is not provided. ( e.g., what constitutes "remediation in stages"? will an AiP be always required for multi-phase developments or will further guidance be provided indicating circumstances when an AiP is not required? Will IR vs AiP still be at the discretion of the applicant if Site ID Release request is not being sought?).</p> <p>As an aside, it is likely that in many cases information necessary to obtain an AiP will not be available early enough in the development process to coincide with</p>	This section is not for release notices relating to site identification. The context is that if an applicant is requesting one or more legal instruments (e.g. Certificates of Compliance, Determinations) for only a part of a site, an Approval in Principle will typically be required for the part(s) still under remediation. This scenario is considered a site undergoing remediation in stages. Protocol 6 reflects the ministry's position on remediation in stages and the use of Approval in Principle instruments.

		the need for permits unless environmental investigation and remediation planning is heavily front loaded. This will be impractical or not cost effective in many cases. This could be addressed by allowing flexibility in the requirements for AiPs in such cases (e.g., adaptive management approach), or maintaining a bridge through AG 5 to allow permits to be granted and work to proceed in coordination with environmental investigation and remedial planning to a level that an AiP can be obtained.	
6	3.1.2	<p>Sentence at end of section 3.1.2 "Note that an Approval in Principle is typically required for scenarios involving remediation in stages." Seems out of place here - not relevant to the section heading. I assume it relates to comments made by ENV regarding seeking Site ID release under Scenario 4 and 5 but this context is not provided. ( e.g., what constitutes "remediation in stages", will IR vs AiP still be at the discretion of the applicant if Site ID Release request is not being sought?).</p> <p>Later in section 4.1.2 there is another statement about Site ID release requests that also seems out of place (as noted below). It would be more clear to carve out a separate section that addresses P6 approvals in the context of Site ID Release requests or to better integrate Site ID Release requests into the existing sections (i.e., the same rules apply to Site ID Release requests as to CofC, AiP and Determination applications).</p>	<p>This section is not for releases notices relating to site identification. The context is that if an applicant is requesting one or more legal instruments (e.g. Certificates of Compliance, Determinations) for only a part of a site, an Approval in Principle will typically be required for the part(s) still under remediation. This scenario is considered a site undergoing remediation in stages. Protocol 6 reflects the ministry's position on remediation in stages and the use of Approval in Principle instruments.</p> <p>The sentence at the end of section 3.1.2 has been moved to section 4 and section 4 has been revised.</p>
6	3.1.2	"Note that an Approval in Principle is typically required for scenarios involving remediation in Stages" suggest adding a phrase and "exceeding 5 years".	<p>This is not intended to be for scenarios only exceeding 5 years. This will apply to every site being remediated in stages. Protocol 6 reflects the ministry's position on remediation in stages and the use of Approval in Principle instruments.</p>
6	3.1.2	It states "Note that an Approval in Principle is typically required for scenarios involving remediation in stages.". As this is a Protocol, this wording makes it unclear if this is a requirement and what would qualify as "stages".	<p>If an applicant is requesting one or more legal instruments (e.g. Certificates of Compliance, Determinations) for only a part of a site, an Approval in Principle will typically be required for the part(s) still under remediation. This scenario is considered a site undergoing remediation in stages. Protocol 6 reflects the ministry's position on remediation in stages and the use of Approval in Principle instruments.</p>

6	3.1.3	For the sentence, ".....must submit the Final Determination draft documents to CSAP....", suggest adding Society to CSAP i.e. CSAP Society.	The ministry has made this change.
6	3.1.3	30 days may not be adequate for all the Q&As and completion of review by the Approved Professional. Suggest increasing it to 45 days.	This section requires only that the Final Determination documents be received by the CSAP Society no later than 60 days after the date that the Preliminary Determination is issued. The section does not alter the CSR 15 (3) comment period, nor does it limit the comment period to 30 days as the CSR says it must be a <i>minimum of 30 days</i> . Section 3.1.3 of Protocol 6 stipulates only that the application for the Final Determination must be provided to CSAP within 60 days, which means that comments received up to the point that the application for the Final Determination documents are submitted may be considered (i.e. comments may be received between 30 and 60 days following issuance of the Preliminary Determination) but the draft documents must be sent within 60 days of issuance of the Preliminary Determination.
6	3.1.3	Introduces new 60 day sunset clause for Preliminary Determinations. Longer delays will require reapplication for Preliminary Determination presumably resetting the comment period shot-clock and incurring duplicate fees (CSAP and ENV). Presumably this is to address an administrative issue that has arisen in the past. However, there should be allowances for special circumstances associated with comments received. I suggest adding the following exception. "The ministry may grant exceptions in cases where the applicant demonstrates that additional time is needed solely for the purposes of addressing feedback received during the comment period."	<p>The ministry has considered this comment but will not be including an exception clause.</p> <p>The ministry has determined that 60 days from the date of issuance of the Preliminary Determination should be more than sufficient to submit documentation for the Final Determination to CSAP. The APs must make the submission of the Final Determination documents on this timeline, even if the director receives comments, but it is recognized that after the director receives the Final Determination documents, there may be a round of edits based on the comments that the director received.</p>

6	3.1.4	This provision indicates that an owner of an affected parcel (i.e., flow-through site) is only responsible for delineation/remediation of the off site sourced contamination within their own property boundary and that an instrument application for a part site can be made but it states that a preapproval is required. It is not clear if the preapproval is required to define the entire offsite property as a part of the overall contaminated area or if this refers to defining a part site within the affected parcel.	If you are an owner of a flow-through site, you are responsible for contamination within your own property boundary. Non high risk sites going through the professional reliance model via CSAP must apply to the ministry under Protocol 6 to be a flow-through site. The ministry will review such applications in full and the applicant will be charged fees for the review time as per Table 3 of Schedule 3 of the CSR.
6	3.1.4	This provision appears to require that flow through sites obtain a preapproval, even though they are not the responsible party and is a potentially significant change. It is somewhat unclear in the wording as the use of the term "part of a site" is unclear and not sure if this is part of the affected parcel or is the overall "site" as defined by AG15. Clarification on this is requested. If the intent is to require a preapproval for all flow through sites there could be an exemption where sites that have been supplied with Notification of Offsite Migration (NoM) from the source site are excluded from obtaining a preapproval.	The revised Protocol 6 does require that flow through sites obtain a preapproval if they intend to remediate their own site. Non high risk sites going through the professional reliance model via CSAP must apply to the ministry under Protocol 6 to be a flow-through site. The ministry will review such applications in full and the applicant will be charged fees for the review time as per Table 3 of Schedule 3 of the CSR.
6	3.1.4	This section states "a person who is not a responsible person for contamination present at an affected parcel need only to have satisfactorily delineated and (if applicable) remediated the entire area of contamination at the affected parcel and may apply for an instrument for a part of a site. In these circumstances, a preapproval for part of a site is required as described in Sections 4.0 and 5.0 of this protocol". Based on this description, it appears that BC ENV is now requiring pre-approval for CofC applications for "flow-through" sites, which were previously exempt from this process under AG 15.	Yes, with the revised Protocol 6, the ministry now requires preapprovals under Protocol 6. Draft Administrative Guidance 15 has been eliminated and the ministry's final position is in the revised Protocol 6.  Non high risk sites going through the professional reliance model via CSAP must apply to the ministry under Protocol 6 to be a flow-through site. The ministry will review such applications in full and the applicant will be charged fees for the review time as per Table 3 of Schedule 3 of the CSR.
6	3.1.4 and 4.0	It is unclear under what scenarios would a preapproval be required to obtain a Certificate of Compliance for part of a contaminated site. E.g., would a preapproval be required to obtain a CofC for migrating substances from a source Site (Site A) to an off Site impacted parcel (Site B) if other parts of Site B are contaminated by a source unrelated to Site A? Or for a large commercial property with numerous tenants and schedule 2 uses, would a preapproval be required to	Yes, all of the scenarios described require a preapproval under Protocol 6.

		obtain a CofC for an individual tenant / business operating on a larger commercial property?	
6	3.2.2	Suggest adding "Site Profile Decisions and Requesting Releases Where Local Government Approvals are Required" to the list.	The Approved Professional recommendations required for release notices are already captured in the existing list in section 3.2.2 (bullet 7 in the proposed revised version, starting with "The ability of a parcel ...").
6	3.2.2	We note the elimination of the words "building permit" in the draft P6, which are in the existing P6 section 5.2. The new Section 3.2.2. includes the list of events <i>before remediation</i> for which Approved Professionals may provide recommendations, reports, and opinions to the (BC MOECCS) Director. We are concerned that the narrowing of the list of events to exclude building permits is another example of the high cost of doing business in BC compared to other Canadian jurisdictions. In particular we are concerned about ongoing operations (i.e. operating service stations) that need building permits to undertake site renovations and environmental improvements.	Building permits will now be a trigger for submitting a site disclosure statement. As such, they will no longer be used as an endpoint for remediation for the purposes of a release notice. For questions about this, please contact <a href="mailto:sitelD@gov.bc.ca">sitelD@gov.bc.ca</a> (case specific email address).
6	3.3	For submissions determined to be incomplete applications it is indicated that " <i>Applications which are not complete may be rejected or returned to the applicant</i> ". This provision is different from the current procedure that ENV rejects the AP submissions by informing the professional society or return the package to CSAP for a Focussed Review. Since all the applications have undergone CSAP's Preliminary Screening and Detailed Screening to ensure that all supporting documents are included in the package, it is better that ENV returns the submissions to the AP and inform the CSAP Society in writing as to the reason they were rejected.	Typically, the information suggested is how it works; however, ultimately the director may reject incomplete/deficient applications. The authorities for this are in the CSR, including for example sections 9 and 52. The main provision for the director's authority in rejecting a protocol application is described is <i>EMA</i> 64 (4).
6	3.3	For submissions determined to be incomplete applications it is indicated that " <i>Applications which are not complete may be rejected or returned to the applicant</i> ". These are P6 submission which will have undergone CSAP Detailed Screening to ensure that all supporting documents are included in the package. Prior the this provision ENV could only reject the instrument by informing the professional society or return the package to CSAP for a Focussed Review. ENV should be required to communicate why an application is rejected or returned and return it to the AP and inform the CSAP Society in writing as to the reason the submissions were rejected.	Typically, the information suggested is how it works; however, ultimately the director may reject incomplete/deficient applications. The authorities for this are in the CSR, including for example sections 9, 47, 49 and 52. The <i>Environmental Management Act, Interpretations Act</i> and other BC laws contains authorities for decisions and rejections by statutory decision makers. The main provision for the director's authority in rejecting a protocol application is described is <i>EMA</i> 64 (4).



6	3.3	Sec 3.3 Incomplete applications - specifically references EMA section 64(4) "On and after the date that a protocol under this section is published in accordance with the minister's regulations, a director may refuse to accept anything governed by the protocol that is not in compliance with it." Given the current time frame for reviewing preapprovals which in some cases has been up to a year, will the ministry consider the date on which the application was received as relevant to the information provided?	Since circumstances at each site are unique the ministry considers each application individually. On the date of application for a Certificate of Compliance, Approval in Principle and Determination, the contaminated site application must meet all applicable laws, protocols and ministry policy/guidance. It is possible that a protocol approval is reconsidered by the director as a part of consideration of the legal instrument. As well, EMA section 60 is explicitly in support of this.
6	4.0	It is unclear where in "the ministry's website" that "provides commonly encountered scenarios that require application for a preapproval." Suggest adding hyperlinks to relevant ENV documents, e.g. AG6, AG15, etc., so that the readers/practioners can follow.	This is explained in a ministry Preapprovals webpage associated with Protocol 6.
6	4	Protocol 6 lacks clarity on what would be considered de Novo TRV selection for ecological receptors	As it explains in the section, the definition of <i>de novo</i> TRV derivation can be found in Protocol 1 "Detailed Risk Assessment".
6	4	This section refers to preapproval requirements where the Instrument application will not include the entire extent of the contamination. This section should clearly state that if the entire extent of contamination will not be delineated or remediated of <i>provincial</i> or <i>federal</i> land, preapproval from BC ENV will be required.	The <i>Environmental Management Act</i> and the Contaminated Site Regulation (like all laws of BC) are applicable to all lands in the province. There may be exceptions to the applicability of BC laws on lands due to treaties with Indigenous Peoples, but otherwise it is a requirement that the entire extent of contamination at a contaminated site is delineated and remediated as per BC legislation and regulations whether or not the land is federal or provincial.
6	4	We recommend adding "Approval in Principle (remediation taking more than five years)" to this list. Since the Ministry now requires an AiP be obtained for multi-phase developments, rather than a P6 Scenario 5 release, it would be good to clarify this here.	This will be explained in a ministry Preapprovals webpage associated with Protocol 6.
6	4	It states "The ministry's website provides commonly encountered scenarios that require application for a preapproval.". Is it possible to include a specific reference here?	The Preapprovals webpage is now available.
6	4.1	Section 4.1 lists a P6 "Preapproval Application" form – however the link sends you to the current P6 "Approval" Application form – the form names are different and no new example form is appended or	The new form is now available.

		provided for review. Will a new form be included with P6?	
6	4.1 and 4.2	Information provided in these sections is useful information that is clearly laid out.	Thank you for this comment.
6	4.1 and 4.2	Information provided in these sections is largely a repackaging of information previously provided in the P6 application form. In general it is useful information that is fairly clearly laid out.	Thank you for this comment.
6	4.1.2	<p>This subsection relates to the new Site ID Release requirements in the Stage 13 CSR Amendments and it seems out of place here - it would fit better at the bottom of Section 4.0 or it could be integrated into a separate section that addresses P6 preapprovals in the context of Site ID requests for various site use/development scenarios (such as subdivision, zoning, development, etc.). In general there is detail/context missing in regard to this topic as noted in regard to 3.1.2 above.</p> <p>CSR Section 6.2 refers to Land Title Act (LTA) 85.1 (2) (b) as well as similar clauses in other Acts related to local government. None of the Acts available on Government website appear to have incorporated the recent changes associated with CSR Stage 13 amendments as they still refer to Site Profiles and don't include the subclauses (iii) and (iv) that are referenced in CSR 6.2. So it's possible that this will be clearer once these updated Acts are available. It might be clearer if the text of P6 (4.1.2) was changed to say: "Where applicable, a preapproval, as described in this protocol, must be obtained prior to requesting a notice described in the CSR section 6.2. The director's decision letter describing the preapproval must be included with the release notice request package."</p>	<p>This section has been moved up to Section 4.0 as paragraph two in that section.</p> <p>The amendments to the <i>Land Title Act</i>, <i>Local Government Act</i>, <i>Islands Trust Act</i> and Vancouver Charter are included in the <i>Environmental Management Amendment Act</i>, 2019 (Bill 17) and will come into effect on February 1, 2021 (linked to the Stage 13 CSR amendment regulatory changes).</p>
6	4.1.2	<p>This subsection relates to Site ID Release requests and seems out of place here - it would fit better at the bottom of Section 4.0 or as noted above it could be integrated into a separate section that addresses P6 preapprovals in the context of Site ID requests. In general there is detail/context missing in regard to this topic as noted in regard to 3.1.2 above.</p> <p>"The reference to 6.2 of the CSR is presumably to the Stage 13 Amendments which come into force on Feb 1st, 2020. The section referred to refers to ""Investigations and reports required on submission of site disclosure statements to municipalities or approving officers"". It is unclear which releases are being referred to as the references to the Land Title Act is for</p>	<p>This section has been moved up to Section 4.0 as paragraph two in that section.</p> <p>The amendments to the <i>Land Title Act</i>, <i>Local Government Act</i>, <i>Islands Trust Act</i> and Vancouver Charter are included in the <i>Environmental Management Amendment Act</i>, 2019 (Bill 17) and will come into effect on February 1, 2021 (linked to the Stage 13 CSR amendment regulatory changes). This would apply to current Scenario 4 and 5 releases (which will be renumbered as Scenario 2 and 3).</p>

		subdivision and is a release where no investigation is required which is a Scenario 2 Release. It is unclear if this applies to Scenario 4 and 5 Releases?"	These releases can include subdivision applications.
6	4.2	Suggest including a section on "Communications Channels". Based on the experience of Approved Professionals, having an active communication channel via telephone calls and emails with the ENV staff is extremely beneficial to avoid delays on project schedules for clarifications on ongoing changes to policies and procedures and associated interpretations and to help manage the changes in the CSAP Society Board members and the ENV staff.	This comment is not relevant to Protocol 6 revisions to support the Stage 13 amendment but may be appropriate for discussion in a different context between the ministry and CSAP.

## Appendix 4. Protocol 9: Establishing Local Background Concentrations in Groundwater.

Protocol #	Section #	Comment/Recommendation	Ministry Response
9	General	If the groundwater encountered during construction meets local background concentration, would it be possible to discharge that water back into the local aquifer?	This question is related to effluent discharge authorization not establishing local background concentration.
9	General	Will this Protocol override Technical Bulletin 3? Will TB3 be rescinded?	Yes. Technical Bulletin 3 will be rescinded.
9	1.0	Suggest adding a phrase "that exceeds numerical standards of the CSR" for the definition of "Contaminants of Concern".	The definition has been amended to include reference to numerical standards.
9	2.0	Last paragraph at the bottom of Page 1 of the pdf <i>"On certain sites, there may be two or more hydrogeologic units that require separate characterization."</i> Does this have a bearing on potential vertical delineation issues for background concentrations?	Background concentrations are delineated based on the natural water chemistry and hydrogeological units.
9	2	References that separate determinations are required should more than a single aquifer be encountered. Is there a requirement that a confining layer be shown to exist to protect other aquifer units similar to provisions in P21?	No. Confining layer confirmation is not required.
9	4.2.2	Under option 2b - there is a hard 500m radius established in order to use data. If it can be determined that relevant concentration data is present at a distance greater than 500m but arguably within the same groundwater flow system and hydrogeological unit, then it should be able to be considered. Suggest that you modify the wording from 'must be collected within 500m' to 'preferably collected within 500m'.	The 500 m distance is considered to be a reasonable distance given the complex geology of British Columbia. However, the director may use their discretion based on the circumstances.
9	4.2.3	In this section the following is stated: 'Furthermore, contaminants of concern (COCs) associated with areas of environmental concern (AECs) must be bounded vertically and laterally to ensure that background wells are located outside of the influence of site contamination'. There are instances where it can be robustly demonstrated that areas of the site are outside the influence of site contamination, however, potentially full downgradient delineation has not yet been achieved for a variety of reasons including potential access issues. It does not seem reasonable to have a precluding factor such as this, i.e. full blown horizontal and vertical delineation of the CoCs in all cases, if it can be demonstrated that an area of the site is unimpacted in the absence of full blown delineation. This is key to allow for a background	The presence of COCs can influence the redox conditions of inorganic parameters. In order to determine natural background conditions, the presence and potential influence on the natural geochemistry must be assessed. However, it is possible to determine unimpacted areas of a site without achieving full delineation. The wording has been adjusted accordingly.

		determination to be undertaken in parallel with downgradient delineation efforts.	
9	4.2.3	<p><i>"Monitoring Well Citing Criteria - Preference should be given to the collection of background groundwater from monitoring wells installed on undeveloped or vacant land that has not received imported fill, or in naturally wooded areas, parks or larger residential lots."</i></p> <p>It may be helpful to provide a qualified statement on citing background wells in urban settings where these criteria are more difficult to meet.</p>	Noted. Wording has been added to provide clarification.
9	4.2.3	<p><i>"Groundwater Data Assessment - The size of the groundwater dataset must be determined according to the variations observed in site conditions."</i></p> <p>This appears to be rather subjective. Can any refinements be made to this statement?</p>	Noted. However, the next sentence provides more stringent advice on how much data is required given the site complexity. No additional refinement warranted.
9	4.2.3	The section on Monitoring Well Siting has unrealistic expectations. Drilling in sensitive environments should not be promoted (i.e. parks). Roadways should be cited as they are the most accessible and have the least potential liability.	Drilling in sensitive areas can be done with limited disturbance; however, if it is not possible then other drilling locations should be selected.
9	4.2.3	The history of adjacent lands to be drilled must meet a level of due diligence as far as land use, however requiring all the information required in the PSI is onerous and in most cases unnecessary. Could be refined to sufficient information to determine the history of adjacent lands with respect to APECs and PCOCs is required.	The Preliminary Site Investigation is a rigorous method of identifying off-site PCOCs and APECs which could impact background parameters on the site of interest. This is a reasonable requirement.
9	4.2.3	Wells with detectable organic constituents are precluded from use as background wells. In urban settings some contaminants (e.g. benzo(a)pyrene) are widely distributed from anthropogenic sources. Professional judgements should be allowed in determining when certain contaminants or concentrations of, preclude the use of the well.	If it can be clearly demonstrated that a COC could in no way influence an inorganic parameter which is considered to be naturally present, then that monitoring well may be used. Rationale can be provided to seek director's discretion.
9	4.2.3	<p>Pg 6, <i>"Groundwater data collected from selected background wells must not be used if the <b>detection limit for any substance</b> is higher than the applicable groundwater standard for the site"</i>.</p> <p>It is unclear whether this statement refers specifically to background substance concentrations being used to calculate 95% percentiles or if it is intended to capture PCOCs as well, i.e. if the APEC is a fuel source and the majority of PHCs and PAHs are non-detect and below standard, but one PAH parameter has a detection limit &gt; CSR standards, can the well still</p>	This refers to background and PCOCs substances. Additional clarity will be added to the sentence.

		<p>be used as a background location for arsenic concentrations?</p> <p><b>Recommendation:</b> Re-word to clarify whether this refers to PCOCs or suspected background substance concentrations or both.</p>	
9	4.2.4	<p><i>"Data Requirements - c) a minimum of two sampling events required, one during the wet and one during the dry seasons (e.g. seasonal high and low water table), to help capture any seasonal variability in the natural groundwater chemistry."</i></p> <p>Is there any consideration for a minimal fluctuation in water table to shorten this timeline for establishing background concentrations?</p>	<p>This requirement is a reasonable expectation. However, if sufficient additional rationale is provided the director has discretion.</p>
9	4.2.5 (g)	<p>Pg.7 – requirement that all COCs be non-detectable in background well may not be realistic in some cases. Metals and other inorganic concentrations at sites where these substances are identified as contaminants are highly unlikely to be non-detect in background areas even if adequately delineated due to low level naturally occurring concentrations of inorganics.</p> <p><b>Recommendation:</b> Limit requirement for concentrations to be non-detectable to organic PCOC constituents that have potential to influence redox conditions</p>	<p>Noted. The wording will be adjusted to add clarity.</p>
9	Table 1	<p>1. Please add the unit of the values included in Table 1.</p> <p>2. "Lower Mainland Sub-region 1" and "Lower Mainland Sub-region 2"</p> <p>It would be beneficial to include a map in the protocol, which shows the 2 sub-regions</p>	<p>Noted. The units will be added to the table. The boundaries can be seen on the iMapBC map layer.</p>
9	Table 1	<p>In Table 1, Sodium ion (Na+) background concentration in Lower Mainland Sub-Region 2 is set to 2,000,000 ug/L, which is 10 times the Na+ CSR standard for the protection of groundwater used for drinking water purpose. In the Metro Vancouver area, elevated sodium concentration typically pairs with elevated chloride concentration in groundwater, and often chloride concentration is even greater than Na+ concentration. It would be beneficial if the Ministry would consider establishing the CL+ background concentration to 2,500,000 ug/L, which is also 10 times the CSR Cl- standard for the protection of groundwater used for drinking water.</p>	<p>The concentrations are naturally derived constituents based on measured dissolved concentration in groundwater in these areas.</p>
9	Table 1	<p>For chromium, presume the values presented are for 'total chromium'?</p>	<p>Total Chromium as footnote 28 of Schedule 3.2 of the CSR.</p>

9	Table 1	"Notes - 95th percentile concentration not calculated when there is $\leq 10$ background sites" The '-' symbol is not listed in the data table. Does it apply to any of the values presented?	Noted. It will be removed
9	Table 1	concentration units not indicated	Noted. The units will be added.
9	Table 1	column 1, "Aluminium" not spelled per CSR "Aluminum"	Noted. It will be changed.
9	Table 1	column 4, beryllium of 1.3 is less than AW standard (1.5), should not be bold	Noted. It will be changed.
9	Table 1	column 4, copper of 32 is greater than AWM standard (20), should be bold	Noted. It will be changed.
9	Table 1	column 2 and 3, nickel of 110 and 100, are > both DW (80) and AWM (83) should be shown as " <b>110, 110</b> " and " <b>100, 100</b> " respectively, as done for cobalt	Noted. The table will be adjusted.
9	Table 1	column 4, selenium of 120 is > both DW (10) and AW (20) should be shown as " <b>120, 120</b> ", as done for cobalt	Noted. The table will be adjusted.
9	Table 1	column 4, uranium of 87 is > both DW (20) and AW (85) should be shown as " <b>87, 87</b> ", as done for cobalt	Noted. The table will be adjusted.
9	Table 1	footnotes, "-", "n" – not present in Table	Noted. The table will be adjusted.
9	Table 1	footnotes, "2" – referring to cobalt, should be added to parameter name in column 1 (Cobalt <sup>2</sup> ), similar as was done for Hardness <sup>1</sup> .	Noted. The table will be adjusted.
9	Table 1	"Notes, n number of background sites used" This information has not been provided in the table?	Noted. The table will be adjusted.
9	Table 1	As soils numbers protective of groundwater are derived from water standards, is therefore is appropriate to develop Site Specific Soils number from the regional estimates?	This is a question directly related to Protocol 2 - Site Specific Numerical Soil Standards, not to Protocol 9. Protocol 2 does not allow the substitution of regional background concentrations for prescribed groundwater standards.
9	Revision History	indicates 33 substances added, but only 27 in Table 1	Noted. The table will be adjusted.
9	4.2.3	Characterization - it says 'all APECs must be assessed...to demonstrate that the suspected naturally occurring inorganic substance is anthropogenic sourced' which on first read sounds logical but that presumably means <i>all</i> APECs on the site. However, some sites are huge in area but small in terms of APECs (widely spaced) and if you are working on the back, upgradient portion of the site where there was an apec, why should you need to investigate another apec 500 m, 1 km or whatever away, especially if	Any APEC that could affect the natural groundwater quality determination should be assessed.



		you are delineated for the pcocs between them. Would suggest you change it to "Relevant APECs" or similar so it doesn't force unnecessary investigations.	
9	4.2.3	<p>Characterization - it notes the COCs and AECs must be bounded vertically and laterally to ensure background wells outside of area of interest. Take a site where you assessed a garage and found BTEX and selenium contamination at a garage and you believe selenium is background. You drill upgradient, cross gradient, and you don't find hydrocarbons in those directions and you find similar elevated selenium upgradient confirming your background hypothesis. However, the BEBTEX plume is not delineated in the downgradient direction at that time (e.g. large plume, access delays). Why you can't apply for a selenium background ruling before the BTEX plume is delineated as its clear at that point they are not related. The way its worded would prevent us from applying for background rulings during the course of a project and force applications to the end. There are often circumstances where you want to move along issues such as background rulings during the course of a project. I suggest you change the wording to "sufficiently vertically and laterally delineated to ensure the background wells are located outside of the influence of site contamination" or similar. The key word being 'sufficiently'. Full delineation of every APEC and PCOC on a site isn't required in some cases to prove that.</p>	The presence of COCs can influence the redox conditions of inorganic parameters. In order to determine natural background conditions, the presence and potential influence on the natural geochemistry must be assessed. However, it is possible to determine unimpacted areas of a site without achieving full delineation. The wording has been adjusted accordingly.
9	all	<p>A reminder this protocol doesn't just effect major industries and these rules can cost everyday property owners in rural settings (land not work much) many, many tens of thousands of dollars to rule out some background hit of an obscure metal like magnesium which is obviously background. Consider some sites the groundwater can be at 50 m and three background wells can cost a fortune to install. Overall well written and well considered document however a word or two here and there can cause many issues so I hope you listen to the feedback you receive although you only have 2 weeks to consider. Overall it needs to balance between technically reasonable and bankrupting everyday people via strict rules</p>	Noted. We have attempted to strike a balance in the document. There are situations where the director's discretion can be used; however, an adequate level of investigation must be implemented on a site.

		that really weren't applicable at their site if considered reasonably. Its generally technically reasonable but some of these instances where "must" has been used should be considered carefully.	
Protocol 9	4	The draft protocol indicates that a local background groundwater assessment should target discrete hydrogeologic units at a site. Can discrete hydrogeologic units be defined within definition (does it mean groundwater represented by one groundwater flow system or groundwater represented by single hydrogeological unit).	A single hydrogeological unit. However, the director has discretion should if a sufficient rationale is presented to combine hydrogeological units.
	4.2.2	The draft protocol indicates that for Option 2a, we can use representative background monitoring wells located on and adjacent to the site of interest. In most cases (within the lower mainland), adjacent sites not influenced by anthropogenic sources are difficult to find. As such, is it possible to define the area to be 500 m of a site of interest as long as the background groundwater assessment should target discrete hydrogeologic units at a site?	Noted. The question is ambiguous.
		This is mentioned within "Monitoring Well Sitting Criteria", where "monitoring wells must be located near the site of interest, or on the site if it can be demonstrated they are not impacted by anthropogenic sources of contamination in areas where measured groundwater chemistry is representative of natural conditions".	
	4.2.3	"To demonstrate an absence of anthropogenic influence, background wells must be sampled for PCOCs that could be sourced from site AECs or that could have migrated onto the site from neighboring site APECs."	
		If the background wells are located up-gradient and/or cross-gradient of site of interest, why is this required if it can be demonstrated by a Stage 1 PSI that the background well site has been undeveloped or vacant land that has not received imported fill, or in naturally wooded areas, parks or larger residential lots.	An up-gradient property could have AECs/COCs which could be migrating onto the site of interest.
	General comment	For the regional background concentrations, which discrete hydrogeologic units is represented by the values presented in Table 1?	Typically, it was the first water bearing unit encountered as the monitoring well screens are installed in contaminated site investigations. However, you can use the regional concentrations for all hydrogeological units.

9	Definitions	"local background concentration": It appears that BC ENV intends to remove non-point sources of anthropogenic contamination from the definition of Natural Background Concentration (it was previously included in the definition of "Background Concentration"). Is this correct?	Correct, these contaminant sources have been removed from the definition.
9	Table 1	The purpose of yellow highlighting is not clear	Noted.
9	Table 1	The bold / bold italics used to denote exceedances to CSR standards appear to be incorrect for a number of background concentrations	Noted. It will be removed.
9	Table 1	Is Local Background concentration for Chromium trivalent, hexavalent or total?	Total Chromium as footnote 28 of Schedule 3.2 of the CSR.
9	Table 1	Why is the cobalt background concentration for lower mainland subregion 1 listed twice (62 , 62)?	Noted. It will be corrected.
9	Table 1	The Hardness values seem bizarre. Is mg/L the correct units? Is 3,000,000 mg/L for Thompson Okanagan correct?	Yes, it is correct.
9	Table 1	What is the rationale for not including anion parameters in Table 1? E.g., sulphate. Not enough data?	Correct.
9	4.1	How were the regional boundaries determined? Do they consider local geology?	Yes. They are based on surficial geology.
9	4.2.2	What is the rationale for limiting the allowable BC ENV groundwater database data to within 500 m of a site? As long as wells are within the same hydrogeological unit, it is suggested that this range be expanded to 1 km from Site, and 2 km upgradient of site.	We consider 500 m to be a reasonable value, given the complex geology of British Columbia. However, the director does have discretion should adequate rationale be provided.
9	4.2.3	Collection of Representative Data: It is unclear what is meant by "Secondary Contaminant Release" in the statement - Sufficient data must be collected to demonstrate that wells are not impacted by secondary contaminant releases.	Secondary Contaminant Releases relate to chemical process that indirectly result in a contaminant release like redox condition changes that dissolve metals into the groundwater. Wording has been added to provide clarification.
9	4.2.3	For the statement - the most current groundwater data is considered representative of groundwater conditions, this may not be true if there is seasonal or temporal variation in the data.	The most current groundwater data doesn't mean the latest round of sampling. It is intended to indicate the most recent dataset that should be used to determine temporal variation. Wording has been slightly adjusted.
9	4.2.3	What is the rationale for not allowing data if detection limit is greater than standard? Is this	If the detection limit is greater than the standard then we

## 2021 Comment Report

		statement intended for test results that are less than detection limit?	don't know if a standard has been exceeded.
--	--	---	---

## Appendix 5. Protocol 11: Upper Cap Concentrations for Substances Listed in the Contaminated Sites Regulation.

Protocol #	Section #	Comment/Recommendation	Ministry Response
11	Text	The text of the protocol has been changed slightly to reflect a revised approach to providing definitions in Protocols, the changes do not change the application of the Protocol and no recommendations are made based on these changes	No response required.
11	1.0	Removed reference to Procedure 8 and added specific definitions in the Protocol. Note: definitions were subsequently removed from the various table footnotes throughout. In some protocol updates, there is reference to Procedure 8 with no definitions provided and then in others like this one, its the opposite. Can this be made consistent?	Procedure 8 will be phased out from use. Terms listed in Protocol 11, version 3.0 (2017) were determined to no longer require a standalone definition, therefore the reference to Procedure 8 has been removed and they are not defined in this protocol. The references to definitions within ministry protocols will be harmonious.
11	3.0	Removed reference to Appendix I - Derivation Details. Note: upper cap concentration derivation information also removed from the various table footnotes throughout. Can some text be provided on what the multiplication factors are or how they were derived or a reference to where this is further explained?	The derivation information will no longer be provided. The intent of a protocol is to provide requirements as opposed to the rationale behind the requirements. This information is still available upon request, by submitting an email to the appropriate address on the Contact Us webpage.
11	Tables - Tabular values	The Tabular data in Tables 1 through 8 is not substantially changed. Spot checks show that the changes implemented in 2017 remain in place and few if any changes in tabular values were observed since the 2017 version.	No response required.
11	Tables	It would be helpful if Table numbers and titles repeated at the top of each page	The ministry agrees and this change will be made.

11	Tables 4, 5, 6	All references to NAPL and odorous substances, and the UCCs of "not present" should be removed from P11. The conditions where NAPL creates a high risk site is documented in Protocol 16. Conditions where odorous substances create a high risk site are determined via vapour UCCs in Table 7, and using applicable P22 attenuation factors. Therefore there is no reason to include NAPL and odorous substances within Tables 4, 5 and 6 of P11. If NAPL and Odorous substances must remain in P11, then it is recommended that footnotes be added to Tables 4, 5 and 6 to reference the applicable protocols used to determine if a Site is high risk based on the presence of NAPL or odorous substances.	This protocol sets the upper cap concentrations for substances with numerical standards in the Contaminated Sites Regulation (CSR). As nonaqueous phase liquids and odorous substances are prescribed substances in the CSR, they are included in this protocol. Practitioners should refer to the full compliment of available protocols; this information does not need to be found within Protocol 11.
11	Table 4	Error found in the table: Substance: pirimiphos- methyl, Column 8 High Density Residential (page 32) should value be 3 000 (not 300).	The ministry agrees and this change will be made.
11	Table 4, page 32	For substance pirimiphos- methyl, Column 8 High Density Residential, should value be 3 000 (not 300)?  (According to derivation of upper cap concentrations as described in the November 1, 2017 version of Protocol 11, Appendix 1, the upper cap multiplier for human health protection soil ingestion exposure Schedule 3.1 Part 2 substances is 10x; therefore, $300 \times 10 = 3\,000$ .)	The ministry agrees and this change will be made.
11	Table 5, page 39	For substance benzo(b+j)fluoranthenes, Column 10 Industrial, should value be 100 (not 10)?  (According to derivation of upper cap concentrations as described in the November 1, 2017 version of Protocol 11, Appendix 1, the upper cap multiplier for environmental health protection invertebrate and plant soil exposure Schedule 3.1 Part 3 substances is 10x; therefore, $10 \times 10 = 100$ .)	The ministry agrees and this change will be made.
11	Table 5	Error found in the table: Substance: benzo(b+j)fluoranthenes, Column 10 Industrial (page 39) should value be 100 (not 10).	The ministry agrees and this change will be made.
11	Table 6	Footnote 54. Garbled formatting. Should be "Upper cap concentration for <u>continuous</u> application on crops.	The footnote formatting appears to be correct as is, it is unchanged from the previous version.

11	Tables - Footnotes	<p>The Footnotes in the tables have been decreased in number and content apparently to streamline the information. Details on how values were derived have been shortened or eliminated for derivation of Toxicity Equivalency Factors for PCDDs and PCDFs; Toxicity Equivalent Quotient for PAHs; and many of the exposure-pathway-specific Upper Cap concentrations (as an example consider the details lost on the Table 4 Upper Cap concentrations for acetone at commercial and industrial sites in soils). Details on the derivation of the Upper Cap concentrations have been stripped from the footnotes.</p> <p>In general the effect of the changes has been to strip away details on the rationale for the derivation of the Upper Cap concentrations and reduce the ability of practitioners to manipulate values in risk assessments or understand their technical basis.</p> <p>This information forms the basis of understanding the technical basis for these concentrations and determining how these concentrations will change when the science changes. The direction of these changes is worrying, as without this information, it impairs practitioners and site owners ability to understand the technical basis for these Upper Cap concentrations. It is recommended that this information be returned to the document or reference made to where this information can be found in other documents.</p>	<p>The derivation information will no longer be provided. The intent of a protocol is to provide requirements as opposed to the rationale behind the requirements. This information is still available upon request, by submitting an email to the appropriate address on the Contact Us webpage.</p>
11	Tables - Footnotes	<p>2005 WHO TEF tables have been removed and replaced by the term “equivalency factors”. Can a reference (i.e., Protocol 28) be provided on where these came from? In footnote or explained in text of Protocol.</p>	<p>The full tables are found within the Contaminated Sites Regulation (CSR) schedule footnotes.</p>
11	Appendix	<p>The Appendix that presented the rationale for the derivation of the Upper Cap concentrations has been eliminated. Without this information, it impairs practitioners and site owners ability to understand the technical basis for these Upper Cap concentrations. It is recommended that this information be returned to the document or reference made to where this information can be found in other documents.</p>	<p>The derivation information will no longer be provided. The intent of a protocol is to provide requirements as opposed to the rationale behind the requirements. This information is still available upon request, by submitting an email to the appropriate address on the Contact Us webpage.</p>



## Appendix 6. Protocol 12: Site Risk Classification, Reclassification and Reporting.

## 2021 Comment Report

Protocol #	Section #	Comment/Recommendation	Ministry Response
12	n/a	A Detailed Site Condition report is referenced numerous times. Does this refer to a Detailed Site Investigation?	No, it does not. The Detailed Site Condition Report (DSCR) is a summary report which includes all available information relevant to the site, including historical and current tables and figures for all investigated media. The definition of DSCR will be included in section 1 of the protocol.
12	1	Definition of "Aquatic Habitat". The use of the word "as" in the second part of the definition "... or as used by aquatic life" seems grammatical awkward. Suggest to replace with "that is" to "... or that is used by aquatic life"	The definitions were reviewed by our legal counsel so that they are enforceable.
12	1	Definition of "complete exposure pathway". Typo of the word "al". Should be "all". It also seems that bullet point e) is missing for "the presence of a receptor to be exposed".	Thank you, we will correct this typo in the final version.
12	1	Definition of "Exposure Pathway Questionnaire" [EPQ]. "EPQ" is never used in the document beyond this point – it is instead written out in all cases. The same is true for most of the other abbreviations listed in Section 1; however, "NAPL" and "UCC" are used extensively through. Consider usage of abbreviations for consistency.	We will make this change in the final version (using EPQ instead of Exposure Pathway Questionnaire).
12	1	Definition "upper cap concentration" Suggest to replace "... when present..." to "...when present and/or exceeded..." This may further clarify that 1) one is comparing site investigation data with the specified concentration limits and 2) upper cap concentrations are not only present when the concentrations at a site are equal to the specified concentration limits. It seems that UCC are used a bit differently in this version compared to the previous versions and so the above suggestion would also provide some continuity with the version 2.0 of P12.	The UCC is a concentration established by the director. The wording "present" or "exceed" is for evaluating high risk condition, not for definition. Also, this definition has not been revised from the previous version.
12	1	Why are there separate definitions for "affected parcel" and "affected site" and why does the definition for "affected site" not include the last statement "...and ultimately from a source site or parcel". There is a further definition for "parcel" but not for "site".	A parcel means a legal parcel; a site may contain one parcel or multiple parcels. These definitions will be consistent with Procedure 8.
12	1	in the definition for "complete exposure pathway", "all" is misspelled	Thank you, we will correct this typo in the final version.

12	1	A number of definitions are inconsistent with Procedure 8. The definitions for "complete exposure pathway", and "exposure pathway" seem to be reversed.	All definitions have been reviewed by the legal counsel and some necessary revisions have been made.
12	2	Section 2.0 Introduction; the first sentence with bullets is awkward and could be more clearly written.	Thank you, but this is consistent with all protocols.
12	4.1	Given the increased understanding of NAPL in the last decade, there should be a risk-based evaluation process (similar to condition 2) if exposure pathways are not present before "high risk" is triggered.	The site should be classified HR if mobile NAPL present (mobile NAPL is defined in P16). The applicant may request site risk reclassification if they believe the mobile NAPL can be "risk-managed" or "risk-based evaluated".
12	Section 4.1.1	High Risk Site Conditions: The high risk conditions related to NAPL do not include exposure pathways to the receptors. Even if the NAPL is mobile and migrating, what happens if the NAPL plume is within the site boundaries and the exposure pathways to the receptors doesn't exist: Is the site still a high risk site? Why? For example, the site is a large commercial or industrial site and has a very slow hydraulic gradient.	-EPQ only addresses UCC, not NAPL - If NAPL is mobile/migrating, even if it is within site boundary, the site is still considered to be HR since NAPL may eventually migrate beyond the site boundary.
12	4.1.2	bullet point a) uses the acronym UCC. Suggest to spell out the word (upper cap concentrations) in full and provide acronym in brackets again. This is the first time the acronym is used beyond Section 1. The acronym UCC is otherwise only listed Section 1 as part of the definition for upper cap concentrations and an unfamiliar user may glance over it when looking for the definition of UCC	The first time the full definition appears in Section 1, where it is spelled out.
12	4.1.2	In the paragraph " <i>Where notifications to the director are triggered under the reporting procedures of this protocol and detailed investigations have not yet been completed, the presence or absence of UCCs (if known) must be indicated. If UCCs are exceeded, exposure pathways must be evaluated.</i> " What is the purpose of the sentence fragment " <i>and detailed investigations have not yet been completed</i> "? Are there different requirements for the case when detailed investigation have been completed?	Thank you for your comment. This wording is provided to address situations with incomplete detailed site investigations where some of the media were not fully investigated at the time of SRCR submission. If a DSI has been completed, the presence/absence of UCC should already be established.
12	5.2	Recommend defining Detailed Site Condition Report in the list of terms for ease of reading the document and in section 5.2. There is a footnote description with Table 2; however, a few more details on what is	The definition will be added in the final version.

		required would be helpful, e.g. is it required to include Stage 1 PSI information?	
12	5.2	What is a Detailed Site Condition Report and how does it differ from a SoSc? A Detailed Site Condition Report now replaces SoSc in Table 2 and first row of Table 3. However, SoSc is not replaced in last row of Table 3 or in Section 6 - is this correct or should it be updated?	<p>A DSCR is not a SoSC nor a DSI. It's a summary report containing all available information relevant to the site, including historical and current tables and figures for all investigated media.</p> <p>The reasons we require a DSCR are:</p> <ul style="list-style-type: none"> <li>- limited information is available at the initiation stage of high risk condition remediation, thus SoSC is left blank for most cases</li> <li>- Unlike a SoSC, a DSCR does not require an AP to sign off, which will facilitate remediation of high risk conditions at the initiation stage.</li> </ul> <p>However, to ensure the high risk conditions are remediated properly, an AP's involvement is required for site risk reclassification.</p>
12	5.2, Table 2 and Table 3	Is Detailed Site Condition Report the Detailed Site Investigation (DSI) Report? If yes, suggest using the DSI name. If not please provide additional details.	No, the Detailed Site Condition Report (DSCR) is a summary report which includes all available information relevant to the site, including historical and current tables and figures for all investigated media.
12	5.2, Table 2, Table 3	Recommend defining Detailed Site Condition Report in the list of terms for ease of reading the document and in section 5.2. There is a footnote description with Table 2; however, a few more details on what is required would be helpful, e.g. is it required to include Stage 1 PSI information?	The definition will be added in the final version.
12	5.3.1, Table 1	Footnote three has an error - it indicates, "This notification trigger could apply, depending on the circumstances, to any of the preceding seven notification trigger..." There are only six preceding notification triggers.	Thank you, we will make this change in the final version.
12	5.3.1 Table 1	It was noted that the grids for the tables are actually images superimposed on the document text. I suggest that they be replaced with table outline formatting as a simpler solution that is much easier to edit and reformat. Portions of words are not fully visible and footnote numbers are detached from the text.	We recommend checking your computer settings.

12	5.3.1. Table 1 Item 7, Column IV	Should it not be Items 1 to 6 instead of Items 1 to 5 in the text " <i>The person who has the duty to submit a Site Risk Classification Report under any of triggers 1 – 5</i> " as an additional item has been added to the Table	We will make this change in the final version.
12	5.3.1, Table 2	Footnote 2 makes a reference to "Summaries" of site condition. Column IV, footnote 6 references "detailed" Site condition reports. Which will be the correct term? Or will there be two forms?	<p>1. The final version will use "summary" instead of "summaries" in footnote which is SoSC</p> <p>2. The detailed site condition report is a summary report which includes all available information relevant to the site, including historical and current tables and figures for all investigated media.</p>
12	5.3.1, Table 3	What is the rationale for requiring a confirmation of remediation report sign by approved professional for Sites that high risk conditions have been removed in fewer than 90 days? It is recommended that this be removed as there would essentially be no difference between the <90 day and >90 day reporting (only difference is inclusion of summary of Site condition (and should this be a detailed Site Condition report?).	<p>The involvement of an AP is required to ensure all remediation of high risk conditions will be conducted properly.</p> <p>There are differences between the &lt;90 days and &gt; 90 days reporting requirements. If HR conditions will be remediated within 90 days, a DSCR is not required at the initiation stage of the remediation. No SoSC is needed when the applicant is applying for site risk reclassification for HR conditions remediated &lt;90 days.</p>
12	Section 5.6	Requirements for "part of a site" are very confusing. Can the SRCR be completed for "part of a Site" for any other triggers? Eg., obtaining a ministry service or CSAP submission for part of a site? For the statement: "All parts of the site where high risk conditions are known to be present must be identified in Section X of that site risk classification report ...", does this only apply to areas of the Site that are not "part of the Site"? If it is unknown if other areas of the site are high risk, would there be a requirement to complete investigations of these other areas? Please clarify the requirements for metes and bounds? Is it for the "part of the site" that the SRCR applies to? Or other areas of the Site that are known to be high risk?	<p>This applies to large sites where independent remediation may be carried out only on a part of the site. If high risk conditions identified for such part (parts) of the site, the detailed information for that part (parts) must be provided in "Section X, Additional Information" of the SRCR.</p> <p>An SRCR can be completed for part site for other triggers. For the ministry service or CSAP submission for part of a site, preapproval may be required in accordance with the director's protocols.</p> <p>If it is unknown if other areas of the site are high risk, the requirements for SRCR submission for those areas may vary:</p> <ul style="list-style-type: none"> <li>- SRCR is not requested if the submitted SRCR is non-HR and there is no trigger for the remaining area.</li> <li>- If the submitted SRCR is high</li> </ul>

			<p>risk, the responsible person must delineate the high risk condition(s), identify/investigate the potential high risk area(s), and make submission as required in Tables 2 and 3.</p> <p>The metes and bounds shall use bearings and distances to measure the circumference of the part and shall be surveyed by a surveyor. The metes and bounds is the description of the "part site" that the SRCR applies to. (Refer to Section I of the SRCR form).</p>
12	6	<p>With regards to the reporting requirements, would a risk assessment report for the risk-based remediation of risk-managed high risk sites be required?</p> <p>If so, it is not entirely clear that this would be captured by the Confirmation of Remediation of High Risk Conditions Report. In the first paragraph of Section 6.0, the term remediation is strictly applied to reclassification from high risk to non-high risk. The term remediation is not used with reference to reclassification to risk-managed high risk sites. So based on the used terminology, it is unclear whether confirmation of risk management of high risk conditions is captured as part of the Confirmation of Remediation of High Risk Conditions Report.</p>	<p>The term 'remediation' includes physical remediation and risk control measures, thus, an RA is required for reclassification from HR to RMHR. The final version of Section 6.0 will be amended accordingly.</p>
12	Section 6.0 Site Risk Reclassification	<p>The words "<i>if necessary with respect to site risk controls</i>" should be added to the bullet that indicates a Performance Verification Plan is necessary for obtaining a site risk reclassification, given there could be cases where a PVP is not necessary.</p>	<p>A PVP is required for a risk-managed high risk site since there is (are) risk control measure(s) in-place.</p>
12	Figure 1	<p>"HS-4 - Is the site land use not wildland (i.e. PL, AL, RL, CL or IL use)? No" - The double negative is confusing and follows a different pattern than the other questions. Suggest revising. E.g.. Is the site land use PL, AL, RL, CL or IL (i.e. not wildland use)?</p>	<p>Thank you, we will make this change in the final version.</p>
12	Figure 1 flowchart	<p>Although NAPL is defined in Section 1, the terms LNAPL and DNAPL only appear in the flowchart</p>	<p>Thank you. Only NAPL will be used in the final version instead of LNAPL and DNAPL.</p>
12	Figure 1 flowchart	<p>It was noted that underlying text is divided into image and cell portions and would be difficult to format or edit.</p>	<p>We recommend checking your computer settings.</p>

## 2021 Comment Report

12	Exposure Questionnaire	It was noted that overlying grid does not align with text.	We recommend checking your computer settings.
12	Exposure Questionnaire	Question HV-1: Should footnote 4 apply here?	Thank you for the comment. Footnote 4 does apply to HV-1. It will be changed in the final version.
12	Exposure Questionnaire	In the past, there has been conflicting advice and interpretation regarding whether indoor air (breathing zone) results supersede soil vapour results. We recommend adding a note to the Exposure Pathway Questionnaire specifying this one way or the other.	Indoor air never supersedes soil vapour results. But, this issue needs to be addressed by Technical Guidance 4/Protocol 22 as those are more appropriate documents to deal with vapour results interpretation.
12	Exposure Questionnaire	Question LIW-1: was footnote 5 intentionally removed (seems to previously have meant to capture backcountry use by horseback where watering holes could be contaminated)	Thank you. This is covered by LIW-2
12	Exposure Pathway Questionnaire, HV-1	Can a footnote be added to this question indicating that UCC are applicable to <b>both</b> ambient air and subsurface vapour (with AF) when both media have been sampled. The word "or" in the question can create some confusion. This was a topic that ENV and the CSAP Society verified via a Members Update a few years ago. Ideally the updated Protocol should clarify things.	We believe it's clear that the site will be classified as HR if one of the sampled media (SV or Air) exceeds UCC. In this case if SV>UCC but air<UCC, the site should be classified as RMHR.
12	Exposure Pathway Questionnaire, TS-4	Does this question need to be answered by a Registered Professional Biologist (RPB)? The same question within Protocol 13 has that requirement.	This questions must be answered by a qualified professional under the <i>Professional Governance Act</i> .
12	Site Risk Classification Report, Part 3, Section V	If you mark "No" under "A" indicating that info is not appropriate and satisfactory to determine site risk classification (and then proceed to provide dates as to when investigations will be performed), should it not then be indicated that Sections VI and IX don't need to be completed?	That is correct.

## Appendix 7. Protocol 13: Screening Level Risk Assessment.



Protocol #	Section #	Comment/Recommendation	Ministry Response
13	General	Revisions appear to be largely administrative to match the revised regulation and minor wording improvements. We note that an Registered Professional Biologist (RPBio) designation as a qualified professional is now required to sign off on a ecological habitat assessment. This is a reasonable addition.	Thank you for the comment.
13	General	Various typographical errors throughout the document.	Thank you for advising of this.
13	General	Per P1, SLRA and DRA are indicated to be exclusive of one another. This is inconsistent with current practice and understanding of ENV policy. SLRA should be used to eliminate inoperable exposure pathways, with DRA used to assess exposures and risks associated with operable exposure pathways only.	The ministry's policy has been updated in Protocol 13 "Screening Level Risk Assessment" (SLRA) and Protocol 1 "Detailed Risk Assessment" (DRA). If any requirement is not satisfied, or any precluding condition is present, or any pathway fails in SLRA, Protocol 13 (SLRA) may not be used at the site. DRA under Protocol 1 or further remediation is necessary.
13	General	Several spelling mistakes throughout document - spell check needed.	Thank you for advising of this.
13	1.0	Definitions should be consistent with those presented in P1 and P28 (inconsistencies noted) (e.g., acceptable risk).	Thank you for the comment. Some differences are intentional, such as acceptable risk in the context of SLRA versus DRA. All relevant definitions that are in addition to those in the <i>Environmental Management Act</i> and Contaminated Sites Regulation will reside in respective protocols. It should be noted that a protocol has legal authority enabled by the <i>Environmental Management Act</i> and the Contaminated Sites Regulation so ensure the latest in-force protocol definitions are followed.
13	1.0	Defn of "active floodplain" has been updated to include requirement for a biologist to make an assessment whether the land in question is " <u>capable of</u> " supporting plant species typical of inundated or saturated conditions " <u>and</u> " distinct from plant species on freely drained upland sites. This	Noted. Thank you for advising on this.

		requirement seems very subjective and prone to differing professional opinions.	
13	1.0	Definition of ' <i>Bioaccumulative Substances</i> '. Part (a) captures most PAHs which do not bioaccumulate in most media/biota and are contaminants on many sites. Is it the intent to preclude such sites from P13? Part (b) wording is vague, open to interpretation and could capture almost all but the most readily excreted/degraded substances. Most substances 'bioaccumulate' to some degree. Given that the presence of bioaccumulative substances is a precluding condition, I recommend revisiting this definition to ensure that it's clear, can be applied consistently, and captures only substances that could pose a risk through bioaccumulation.	DRA is the appropriate tool for evaluating risks associated with bioaccumulative substances. This is due, in part, to consideration of toxicological processes and environmental fate and transport mechanisms that are beyond the scope of an SLRA process.
13	1.0	There are definitions for "LNAPL" and "DNAPL" but none of these two terms have been used in the protocol. Suggest deleting them.	Thank you for catching this. The terms have been deleted from the protocol.
1 and 13	1.0	definition of bioaccumulative substance: "(b) the substance is determined by best professional judgment of the qualified professional biologist preparing the SLRA report to have the potential to bioaccumulate based on relevant scientific information."  1) It has been our experience that professional judgement often identifies substances as bioaccumulative in direct contradiction to recent decision by Health Canada and Environment Canada. It is our recommendation that decisions regarding the bioaccumulative potential of a given substance be consistent with decisions by Environment Canada and Health Canada. 2) Should this clause be retained, the wording of the clause in Protocol 13 should be consistent with Protocol 1 such that a qualified professional is not limited to qualified professional biologists.	Thank you for your comment. While part (a) provides measurable thresholds that can be used to screen substances for their potential to bioaccumulate, there are substances which have the potential to bioaccumulate and would not be captured by those thresholds, such as ionic organic substances (e.g., per- and polyfluoroalkyl substances), and thus professional judgment is an important safety net to ensure substances not captured by part (a) are not excluded from consideration. The definition has been revised in reflection of comment 2).
1 and 13	1.0	"bioconcentration means the process leading to a higher concentration of a substance in an organism compared to the concentration of the substance in the <u>aquatic environmental media</u> to which the organism is exposed."  Recommend changing "aquatic environmental media" to "water column" since bioconcentration does not reflect sediment exposure.	Aquatic environmental media includes the water column above sediment and porewater within sediment. It is noted that the biota sediment accumulation factor is often used for modeling uptake potential from sediment and associated organic material. Future revision may expand on these concepts.

13	2.0	"submission to the director" should be clarified. What is the process of submission, assuming that per current practice that P13 can be used in P6 submissions? Wording in other sections (e.g., 5) is confusing (e.g., submitted to the ministry). Assuming that the intent is submitted in application for an AiP or CofC, including through the P6 process. Is a director's agreement required? see last comment below. [section 5.0].	Submission of an SLRA report completed as per Protocol 13 v. 4 is the same as previously: the SLRA may be submitted as part of an instrument application for a non-high risk site to the ministry (and, therefore, the director) through the Contaminated Sites Approved Professional (CSAP) Society of BC.
13	3.0	Clarification on whether a Professional Biologist visit is REQUIRED would be useful. Currently it is unclear.	As indicated in Appendix B, the habitat and receptor assessment, including a site visit for these purposes, may only be completed by a qualified professional.
13	3.1	Suggest to add: "It should be demonstrated that the existing contaminant plume is fully delineated and the extent of the plume is not reaching the potential human/aquatic receptors at a level exceeding applicable water use standards."	The suggested additions have not been included in the protocol. It is the ministry's opinion that the protocol language is sufficient to address the comment in that a Detailed Site Investigation (DSI), by definition, means full delineation and plumes extending to receptors are restricted by the precluding condition in section 3.2.
13	3.1	This section could likely use some additional text from Protocol 1, Section 2.4. In particular that the DSI must assert <i>"that for each potential contaminant of concern, the horizontal and vertical extent of contamination has been delineated"</i> .	The suggested addition has not been included in the protocol. It is the ministry's opinion that the protocol language is sufficient to address the comment in that a DSI, by definition, means full delineation (lateral and vertical extent) of any and all contamination.
13	3.2	Why are bioaccumulative substances a precluding condition for all depths? Could this be revised to "bioaccumulative substances, unless contaminants are not present in upper 1 m".	DRA is the appropriate tool for evaluating risk of bioaccumulative substances at all depths. However, the ministry may consider this comment in future revisions.

13	3.2	States ' <i>this protocol must not be used at contaminated sites where any of the following conditions are present: - deep-rooting plants or trees (root structures extending below 1m depth) in areas of soil or groundwater contamination (at sites where wildlands (natural or reverted), agricultural or low density residential land uses apply.</i> ' This wording implies that the condition does not consider certain potential mitigating factors. such as the nature and magnitude of the soil contamination present (what if only soil standards for groundwater protection are exceeded?) e.g. or the depth to groundwater (what if groundwater contamination is 5m deep?). Is it the intent for these conditions to be interpreted in absolute terms?	Yes, in absolute terms. SLRA is a conservative screening tool. However, the comment about the site-specific factor exceeded for the deep-rooting plants or trees precluding conditions is carried forward for future consideration.
13	3.2	Suggest adding a qualifier here such as "except in instances where existing deep-rooting plants/trees are thriving with no indication of contaminant-related stress." This is because some sites warrant SLRA when it is obvious that mature trees are quite happy with the contaminant conditions and there is no justification to remediate and remove the trees.	Thank you for the suggestion. While deep-rooting plants/trees may appear to be thriving when exposed to contamination, they may be providing a transport pathway for subsurface contaminants to reach the surface (e.g., leaf deposition). DRA is the appropriate tool for evaluating potential risk where deep-rooting vegetation is present within contamination.
13	3.2 & Questionnaire	The use of Protocol 13 is precluded for sites that have deep-rooting plants or trees at sites where wildlands, agricultural or low density residential land uses apply. Question TS-2 of the questionnaire relates to contamination within the top 1 m, whereby if contamination is greater than 1 m in depth, the question could be answered 'no' and therefore it is considered that a contaminant, pathway or receptor is not present for that pathway and that the pathway is inoperative. Can this be interpreted that ENV is not concerned with deep-rooting exposures to contamination to sub-surface soil (> 1 m bgs) for the other land uses not listed in the precluding conditions?	Precluding conditions are evaluated before entering the questionnaire. Therefore, if deep-rooting plants or trees are present, SLRA cannot be used at the site.

1 & 13	4.2 and 3.2/Figure 1	Draft Protocol 13 indicates that deep-rooted trees at a Commercial, Industrial or High-density Residential Land Use are not a precluding condition. Does deep-rooting vegetation exposure to subsurface contamination need to be evaluated at a Commercial, Industrial or High-density Residential Land Use in a SLRA or DRA? Contamination may not be present in the top 1 m of soil, resulting in a "N" in Question TS-2, potentially resulting in a No Unacceptable Risk in the SLRA, while there may still be subsurface contamination and exposure to deep-rooting vegetation. We recommend explicitly stating that deep-rooting vegetation exposure to subsurface contamination does not need to be evaluated at a Commercial, Industrial or High-density Residential Land Use since populations of these receptors are unlikely to occur.	For the purpose of an SLRA, deep-rooting vegetation exposure to subsurface contamination (below 1 metre) is not a precluding condition for Commercial, Industrial or High-density Residential Land Use. This "exception" exists because it is unlikely that populations of deep-rooting vegetation will be adversely impacted at these types of sites; however, this is appropriate for SLRA due to the limited scope and interplay with other precluding conditions that are not present for sites requiring DRA. The recommended statement wouldn't be appropriate for all Commercial, Industrial and High-density Residential Land Use sites. Further consideration may be given to this topic in future revisions.
13	Table 3.3.1	Sodium and chloride are mobile in the environment and a larger radius of beneficial use could be considered based on professional judgement. In addition, parking lots are not referenced and could be added.	The beneficial use exemption was developed for more highly trafficked areas such as roadways. While it is true that a larger radius may apply for salt contamination, a smaller radius may also apply, depending on the site-specific situation. Further consideration of this topic may be given in future revisions.
13	4.0	The steps outlined in this section could be refined. Step 1, under Problem Formulation, is to ' <i>review site information, prepare a report documenting site conditions, and include a conceptual site model</i> '. This is followed by a bulleted list of elements that the report should include. During Problem Formulation I agree that it is appropriate to review site information and develop a conceptual site model, based on site conditions. But it's premature to engage in reporting until Steps 2 and, arguably, Steps 3 and 4 are carried out to be sure that the protocol can be applied successfully. I suggest moving to Section 5 the general reporting text currently in Section 4.1.	Yes, the ministry concurs that refinement may be warranted. The ministry is reviewing this matter as a future consideration. Note that from a practical perspective, it is anticipated that most practitioners use SLRA as a screening tool throughout site investigation and remediation to identify those pathways requiring remediation for a successful SLRA. In such cases, complete reporting is likely not done until completion of all investigation and remediation activities.

13	4.3	<i>Bullet near bottom of page 11, "Qualified professionals must follow Appendix B when answering TS-4 and TS-5." To be consistent with the Questionnaire, should this text instead state "Registered professional biologists must follow Appendix B when answering questions TS-4 and TS-5"? IE) RPBio rather than "qualified professionals".</i>	Noted. Thank you for advising on this.
13	4.3	Could/should the Protocol 13 Questionnaire only require a R.P.Bio. to answer question TS-5? Could the simpler question TS-4 be answered by any type of professional preparing a screening level risk assessment. Note that Protocol 12's Site Risk Classification Questionnaire does not require an R.P.Bio. to answer the same identical TS-4 question in its Exposure Pathway Questionnaire.	To evaluate question TS-4, the qualified professional must have relevant experience in identification of ecological and sensitive habitat.
13	4.4	Sites that which have a 'yes' response to all questions within an exposure pathway series are considered to have unacceptable risk and to fail the SLRA and further remediation or detailed risk assessment is necessary. Can ENV clarify as to whether it is necessary to assess the entire site in DRA or just the failed exposure pathway series. It is unclear if Protocol 1 and Protocol 13 agree on this.	The ministry's policy has been updated in Protocol 13 and Protocol 1. If any requirement is not satisfied, or any precluding condition is present, or any pathway fails in SLRA, SLRA may not be used at the site. DRA or further remediation is necessary.
13	5.0	Must Screening Level Risk Assessments be stand-alone reports, or can SLRAs be a section in a combined DSI, Confirmation of Remediation, and Screening Level Risk Assessment document?	The ministry's preference is for a stand-alone report but the required report may be submitted as a section of a larger report, for example, as an appended document. Either way, the report must satisfy the reporting requirements prescribed in section 5.0.
13	5.0	It would now be required that SLRA be prepared as a standalone document submitted to the director and no longer seems that it can be submitted concurrently with an AP application. How review of a SLRA fits into the overall process for obtaining a regulatory instrument is not clear but it would now appear that using SLRA would be considered a pre-approval. However, this change does not seem to be reflected in the revised Protocol 6 document (and presumably the preapproval application form).	Submission of a SLRA report under Protocol 13 v. 4 is the same as previously. The SLRA may be submitted as part of an instrument application for a non-high risk site to the ministry (and therefore, the director) through the CSAP Society. Pre-approval from the director is not necessary for SLRA.
13	5.0	Bullet #5. Does the SLRA report need to include <i>"groundwater monitoring and geochemical data and trend analyses demonstrating plume stability in accordance with Section 6.0 and where applicable"</i> . Or can that information, typically in a Detailed Site Investigation, just be referenced?	The plume stability supporting documentation may be referenced from the companion DSI submission.

13	6.0	<p>Plume stability used in SLRA requires a minimum of 2 years of groundwater monitoring including seasonal variations. How many seasons does ENV require over the two years and must they be the same seasons in both years? Is quarterly sampling with samples collected three months apart sufficient, or are select months to be targeted?</p>	<p>As SLRA is a risk-based approach, the ministry has not prescribed the exact number of seasons and samples that must be collected for plume stability assessment. Instead, the qualified professional undertaking any plume stability assessment under the protocol must exercise their professional judgement in determining any spatial and seasonal variations and ensuring that the data collected is representative of the potential variations at the site. It is noted that trend analysis, or ascertaining seasonality, cannot be done without a minimum of two years of data.</p> <p>Also note that the protocol has been modified to incorporate plume stability language from the recently amended Technical Guidance 8 "Groundwater Investigation and Characterization", Version 3. A signatory page has also been added to Form C for the qualified professional undertaking any plume stability assessment under Protocol 13.</p>
----	-----	---	---

13	6.0	<p>Plume stability requirements are 2 years of data and consideration should be given to allow for professional judgement.</p> <p>Also consider adding "Plume stability evaluation is not required for flow-through sites which are evaluated using Administrative guidance 15."</p>	<p>As SLRA is a risk-based approach, the ministry has not prescribed the exact number of seasons and samples that must be collected for plume stability assessment. Instead, the qualified professional undertaking any plume stability assessment under the protocol must exercise their professional judgement in determining any spatial and seasonal variations and ensuring that the data collected is representative of the potential variations at the site. It is noted that trend analysis, or ascertaining seasonality, cannot be done without a minimum of two years of data.</p> <p>Where exercise of greater professional judgement is desired, this may be evaluated under DRA as per the recently amended Technical Guidance 8, Version 3.</p> <p>The requirement for plume stability for flow-through sites has not been changed in the protocol. The requirement is necessary to limit the potential for increasing concentrations at the affected parcel.</p>
13	6.0	<p>A 2 year requirement has been specified for data collection to demonstrate plume stability but the number of data points to be collected has not been specified. In order to avoid delays of brownfield / industrial land redevelopment, would quarterly sampling of one data not suffice?</p>	<p>As SLRA is a risk-based approach, the ministry has not prescribed the exact number of seasons and samples that must be collected for plume stability assessment. Instead, the qualified professional undertaking any plume stability assessment under the protocol must exercise their professional judgement in determining any spatial and seasonal variations and ensuring that the data collected is representative of the potential variations at the site. It is noted that trend analysis, or ascertaining</p>



			<p>seasonality, cannot be done without a minimum of two years of data.</p> <p>Where exercise of greater professional judgement is desired, this may be evaluated under DRA as per the recently amended Technical Guidance 8, Version 3.</p>
13	6.0	<p>Regarding the requirements for demonstrating plume stability (per Protocol 13 and generally), please consider the possibility of allowing QPs to use professional judgment in making this determination. In particular, sites that have small plumes or where remediation has shown a substantial reduction leaving minor residual plumes, our experience has shown that there is often little chance for gross plume instability leading to subsequent migration. Maybe there could be a tiered process for 'low' to 'high' risk plumes and conditions where the minimum monitoring requirements described in Section 6.0 and the CS e-link update dated February 1, 2019 could be prioritized for high risk plumes, leaving some professional judgment on moderate risk plumes and full professional judgment on low risk plume.</p>	<p>As SLRA is a risk-based approach, the ministry has not prescribed the exact number of seasons and samples that must be collected for plume stability assessment. Instead, the qualified professional undertaking any plume stability assessment under the protocol must exercise their professional judgement in determining any spatial and seasonal variations and ensuring that the data collected is representative of the potential variations at the site. It is noted that trend analysis, or ascertaining seasonality, cannot be done without a minimum of two years of data.</p> <p>Where exercise of greater professional judgement is desired, or to address more site-specific cases such as those identified in the commentary, this may be evaluated under DRA as per the recently amended Technical Guidance 8, Version 3.</p>
13	Appendix A/Intro	<p>States '<i>Steps 1, 2 and 3 must be completed</i>'. Is this accurate? You would only do Steps 1 and 2 if you didn't have relevant groundwater data (e.g. there is a confining layer).</p>	<p>Steps 1, 2 and 3 must be completed. The presence of a confining barrier is not considered in the pathway evaluations. Relying on groundwater data alone is not possible in SLRA as it does not meet protocol requirements.</p>
13	Appendix A/Intro	<p>it should be indicated that calculation can only be done using the BC GPM in the intro instead of at the end of Appendix A by a one liner (i.e., reference TG13 etc. as well). The entire last paragraph of App</p>	<p>The Groundwater Protection Model (GPM), as provided in Technical Guidance 13 "Groundwater Protection</p>

		A could be moved to the last paragraph in the intro of App A.	Model", is used in Section 4.0/Step 4 and the ministry considers this the appropriate place to reference the model.
13	Appendix A/Sections 1.1 and 1.2	Could not find the BC Soil Leachate Tests in the updated Section B of the 2020 BC ENV Lab Manual even though it is indicated as such on their webpage. Why?	The leachate test methods are provided in Sections B and D of the BC Environmental Laboratory Manual.
13	Appendix A/Section 1.3	first paragraph, last sentence - we tried to find out which inorganic substances cannot be leachate tested under the BC Soil Leachate Test by reviewing Protocol 27 and BC Lab Manual. Protocol 27 indicates that the BC Leachate Test only applies to matrix substances (schedule 3.1) and we couldn't find the BC Leachate test in the updated 2020 BC ENV Lab manual to determine which substances can be tested under that method. So it is unknown which inorganic parameters can or cannot be subjected to the BC Leachate Test, can ENV provide a list of parameters in which leachate concentrations can be calculated based on soil concentrations? and also why the BC Leachate Test method is not in the BC ENV lab manual (as above)?	The parameters for leachate testing are the same as the previous version of the protocol. The leachate test methods are provided in Sections B and D of the BC Environmental Laboratory Manual.
13	Appendix A/Section 4	<p>For Equation A-5, the distance to point of compliance, x, is measured "<i>from all points along the <b>boundary of the contaminant plume</b> or, where groundwater contamination is not present, all points along the boundary of the contaminant source are.</i>" This is not consistent with the definition of maximum predicted/measured groundwater concentration, <math>C_{gw}/C_{gwmax}</math>, which is right "<b>below the source</b>".</p> <p>It is common that groundwater concentration decreases significantly within a short distance from the source area under the natural attenuation (typically, first-order) process. Therefore, it is scientifically more accurate to define "x" as the distance from the point of compliance to "the centre of the source area" where the maximum concentration is obtained instead of "the boundary of the contaminant plume".</p>	SLRA is a conservative screening tool. Using the plume boundary as the starting point is similar to previous versions of the protocol.

13	Appendix A/Section 4	<p>Points of compliance (PoC) are set at the property boundary in the case of applicable DW, IW and LW rather than the receptor which is the PoC for DW. This is restrictive and consideration should be given to the receptor (i.e. Water Well or Spring).</p> <p>We understand that ENV is concerning about the potential of adjacent property owners having to address contamination sourced from other properties in the future; however, this would not be a concern if the contaminant plume has been demonstrated to be <b>(i) stable via a 2-year monitoring or a steady-state transport modelling stated in Appendix A; and (ii) not reaching the potential human/aquatic receptors based on current and future land uses.</b></p> <p>Note that Equation A-5 in Appendix A is a <b>steady-state analytical solution of Domenico Model</b> (1987). The modelling results from Equation A-5 represents a steady (i.e. completely stabilized) plume when the simulation time is reaching infinity - which is much more conservative than the results from a 2-year monitoring.</p>	SLRA is a conservative screening tool. Using the property boundary as the compliance point is similar to previous versions of the protocol.
13	Appendix A/Section 4	<p>Current version of P13 includes the use of the public domain US EPA model BIOSCREEN as the groundwater contaminant transport model in place of Equation A-5 with prescribed conditions. However, the new draft version of P13 does not have it.</p> <p>The US EPA BIOSCREEN (and the BIOSCREEN-AT which is the updated version of BIOSCREEN using the exact 3-D transient analytical solution) program is widely used by the practitioners world wide as a screening model based on the same Domenico model used by ENV as laid out in Appendix A. The benefits of allowing the use of BIOSCREEN/BIOSCREEN-AT program are that:</p> <ul style="list-style-type: none"> <li>- it is programmed in a user-friendly Microsoft Excel spreadsheet environment;</li> <li>- it provides transient results showing how the plume evolves with time;</li> <li>- the plume stability can be easily evaluated based on the simulation results at various time steps;</li> <li>- the numerical results from a large time scale (e.g. 500 years) simulation are comparable to the results from Equation A-5 of Appendix A;</li> <li>- it incorporates field data that allows the user to calibrate the site-specific model parameters;</li> <li>- it simulates a two-dimensional plume that allows</li> </ul>	SLRA has been simplified to remove use of the US EPA BIOSCREEN model from the protocol as the GPM provides similar functionality for purposes of SLRA calculations and the ministry has observed only limited use of BIOSCREEN in SLRA report submissions. Practitioners may wish to use BIOSCREEN as part of remediation activities for the purposes identified in the commentary or for preliminary SLRA calculations. However, where SLRA is submitted to a director, the GPM must be used.

		<p>the user to validate the model with spatial data collected in the field; and</p> <ul style="list-style-type: none"> <li>- It also includes numerical tools for the evaluation of natural attenuation potential/capacity and total mass balance that would be useful for the remediation design</li> </ul> <p>Therefore, it is strongly recommended to keep the option of using the public domain model BIOSCREEN/BIOCREEN-AT in Appendix A of P13.</p>	
13	Appendix A /Table A-1	log Kow could be provided in this table to allow practitioners easy reference for BAS.	Noted. Thank you for suggesting this. The ministry may consider this in future revisions.
13	Appendix A/References	The references have been deleted. References are necessary for the protocol. Consider reinstating the references in the protocol.	Reference sources may be requested from the ministry as an enquiry by using the ministry's Contact Us webpage.
13	Appendix A/References	We have noticed that the reference in the tables have been removed and new substances have been added. The references are useful and should remain in the table so that is clear where the values have originated. Consider keep in the references sources.	Reference sources may be requested from the ministry as an enquiry by using the ministry's Contact Us webpage.
13	Appendix B/Section 2	In selection of site-specific receptors, text added that the potential presence includes assessment of <u>"what would be anticipated if the site was not developed"</u> in addition to what is there currently. What does "not developed" mean (i.e., from it current development, never developed, other)? This requirement is subjective and would be prone to differing professional opinions.	Thank you for the comment. The intent of this statement is to consider what the site may look like in a natural undisturbed condition (i.e., never developed). The protocol has been revised to reflect this comment.
13	Appendix B/Section 3	Text has been added that the assessor must state if it is their professional opinion as to whether the vegetation or invertebrates at the site are stressed because of site contamination or whether the conditions are typical for that geographic area at the time of the site inspection. This requirement could require the assessor to carry out investigation work to see what is there; specifically, in regard to invertebrates, it would appear to require more than just a visual observation during a site recon.	Correct. Thank you for your comment.
13	Appendix B/Section 3	States, <i>'The assessor must state if it is their professional opinion as to whether the vegetation or invertebrates at the site are stressed because site contamination or whether the conditions are typical for that geographic area at the time of the site inspection.'</i> How does this factor into the SLRA? It is not included in the questionnaire.	This statement addresses an indicator of the quality of habitat, which is a key consideration in determining habitat suitability. Section 3 of Appendix B describes the process a qualified professional must follow to determine habitat suitability for the purpose of answering Question TS-5 in the questionnaire.

13	Appendix B/Section 3.0 and Form B-3	Habitat size. " <i>A no indicates that the land is too small to support the receptor</i> ". Reference is made to checking home range to answer this question. What degree (fraction or percent) of home range is considered too small to "support" the animal? Or is this question to be answered solely on professional judgement?	The term "potential terrestrial habitat" is defined at the beginning of the protocol and provides information related to habitat size to be considered for various land uses. Figure 4 of Protocol 13 reiterates this information. If the area of the site is smaller than the range needed by the receptor, it may still be used by the receptor and should be considered in the SLRA. Only in a DRA can this exposure term be adjusted to account for this.
13	Appendix B/Section 3.0 and Form B-3	Habitat quality. Why is habitat quality "Not Applicable" for sites of sufficient size and having physical connectivity to another habitat? Couldn't there still be aspects of a site, e.g. adjacent to a noisy roadway that made it low quality for some types of wildlife?	Pre-set entries in Form B-3 are based on the limited scope (i.e., simple pathways evaluation) for which an SLRA may be used. DRA is the appropriate tool for consideration of site-specific factors such as limited habitat quality in areas of sufficient size and connectivity as described in Protocol 13.
13	SLRA Questionnaire HW-3	Question asks, ' <i>Is there the potential for soil leachate or contaminated groundwater to migrate to a water well used for drinking water on the parcel or to migrate beyond the parcel boundary at concentrations greater than the drinking water standards?</i> ' Why does migration beyond a parcel boundary at concentrations above drinking water standards result in a failed SLRA? Appendix A contains methods for predicting contaminant concentrations in groundwater at a point of compliance, which could be an offsite drinking water well. We know that the analytical results from Equation A-5 in Appendix A represent an ultimate, stabilized plume at the time of infinity (i.e. a steady-state condition) which is more conservative than the 2-year monitoring results. If a pathway can't be ruled out, this can be addressed with simple risk controls. It seems to be an unnecessary limitation on the applicability of SLRA.	The ministry's intent is to not inadvertently cause contamination of adjacent properties. In such cases, the adjacent properties would become encumbered and would need to deal with the contaminant migration. Accordingly, the ministry seeks to minimize transference of this potential responsibility/problem to adjacent property owners. This provision is the same as in the previous protocol version.

13	SLRA Questionnaire AW-3	Question asks, ' <i>Is there the potential for soil leachate or contaminated groundwater to migrate to an aquatic receiving environment on the parcel or to migrate beyond the parcel boundary at concentrations greater than the aquatic life water standards?</i> ' Why does migration beyond a parcel boundary at concentrations above aquatic life water standards results in a failed SLRA? Appendix A contains methods for predicting contaminant concentrations in groundwater at a point of compliance, which could be an offsite aquatic receiving environment. We know that the analytical results from Equation A-5 in Appendix A represent an ultimate, stabilized plume at the time of infinity (i.e. a steady-state condition) which is more conservative than the 2-year monitoring results. It seems to be an unnecessary limitation on the applicability of SLRA.	The ministry's intent is to not inadvertently cause contamination of adjacent properties. In such cases, the adjacent properties would become encumbered and would need to deal with the contaminant migration. Accordingly, the ministry seeks to minimize transference of this potential responsibility/problem to adjacent property owners. This provision is the same as in the previous protocol version.
13	SLRA Questionnaire IW-3	Question asks, ' <i>Is there the potential for soil leachate or contaminated groundwater to migrate to a water well used for drinking water on the parcel or to migrate beyond the parcel boundary at concentrations greater than the drinking water standard?</i> ' Why does migration beyond a parcel boundary at concentrations above irrigation standards results in a failed SLRA? Appendix A contains methods for predicting contaminant concentrations in groundwater at a point of compliance, which could be an offsite irrigation well or agricultural property. We know that the analytical results from Equation A-5 in Appendix A represent an ultimate, stabilized plume at the time of infinity (i.e. a steady-state condition) which is more conservative than the 2-year monitoring results. If a pathway can't be ruled out, this can be addressed with simple risk controls. It seems to be an unnecessary limitation on the applicability of SLRA.	The ministry's intent is to not inadvertently cause contamination of adjacent properties. In such cases, the adjacent properties would become encumbered and would need to deal with the contaminant migration. Accordingly, the ministry seeks to minimize transference of this potential responsibility/problem to adjacent property owners. This provision is the same as in the previous protocol version.
13	SLRA Questionnaire LW-3	Question asks, ' <i>Is there the potential for soil leachate or contaminated groundwater to migrate to a water well used for livestock watering on the parcel or to migrate beyond the parcel boundary at concentrations greater than the livestock watering water standards?</i> ' Why does migration beyond a parcel boundary at concentrations above livestock watering standards results in a failed SLRA? Appendix A contains methods for predicting contaminant concentrations in groundwater at a point of compliance, which could be an offsite livestock well or agricultural property. We know that the analytical results from Equation A-5 in Appendix	The ministry's intent is to not inadvertently cause contamination of adjacent properties. In such cases, the adjacent properties would become encumbered and would need to deal with the contaminant migration. Accordingly, the ministry seeks to minimize transference of this potential responsibility/problem to adjacent property owners. This

		<p>A represent an ultimate, stabilized plume at the time of infinity (i.e. a steady-state condition) which is more conservative than the 2-year monitoring results.</p> <p>If a pathway can't be ruled out, this can be addressed with simple risk controls. It seems to be an unnecessary limitation on the applicability of SLRA.</p>	<p>provision is the same as in the previous protocol version.</p>
13	SLRA Questionnaire DF-2	<p>Question asks, 'Is there the potential for soil leachate or contaminated groundwater to <b>migrate beyond the parcel boundary at concentrations greater than the VHW6-10 or EPHW10-19 water standard?</b>' Why does migration beyond a parcel boundary at concentrations above these default standards results in a failed SLRA? Appendix A contains methods for predicting contaminant concentrations in groundwater at a point of compliance.</p> <p>We know that the analytical results from Equation A-5 in Appendix A represent an ultimate, stabilized plume at the time of infinity (i.e. a steady-state condition) which is more conservative than the 2-year monitoring results.</p> <p>It seems to be an unnecessary limitation on the applicability of SLRA.</p>	<p>The ministry's intent is to not inadvertently cause contamination of adjacent properties. In such cases, the adjacent properties would become encumbered and would need to deal with the contaminant migration.</p> <p>Accordingly, the ministry seeks to minimize transference of this potential responsibility/problem to adjacent property owners. This provision is the same as in the previous protocol version.</p>
13	SLRA Questionnaire, Future Drinking Water Use	<p>I suggest that for the drinking water pathway, current drinking water be separated from future drinking water. The future drinking water questions would be adjusted to include additional questions along the line of "is a municipal supply available in to service the site?" "will a Schedule B condition be imposed to prohibit the use of site groundwater for drinking?". Many of the sites I work on have only a future drinking water pathway and although we do not have to do calculations, we are bumped into a detailed risk assessment when it could be assessed as an SLRA.</p>	<p>This may be done currently under SLRA as long as all requirements, section 3.2 and the questionnaire are satisfied. In such cases, an institutional control, or Type II condition, such as restriction of drinking water use at the site, would be applied in a Performance Verification Plan (PVP) as part of instrument application. See the ministry's PVP webpage for further information.</p> <p>The ministry will evaluate clarification language on this matter in the protocol as a future consideration.</p>

13	SLRA Questionnaire, Questions HW-1 to HW-3 Section 4.3 Evaluation of Potential Exposure Scenarios Section 5.0 Reporting	Protocol 13 only evaluates the drinking water exposure pathway with respect to migration to existing wells on the parcel or to property boundary. In regards to future drinking water use shouldn't Protocol 13 include the same requirements as Protocol 1, i.e. need to provide " <i>rationale by which the future drinking water pathway was determined to be incomplete or inoperative</i> ", and recommendations for a risk control prohibiting use of site groundwater as potable water?	This may be done currently under SLRA as long as all requirements, section 3.2 and the questionnaire are satisfied. In such cases, an institutional control, or Type II condition, such as restriction of drinking water use at the site, would be applied in a Performance Verification Plan (PVP) as part of instrument application. See the ministry's PVP webpage for further information.  The ministry will evaluate clarification language on this matter in the protocol as a future consideration.
13	SLRA Questionnaire, Question TS-4 Section 3.0 Form C Professional Statements	The present wording of the Questionnaire, Section 3.0 and Professional Statements pages introduces a new requirement to SLRA that only RPBios with <b><u>experience in habitat assessment</u></b> can perform a simple evaluation of "Potential Terrestrial Habitat". Can ENV clarify if that is correct, or can any RPBio regardless of experience in wildlife habitat be able to answer Question TS-4 regarding potential terrestrial habitat? Question TS-4 is often a relatively simple evaluation of area of undeveloped land. TS-4 could also potentially be answered by any professional preparing a screening level risk assessment.	A qualified professional with relevant experience in identification of ecological and sensitive habitat must evaluate questions TS-4 and TS-5.
13	Form C Professional Statements	Does ENV wish these professional statements to be within the text of a SLRA report? Or does ENV prefer they are separate signed pages in an Appendix?	Yes, the ministry's preference is for signed pages in an appendix. Please note that forms provided in Protocol 13 include signature lines and must be used.



## Appendix 8. Protocol 16: Determining the Presence and Mobility of Non-Aqueous Phase Liquids and Odorous Substances.

Protocol #	Section #	Comment/Recommendation	Ministry Response
16	Cover Page	Is P12 being updated to base the high risk classification on "migrating" NAPL rather than "Mobile" (which should be termed "Potentially Mobile" to be scientifically correct)	In accordance with proposed updates to Protocol 12, if mobile NAPL is present at a site, the site is classified as high risk until it can be demonstrated that the NAPL source is not migrating.
16	General	It is not clear why the introduction of a new term "migrating NAPL" was required and how that would be different from "Mobile LNAPL".	The term "migrating" NAPL was introduced based on new ITRC definitions. Mobile NAPL= it has the potential to move Migrating NAPL= it is moving
16	General	For determining DNAPL presence/mobility using 1%/10% theoretic solubility – use theoretic solubility cited in RAIS?	The solubility limits that are acceptable are the ones used on the groundwater model from Technical Guidance 13 (PHYSPROP theoretical solubility value).
16	General	For parameters with a range of theoretic solubilities, does the ministry have guidance on which value to select?	Please use the Technical Guidance 13 values.
16	General	Will the ministry be providing an updated table with theoretic solubilities for regulated substances?	Please use the Technical Guidance 13 values.
16	General	The addition of a definition for migrating NAPL vs. mobile NAPL is a notable improvement, along with incorporating the use of science-based approaches to demonstrate NAPL mobility	Thank you for your comment.
16	1	Suggest change: "mobile NAPL" to "Potentially Mobile". See comment below regarding Section 3.0.	The expression "potentially mobile" was changed to "mobile" because the new term "migrating NAPL" was introduced. Mobile NAPL is determined based on presence/absence as explained in the protocol; this does not imply that the NAPL is actually moving. For the NAPL to be considered moving it has to meet the criteria specified in the "migrating NAPL" section.
16	1	Suggest change: "“nonaqueous phase liquid” [NAPL] means a liquid that does not dissolve in water and forms a separate physical density phase from water." to "NAPL does not mix with water, but as soluble in water."	We amended the definition to provide more clarity.
16	1	Suggest change: "...of a chemical compound..." to "...of a single chemical compound..."	The ministry believes that is implicit that the theoretical solubility limit is for a single chemical compound.

16	1	Comment on theoretical solubility limit: It would be helpful if BC ENV provided a technical reference or appendix for this. For example, BC ENV previously used 150 mg/L for PCE, although the industry value was 200 mg/L. In the draft Protocol 28, they are now accepting 206 mg/L. For mobile DNAPL in the context of PCE, common for dry cleaners, that moves the concentration from 15 mg/L to 20.6 mg/L for determining mobile DNAPL and classification as a 'High Risk' site. This has implications for many projects and a technical reference or appendix to this protocol would be helpful.	Theoretical solubility values are the ones used in Technical Guidance 13 (groundwater water model).
16	1	"nonaqueous phase liquid [NAPL]" definition is ambiguous due to the "and" construct. What if a liquid has low solubility in water, has reached saturation and remains in free phase? It still qualifies as a NAPL. Same with current definition in P8.	The definition has been amended for clarity.
16	1	"free phase liquid" definition: suggest using "adsorbed" rather than "absorbed" for accumulation at the solid/liquid interphase (i.e. "onto soil" not "into soil")	This change has been made.
16	2	Suggest rewording: "evaluates site conditions for classifying sites as high risk sites based on an evaluation of risk to human health and the environment." to better match the wording in Section 3.2 "Mobile NAPL is therefore a factor which is considered in classifying the risks a site poses to human health and the environment."	Draft protocol wording follows that in the Environmental Management Act (EMA) and the Contaminated Sites Regulation (CSR).
16	3	Suggest change: "Present, mobile and migrating nonaqueous phase liquids (NAPLs)" to "Present and potentially mobile nonaqueous phase liquids (NAPLs)"	The expression "potentially mobile" was changed to "mobile" because the new term "migrating NAPL" was introduced. Mobile NAPL is determined based on presence/absence as explained in the protocol; this does not imply that the NAPL is actually moving. For the NAPL to be considered moving it has to meet the criteria specified in the "migrating NAPL" section.
16	3.1.1	Comment: "a) free phase liquid is found in soil or on the soil surface." These visual observations are subjective and difficult to ascertain. It is difficult to determine the difference between heavy staining and observation of free-phase liquid, unless the soil is dripping with NAPL."	Thank you for your comment. At this time, the ministry does not intend to be more prescriptive.

16	3.1.1	Comment: "...on the soil surface". For LNAPL and DNAPL this seems more relevant to an Emergency Spill Response than typical investigations that fall under the CSR.	A site can still be considered high risk from an Emergency response. If there is product on the surface, the site is high risk.
16	3.1.2	Same comments as for 3.1.1.	A site can still be considered high risk from an Emergency response. If there is product on the surface, the site is high risk.
16	3.1.2	Consider adding: Or at 10% of the estimated co-solubility of the substance. It is relatively easy to estimate the co-solubility for some DNAPL (chlorinated solvents) but more difficult for others (creosote).	We consider having 1% of individual substances to be conservative for the purposes of this protocol.
16	3.2	Similar to comment in 3.1.2, for PCE, the 1% would now be 2,060 ug/L instead of previous 1,500 ug/L.	This is based on the values provided in Technical Guidance 13.
16	3.2.1 a)	Comment on "LNAPL is present over an area greater than 10 m <sup>2</sup> on the land surface;" Similar to Section 3.1, this is subjective. We suggest it should be based on pooling or dripping of liquid; and not merely staining.	The protocol doesn't reference "staining". It is expected that for a site to be high risk due to surface free phase liquid, it is due to the presence of a readily discernible volume of product.
16	3.2.1 b)	Comment on "LNAPL is present in fractured bedrock;" This is subjective. It would help with some guidance of what to look for, liquid running out of fractures in cores, etc.	This is not a site investigation protocol. It is up to the opinion of a professional to determine if there is LNAPL present in fracture bedrock.
16	3.2.2 - subheader	Suggested change from "When DNAPL is mobile" to "When DNAPL is potentially mobile"	The expression "potentially mobile" was changed to "mobile" because the new term "migrating NAPL" was introduced. Mobile NAPL is determined based on presence/absence as explained in the protocol; this does not imply that the NAPL is actually moving. For the NAPL to be considered moving it has to meet the criteria specified in the "migrating NAPL" section.
16	3.2.2	General comment: Three of the conditions in this section are the same as for "Presence" and are redundant. Determining "Actual Mobility" should be based on scientific assessment, and "not rule of thumb" conditions as is done in the next section.	The conditions for DNAPL mobility are not the same as the conditions for DNAPL presence. This section refers to the presence of mobile DNAPL, the next section 3.2.3 determines if the DNAPL is migrating (actually moving).

16	3.2.2 a) and b)	<p>Comment on "a) DNAPL is present in fractured bedrock;" and "DNAPL is present over an area greater than 10 m2 on the land surface;"</p> <p>This is the same condition as for "Presence". The classification of mobility should be set at a higher level, or overridden by a more detailed assessment, like what is described in point (c).</p>	Section 3.2.2 of protocol amended for clarity.
16	3.2.2 d)	<p>Comment on "DNAPL is present over an area greater than 10 m2 on the land surface;"</p> <p>This is the same condition as for "Presence". The classification of mobility should be set at a higher level like 20 mm, similar to point (e) (10% up from 1% of theoretical solubility).</p>	The conditions on Section 3.2.2 have been amended.
16	1, 3.2.1, 3.2.2, 3.2.3	<p>The draft P16 has added a new definition of "migrating NAPL" which is different from "mobile NAPL". Please confirm that if mobile NAPL is identified on the Site via 3.2.1 and 3.2.2, the Site will remain high risk until the mobile NAPL is removed, and that NAPL would still be considered Mobile if it is not determined to be migrating, per section 3.2.3. The regulatory purpose of the term "migrating NAPL" is not clear therefore, as the site would still be high risk if NAPL is determined to not be migrating.</p>	The site would not be high risk if the NAPL was determined to not be migrating. This is addressed in Protocol 12.
16	3.2.1e and 3.2.2.e	<p>"advancement of LNAPL across a monitoring well network" is not defined. Which conditions would be interpreted as advancement across a MW network? While we all have an idea, it would be beneficial to further define this.</p>	We rely on the professional judgement of the consultants to determine if LNAPL is advancing through a well network.

## Appendix 9. Protocol 17: Site Remediation Forms.

Protocol #	Section #	Comment/Recommendation	Ministry Response
17	General	We note the addition of Appendix 3 to include the SOSC (Summary of Site Condition) form.	Yes, this is the main revision to Protocol 17.
17	General	In the form -"Notification of Independent Remediation" and Section VIII, Section X and Section XII; a correction is required from "Evacuation and Disposal" to "Excavation and Disposal"	Thank you, we will have this typo corrected on the form.
17	General	The Summary of Site Condition form requires a separate section if ENV were to complete the review to reflect sections 7.0 to 9.0 accordingly. The current form is limiting in its ability to make any substantial changes.	Thank you, the fillable pdf version of the form is available on the forms webpage. The form is not intended to be changed.
17	General	Will these be provided also as fillable forms?	Yes - fillable forms can be accessed and downloaded from our forms webpage
17	General	Should include a list of what ENV applications require a SOSC.	This information can be found on the "Apply for services" page on the ENV website. It's also included in Protocol 6 and Protocol 12.
17	1.0	The number of terms is reduced considerably and the reference/link to Procedure 8 is removed. A general reference to Procedure 8 in this section would be helpful for readers who are not intimately familiar with the full list of words, acronyms, terms and expressions defined by the Ministry.	Procedure 8 will be gradually taken out of circulation. You can find definitions in the <i>Environmental Management Act</i> and the Contaminated Sites Regulation. Other definitions have been provided in the relevant protocols.
17	5.0	A SoSC is required as part of some ENV service applications (e.g. COC, Determination, AIP, Background Release, etc.) but not others (AG-6 Release, P6 Pre-Approval, etc.). Suggest including some further discussion to clarify which ENV service applications require submission of a SoSC.	This information can be found on the "Apply for services" page on the ENV website. It's also included in Protocol 6 and Protocol 12.
17	SoSC Section 4.4	We recommend the row about Protocol 2 and Protocol 4 be split. i.e.: <ul style="list-style-type: none"> <li>o <b>Has a Protocol 2 (site-specific) standard been applied?</b></li> <li>o <b>Has a Protocol 4 (background) standard been applied?</b></li> </ul> In our opinion, it might be preferable to list substances here for which P4 or P9 concentrations have been applied (see note below)	Thank you for your comments, we will make this addition to the SoSC form in the final version.

17	SoSC Section 4.4	For vapour, we recommend removing the "other" box and replacing it with a row underneath below asking if a Vapour Attenuation Factor has been applied? This would be more direct.	The "other" check box is to indicate that a different land use and corresponding Vapour Attenuation Factor are being applied, other than that for the current land use.
17	SoSC Section 5.3	The inclusion of background can somewhat confusing here. If concentrations originally exceeded the P4 or P9 concentrations and were remediated to meet P4/P9 concentrations, then it makes sense to include this here. However, if the concentrations never exceeded the P4/P9 concentrations, then by Section 11(3), this is not considered contamination. As such, remediation has not occurred. In our opinion, it would make more sense to add to Section 4 somewhere, a list of substances that exceed numerical standards but are less than P4/P9.	This column should only be filled out if remediation was or will be to background concentrations, otherwise it will be left blank and either numerical or risk-based will be indicated.
17	Appendices 1-3	The fillable forms provided are locked and don't allow insertion of attachments into the electronic document. However, attachments are specifically required (site plan, LTO, list of PCOCs, etc.). An unlocked version of the Appendices should be made available to practitioners or the form protections should be modified to allow attachments.	The forms are enforceable so they could not be changed/edited. The attachments could be submitted separately.
17	Appendices 1-3	The current Site Profile form allows for checking a box as a means of 'signing' rather than printing/signing/dating/scanning/re-inserting. Suggest updating all forms to allow for a signature check box rather than requiring an actual signature.	A signature and stamp are required for these prescribed forms. However, they do not require a 'wet' signature and can be a digital signature.
17	Appendices 1-3	Have these forms been updated for this protocol? NOIR version needs to be added to first page of form (version 4.1). Can ENV add date of update to form so that it is clear if a new or old form is being used after Feb. 1, 2021?	All of the previous versions of these forms will no longer be available online. Only the current form versions will be posted on our webpage. We do not recommend saving the forms to your computer; rather we expect that you download them from our webpage every time you need them.
17	Appendices 1-3	will these forms be electronically accessible for filling out?	Yes - fillable forms can be accessed and downloaded from our forms webpage
17	Appendix 3	SoSC form - Part 6 needs some formatting	We could not identify any formatting issues with Part 6.



## Appendix 10. Protocol 28: 2016 Standard Derivation Methods.

Protocol #	Section #	Comment/Recommendation	Ministry Response
	Overall	<p>The revisions to P28 appear to be substantial, as the existing version is limited to Chapter 4 (Derivation of Soil and Groundwater Protection Soil Matrix Standards), and the revised P28 has included at least 7 other additional Chapters into the Protocol (listed below). On initial review of P28 we did not find note significant concern in the revisions, but similar to our comments for P1 above, we believe that professional risk assessors will be in a better position to provide substantive P28 comments. <u>Additional Chapters:</u></p> <ul style="list-style-type: none"> <li>o Derivation of Human Health Protection Soil Standards</li> <li>o Derivation of Ecological Protection Soil Standards</li> <li>o Derivation of Generic Water Use Standards</li> <li>o Derivation of Generic Vapour Standards</li> <li>o Derivation of Generic Sediment Standards</li> <li>o Toxicity Reference Value Database</li> <li>o Background Adjusting Soil Standards</li> </ul>	Thank you for the comment. Many professional risk assessors provided comments for the ministry's consideration, although it is noted that the ministry has staff who are professional risk assessors and they wrote this revised protocol.
28	1.1	TR 1E-06 is included, but TR of 1E-05 is not?	Thank you for your comment, it has been deleted from the acronym list.
28	1.1	FCSAP = Federal Contaminated Sites Action Plan	Thank you for your comment, this change has been made.
28	1.2	<p>In the paragraph at the top of page 8, there is the statement "<i>Thus, this protocol provides qualified professionals with the toxicological equations, assumptions and parameters used in setting generic numerical standards, thereby providing information for deriving risk-based standards via risk assessment processes.</i>" There are numerous sections (e.g., 2.6, 3.3, 5.2.1, 5.2.3.1) in which "must" statements are made regarding requirements for deriving risk-based standards.</p> <p>Protocol 1 should be clear that such requirements are contained in Protocol 28. Or perhaps these "must" statements should be included in Protocol 1 rather than Protocol 28.</p> <p>Does/will ENV support use of their assumptions (e.g., soil ingestion rates, exposure terms) in risk assessments submitted in support of recommendations made by risk assessment approved professionals under Protocol 6 (further</p>	The ministry has considered this comment and made changes to relevant protocols. Ensure the requirements of conducting detailed risk assessment in BC at contaminated sites are followed as legally required in Protocol 1 "Detailed Risk Assessment".

		specific details are provided in comments below)?	
28	2.1	First bullet - "Part 1 Matrix Soil Standards". This should probably be "Matrix Numerical Soil Standards" per Section 11 (1) (a) (ii) of the CSR	Thank you for your comment, this change has been made.
28	Table 2-2	Soil ingestion rates for CL and RLHD not consistent with HC guidance.	The ministry assumes commercial and high density residential land uses will have less contact with soil, therefore their soil ingestion rates are lower. The values identified in this protocol are the legal requirement for calculating numerical standards for the Schedules of the Contaminated Sites Regulation (CSR).
28	Table 2-3	For IL ET, the use of an ET that includes 35/80 for non-carcinogens is not consistent with HC guidance.	The ministry's default parameters (e.g. exposure terms) are not necessarily adopted outright from another jurisdiction. The nature of the CSR standards is to be conservative, which is reflected in the equation parameters selected. The values identified in this protocol are the legal requirement for calculating numerical standards for the Schedules of the CSR.
28	Table 2-3	For PL and CL ET, the use of an ET that includes 12/24 for the soil ingestion pathway, along with the soil ingestion rates included in the doc, is not consistent with HC guidance.	The ministry's default parameters (e.g. exposure terms) are not necessarily adopted outright from another jurisdiction. The nature of the CSR standards is to be conservative, which is reflected in the equation parameters selected. The values identified in this protocol are the legal requirement for calculating numerical standards for the Schedules of the CSR.
28	2.4	In the second paragraph (at the bottom of page 10), it is stated " <i>It is expected that toddler and adult receptors at high density residential and commercial sites would come into contact with much smaller amounts of soil due to greater proportion of paved surfaces and areas covered by buildings. The ministry therefore assumes that half the amount of soil is ingested, i.e., 40 mg/day of soil for toddler and 10 mg/day for adults (Table 2-1).</i> " Technical Guidance 7 refers to following Health Canada guidance for exposure parameters (i.e., PQRA Part I). The reductions in soil intake rates are not	Submissions are considered on a site-specific basis, and technical rationale supporting the assumptions should be provided for evaluation during the submission of application. Follow the requirements of conducting detailed risk assessment in BC at contaminated sites as legally required in Protocol 1.

		<p>considered in PQRA Part I.</p> <p>Does/will ENV support use of these reduced soil intake rates in risk assessments submitted in support of recommendations made by risk assessment approved professionals under Protocol 6, or as direct submission made to and reviewed by ENV?</p>	
28	2.5	<p>In the second paragraph in Section 2.5, it is stated "<i>For industrial land use, where only adult workers are to be expected, however, the ministry estimates workers are not expected to work more than 8 hours per day in B.C. and that exposures would be limited to 35 years, considered to be a likely maximal span of a person's career.</i>" This assumption is reflected in the exposure term (ET) in Table 2-3 (8 hr/24 hr). PQRA Part I lists 10 hours per day for industrial workers - presumably ENV supports 8 hours for IL land use in risk assessments prepared under CSR requirements. In the derivation of numerical standards, it appears this ET term of 8 hr/24 hr has been used for soil ingestion (i.e., for the mandatory human "Intake of contaminated soil" matrix numerical soil standards). This ET term is reflected in the equations in Section 2.7.1 "Derivation non-carcinogenic (threshold) substances" and Section 2.7.2 "Derivation carcinogenic (non-threshold) substances". These equations assign a value of "0" for dust inhalation rate (DR) and soil dermal contact rate (SR), which results in the the soil standards derivations being solely based on the soil ingestion pathway. Including 8 hr/24 hr in the ET term results in amortizing the daily soil ingestion rate by a factor of 3 (e.g., 20 mg/day becomes 6.67 mg/day). Since the soil ingestion rate is not based on hourly exposure, this results in the numerical standard for "Intake of contaminated soil" being lower than a risk-based standard if other exposure assumptions (days per week, weeks per year, years of exposure (for carcinogens), absorption factor, body weight) remain the same. From a technical perspective, applying this adjustment of 8 hr/24 hr is not supported by Health Canada or US EPA in their soil ingestion exposure equations.</p> <p>Does/will ENV support use of an amortized</p>	<p>Follow the requirements of conducting detailed risk assessment in BC at contaminated sites as legally required in Protocol 1. This comment applies to recommendations made by risk assessment approved professionals under Protocol 6 and in submissions direct to the ministry that are reviewed by the ministry, both of which are considered by the director.</p>

		soil intake rate in risk assessments submitted in support of recommendations made by risk assessment approved professionals under Protocol 6, or as direct submission made to and reviewed by ENV?	
28	2.5	<p>Table 2-3 indicates exposure term factors of 12 hr/24 hr for both PL and CL land uses. Therefore, the same comment made above regarding IL land use and 8 hr/24 hr amortization of the daily soil ingestion rate (e.g., 20 mg/day becomes 6.67 mg/day) also applies to urban park and commercial standards for human "Intake of contaminated soil", with adjustment being a factor of 2 (12 hr/24 hr - e.g., 20 mg/day becomes 10 mg/day). Since the soil ingestion rate is not based on hourly exposure, this results in the numerical standard for "Intake of contaminated soil" being lower than a risk-based standard if other exposure assumptions (days per week, weeks per year, years of exposure (for carcinogens), absorption factor, body weight) remain the same. From a technical perspective, applying this adjustment of 8 hr/ 24 hr is not supported by Health Canada or US EPA in their soil ingestion exposure equations.</p> <p>Does/will ENV support use of an amortized soil intake rate in risk assessments submitted in support of recommendations made by risk assessment approved professionals under Protocol 6, or as direct submissions made to and reviewed by ENV?</p>	Follow the requirements of conducting detailed risk assessment in BC at contaminated sites as legally required in Protocol 1. This comment applies to recommendations made by risk assessment approved professionals under Protocol 6 "Applications with Approved Professional Recommendations and Preapprovals" and in submissions direct to the ministry that are reviewed by the ministry, both of which are considered by the director.
28	2.5	<p>"Assuming a worst-case scenario, human receptors may reside in a wildlands, agricultural, or residential land use site for the entire day and throughout the year."</p> <p>The Land Use-specific exposure durations for WL in Table 2-3 is <math>ET = (24\text{hr}/24\text{hr} \times 7\text{d}/7\text{d} \times 26\text{wk}/52\text{wk} \times 80\text{yr}/80\text{yr})</math>, based on the above text, it would imply that human receptors could reside on wildlands for the entire year.</p> <p><i>Recommendation: (1) adjust exposure duration for WL in Table 2-3; (2) provide explanation/rationale for a human receptor to be present for 26 out of 52 weeks.</i></p>	Thank you for your comment, the text has been revised to clarify the receptor is present for 26 out of 52 weeks.
28	2.5	para 2 - last sentence. Considered to be a likely maximal span of a person's career at one location?	The ministry intends this to mean at one location.

28	2.5	It appears that the CL and IL human health standards for intake of contaminated soil (e.g. copper, cobalt were checked) were back-calculated using ET exposure terms based on the full equations shown in Table 2-3. These include hours/day, and years/lifetime exposure dose averaging. Such an approach is inconsistent with Health Canada (2012) guidance (page 13) and equations (page 17) in which fraction-of-a-day dose averaging is not applied to soil intake. Such an approach would also rarely be used for non-carcinogens, whereby threshold effects would typically occur after chronic exposure of months to years, rather than lifetime. Why was such an approach used?	The ministry does not concur with this concept of back-calculation. The derivation method for human health soil standards is the same for all substances, unless indicated in Protocol 28 "2016 Standards Derivation Methods" or the CSR (e.g., lead is identified as different). By publishing these exposure terms and equations in Protocol 28, these become BC's legally enforceable standards derivation methodology (as per the <i>Environmental Management Act</i> (EMA) section 64 and CSR section 67), rather than adoption from another jurisdiction. Further details could be provided in an enquiry through the ministry's Contact Us webpage.
28	2.5	Is ENV endorsing use of the exposure dose averaging (ET equations) shown in Table 2-3 for calculation of human health risks. Or should risk calculations be performed per Health Canada's guidance on dose averaging. Note, Protocol 1 (page 15) indicates " <i>human health exposure assessment must consider Protocol 28 as the default source of human health risk exposure parameters and scenarios</i> ".	The equations and assumptions for standards derivation are inherently conservative and should therefore be considered the default. Modifications to these parameters may be appropriate, which would be determined on a site-specific basis. Protocol 28 is provided to describe how the ministry derives toxicologically-based numerical standards in the Schedules of the CSR, whereas Protocol 1 describes how to conduct risk assessment for contaminated sites in BC.
28	2.5, Table 2-3, 2.8	PL standards calculated mathematically should be double the RLLD standards based on Section 2.5 Table 2-3 and Section 2.8 Point 1 bullet 3. There are numerous human health standards that do not appear to follow this pattern, both more or less than 2 times the RLLD standard. Was this due to the rounding rule? <i>Recommendation (1) clarify the calculations and rounding of substance standards that do not appear to follow the mathematical pattern of <math>PL = 2 \times RLLD</math></i>	Yes, this is due to the rounding rule as described in Protocol 28, Chapter 10, which is the final step in standards setting. The derived standards are adjusted for land use (e.g., doubled for low density residential to urban park land use standards), then rounded.

28	2.6	<p>Section 2.6 states "<i>Selecting a TRV not found in the ministry approved appendix must have a technical rationale and be justified within a risk assessment.</i>" The ministry appendix (Appendix 8A) does not provide sources/references for these TRVs. Some of the values are out of date (e.g., the oral slope factor for benzo(a)pyrene is listed as 7.3 (mg/kg/d)<sup>-1</sup>, which is a value from IRIS that was updated in January 2017 and is now 1 (mg/kg/d)<sup>-1</sup>).</p> <p>Will ENV provide the sources of the TRVs listed in Appendix 8A (and all of Appendix A), or at least a means to request the sources on a substance-specific basis (although that seems inefficient)?</p>	The source information will not be included in this protocol, but remains available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage.
28	2.6	<p>"Selecting a TRV not found in the ministry approved appendix must have a technical rationale and be justified within a risk assessment report." When using "must" in a protocol, there needs to be more information within the protocol to adhere to the request. The TRVs within the protocol do not include references and the list is not complete for all substances. Therefore, for some substances there is limited certainty of the TRV used in calculation of the standard.</p> <p><i>Recommendation:(1) either remove the word "must" or the sentence or better define the expectations for technical rationale and justification. (2) provide a full list of the TRVs used in the calculations with references, (3) note which method of derivation was used for each standard (4) The "must" statements may be better located in P1.</i></p>	The ministry agrees this statement would be better suited to Protocol 1, and it was removed from Protocol 28.
28	2.6	Protocol should be specific to Standard Derivation and should not include guidance for conducting RA. Section 2.6 and throughout the doc includes guidance for conducting HHRA and ERA. This guidance should be included in P1 only.	The ministry agrees these statements would be better suited to Protocol 1 and thus they have been removed from Protocol 28 and clarity provided in section 1.2.
28	2.6	A requirement to use the TRV hierarchy presented in Section 8.2.1 for RA would seem to be more appropriate than the requirement to use the TRVs included in Appendix 8A for HHRA. As above, this guidance should be provided in P1, not in P28. No references are provided in Appendix 8A and select values are outdated (e.g., B(a)P). This will be an on-going issue, and thus, QPs should refer to the	The ministry agrees that toxicity reference value (TRV) selection for conducting risk assessment in BC would be better described in Protocol 1.

		original source/database for TRVs, not to this appendix.	
28	2.6, 8.2 and Appendix 8A	For the numeric standards VPHs, LEPHs and HEPHs there are no TRVs provided in Appendix 8A or explanation in Section 8.2 as to the TRV and derivation of these parameters. These are common parameters that require a risk based remediation. <i>Recommendation (1) provide the equations, exposure factors and TRVs used in the derivation of VPHs, LEPHs and HEPHs.</i>	This may be considered for inclusion in a future version of Protocol 28.
28	2.6 and Appendix 8A	As noted in previous comment, the TRVs for select substances (e.g., B(a)P) used in the derivation of the standards are outdated. For common contaminants like B(a)P, where large costs could be incurred to address contamination, could the director derive and recommend interim standards?	Standards are in-force (i.e., legal) until regulatory change, even upon release of a more recent TRV. Thus it is possible that a risk based standard calculated with a defensible TRV may be lower than the CSR numerical standard. The ministry will consider TRVs during the 5 year cycle of review as per CSR section 68.
28	2.7.1	what is the rationale/reference for using an Afi = 0.6 for arsenic?	This was consulted on during Stage 10 regulatory amendment and included in final proposal papers issued in February 2016. For further details, an enquiry may be submitted to the appropriate email address on the ministry's Contact Us webpage.
28	2.7.2	It is my (and other's) understanding that the ENV had always taken the position that it is incremental risk from a site above background that is evaluated in an HHRA for a non-threshold substance. This does not appear to be the case in the derivation of the standards for non-threshold substances. Will ENV support subtracting out the background risk and only looking at the additional risk associated with exposure to the increment above background at a site in an HHRA?	This is not conducted in the deriving of standards. The remainder of the question is outside the scope of Protocol 28, which is for calculating CSR numerical standards.
28	2.7.2	Page 13, Note #2. Can human health risk assessments adopt ENV's assumed 60% bioavailability of arsenic in ingested soil? Or does ENV expect sites to undertake bioavailability testing?	This question is outside the scope of Protocol 28, which is for calculating CSR numerical standards, but the ministry's position will be included in the final posted Protocol 1.



28	2.7.3 Point 1 and 2.8 Point 3	<p>Point 1 states "Determine if a substance is a "carcinogenic substance" in accordance with Protocol 30" and Point 3 states "The classification of substances as non-carcinogenic or carcinogenic substances was adopted from the US EPA rather than determined by the ministry's Protocol 30". This is confusing to change classification rules as some substances may or may not be included as carcinogenic under P30 rules. Also, it is unclear which substances are determined by Method 2.</p> <p><i>Recommendation: (1) have P30 rules followed by Method 2 (2) or note which method of carcinogenic classification was used for each standard</i></p>	<p>Sections 2.7.3, Point 2b and 2.8, Point 3 both support selecting the most stringent (conservative) standard between carcinogenic and non-carcinogenic endpoints/substances for their respective derivation methods. For purposes other than deriving CSR standards, Protocol 1 and Protocol 30 "Classifying Substances as Carcinogenic" contain the appropriate requirements. Specific substance-related questions and their derivation methodology is available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage.</p>
28	2.8	<p>P28 standard derivation uses the US EPA 2015 Regional Screening Levels (RSL) and modification of the RSL to exposure factors aligning to Method 1. The derivation of the US EPA RSLs was not included in P28. There is no reference or explanation of the differences and similarities in the exposure factors used in the US EPA RSLs other than those modified in Point 2.</p> <p><i>Recommendation (1) provide a brief summary of the exposure factors used in the RSL calculation and (2) a brief summary of the TRV used in the RSL calculation.</i></p>	<p>The ministry will consider adding this to Protocol 28 in a future revision. For now, please consult the United States Environmental Protection Agency (US EPA) website for this information.</p>
28	2.8	<p>Can you please provide rationale for using the modified US EPA RSL values adjusted to 20% soil allocation for non-carcinogens instead of simply using the underlying TRV from which the RSL was derived? While I haven't looked into this extensively, I am aware that with Lithium in soil, if the underlying TRV were used in accordance with CSST methods a less conservative soil standard for human soil intake could be justified (i.e., ~80mg/kg instead of 30 mg/kg). This specific example alone could help alleviate the need for arguably unnecessary investigation/remediation of Lithium in soil, and it would be interesting to know if there are other similar benefits.</p>	<p>The decision for 20% apportionment and adoption from the US EPA (with modifications) was consulted on during the CSR Stage 10 amendment and included in final proposal papers issued in February 2016. For further details, an enquiry may be submitted to the appropriate email address on the ministry's Contact Us webpage.</p>

28	2.8 Point 4 and Section 10	<p>Rounding rule: "standards are to be expressed to no more than one significant digit which must always be rounded to either 0 or 5, whichever is closer." Most of the standards have more than one significant digit. Is this supposed to be "the last significant digit must always be rounded to either 0 or 5"? There are some human health standards that do not appear to follow this rule.</p> <p><i>Recommendations (1) please clarify the rounding rule (2) please clarify the standards for the substances that do not follow this rule.</i></p>	<p>The protocol will be revised to clarify this. The rounding rule is for one significant digit, followed by either a 0 or 5 as a second significant digit. The ministry chose to set standards to 2 or more significant digits, where warranted.</p>
28	3.2	<p>Ecological protection levels in Table 3-1 are inconsistent with those in Section 4.2.4 (Table 1) of draft Protocol 1.</p>	<p>The intent of Protocol 28 is to derive numerical standards. Follow the requirements of conducting detailed risk assessment in BC at contaminated sites as legally required in Protocol 1.</p>
28	3.2 Table 3-1	<p>Land uses IL, CL and RLHD do not include the indirect exposure pathway of contaminant transfer to groundwater affecting plants.</p> <p><i>Recommendation: Confirm that the groundwater pathway to plants is insignificant for the land uses IL, CL, and RLHD.</i></p>	<p>The ministry is not able to confirm this pathway is insignificant at any or all contaminated sites. At this time, the ministry has not set a factor for a groundwater pathway to plants in the CSR matrix standards of Schedule 3.1.</p>
28	3.3	<p>Page 16 states: "Tables containing ecological health TRVs used to derive soil standards are contained in Appendix 8B of Chapter 8. Selecting a TRV not found in the ministry approved appendix must have a technical rationale and be justified within a risk assessment report". Would such selection of one single study test endpoint from the Appendix B lists of multiple test results be considered de Novo TRV derivation? Can ENV add a column to the Appendix 8B tables showing the References for the test endpoints. Without such information they can't be properly referenced in a risk assessment or reviewed for applicability to a site.</p>	<p>Protocol 1 contains the requirements for deriving a <i>de novo</i> ecological TRV. References for test endpoints are available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage.</p>
28	3.3	<p>TRVs were selected based on "Additional toxicity information was obtained from scientific reports and theses."</p> <p><i>Recommendation: Provide a complete reference list of the toxicity information used to derive standards. This is important because when deriving a TRV in a risk assessment that is different than the one used by ENV, rationale is required in P28.</i></p>	<p>The source information is not included in the protocol, but remains available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage.</p>

28	3.3	<p>"Wildlife receptors must be considered ... where appropriate in detailed risk assessment at contaminated sites."</p> <p><i>Recommendations (1) either remove the word "must" in the sentence or better define the expectations (2) This statement may be better located in P1.</i></p>	Thank you for your comment. This language is found in both Protocols 1 and 28.
28	3.3	<p>"Selecting a TRV not found in the ministry approved appendix must have a technical rationale and be justified within a risk assessment report." When using "must" in a protocol, there needs to be more information within the protocol to adhere to the request. The TRVs within the protocol do not include references and the list is not complete for all substances. Therefore, for some substances there is limited certainty of the TRV used in calculation of the standard.</p> <p><i>Recommendations: (1) either remove the word "must" from the sentence or better define the expectations for technical rationale and justification. (2) provide a full list of the TRVs used in the calculations with references, (3) note which method of derivation was used for each standard (4) The "must" statements may be better located in P1.</i></p>	The ministry agrees this statement would be better suited to Protocol 1, and it was removed from Protocol 28.
28	3.3, 8.3, Appendix 8B	<p>For the numeric standards VPHs, LEPHs and HEPHs there are no TRVs provided in Appendix 8B or explanation in Section 8.3 as to the TRV and derivation of these parameters. These are common parameters that require a risk based remediation.</p> <p><i>Recommendation (1) provide the equations, exposure factors and TRVs used in the derivation of VPHs, LEPHs and HEPHs.</i></p>	This may be considered for inclusion in a future version of Protocol 28.
28	3.4.1	<p>"Three methods are used to derive environmental protection soil standards for soil invertebrates and plants." There is no description of Method 3.</p> <p><i>Recommendations: (1) Provide description of Method 3 and (2) note which method is used to derive each standard.</i></p>	Thank you for your comment. The reference to Method 3 in this chapter has been removed.
28	3.4.1.1 and 3.4.1.2	<p>Method 1 regression and method 2 geometric mean calculations are not included in P28. When selecting a TRV not found in Appendix 8B, rationale is to be included in a risk assessment.</p> <p><i>Recommendation: the details of the standard derivation of each substance by method 1 and 2 should be available upon request for modifying a TRV for a risk assessment submission.</i></p>	Details on standards derivation are available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage.

28	3.4.1.1 and 3.4.1.2	Toxicity data was assessed for acceptability against data quality assurance/quality control criteria and data bias checks. <i>Recommendation: Provide the data quality criteria and data bias check lists for clarity on how the TRV data was screened and accepted.</i>	The data quality criteria and data biases are not included in the protocol, but remain available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage.
28	3.4.2	The substance TRV is calculated generally using the lower bound of the estimated high dietary concentration range for the contaminant as reported by Puls. <i>Recommendation: Provide a table in the P28 with the TRV cited in Puls. This would provide clarity and have the information in P28 without having to look up a reference and determine the TRV.</i>	Thank you for your comment. The ministry may incorporate the data from R. Puls (1994) during future protocol revisions.
28	3.4.2	Para 2 - misplaced bracket in first sentence	The ministry agrees and this change has been made.
28	3.4.2	Should footnote 1 below equation for livestock ingesting soil and fodder equation indicate that a conservative value of 1/100% has been used? Footnote as is doesn't seem relevant to assumed value.	The ministry agrees this footnote is of limited use and it has been deleted.
28	3.4.2	I believe there is an error in the equation presented for the soil standards derivation for livestock ingesting soil and fodder. Based on the original CSST document, it looks like the AB, ED and AUF terms should be multiplied to the denominator terms of the division rather than multiplied as in this draft document. Since these values are all set to 1.0 for standards development, this change has no effect, but it may cause confusion for QPs seeking to use this equation in the estimation of risks.	The ministry agrees and this change has been made.
28	3.4.2	Minor error, but it appears that below the equation, the value presented for IRf (food ingestion rate) should be 13.5 kg/d. The extra '2' may have been a leftover from a footnote in the CSST document.	The ministry agrees and this change has been made.
28	3.4.2	The source cited in establishing TRVs for livestock is Puls R., (1994), which I've not been able to obtain for review. It would be beneficial if ENV could present the "lower bound values for the estimated high dietary concentrations range" from this document. Also, does ENV plan to review and update these standards?	Thank you for your comment. The ministry may incorporate the data from R. Puls (1994) during future protocol revisions. Standards are reviewed and considered for revision as part of a 5 year amendment cycle, as per the CSR, section 68. The scope of future proposed standards amendments is not currently established.

28	3.4.3	The CCME guidelines were used for the protection of microbial function. <i>Recommendation: Provide a crystallization date or clarify if this included in Section 8 statement of crystallization date.</i>	The following is found in Protocol 28, Chapter 8: "The crystallization date of TRVs and guidelines used to develop standards for amendments to the CSR was November 30, 2015." The ministry intends for this to be broadly applicable to all chapters of the protocol, which includes the Canadian Council of Ministers of the Environment guidelines for protection of microbial function.
28	Appendix 3A	Method 1 regression and method 2 geometric mean data quality details are not included P30. P30 states that when selecting a TRV for a risk assessment not found in Appendix 8B, rationale is to be included in the risk assessment. <i>Recommendation: the details of the standard derivation of a substance by method 1 or method 2 should be available upon request for modifying a TRV for a risk assessment submission.</i>	The ministry believes the reference is to Protocol 28, rather than Protocol 30. The data quality details are available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage.
28	4.2	Missing closed bracket in following sentence " Thus, allowable groundwater concentrations at the point of compliance are based on the respective drinking water use, aquatic water use (freshwater or marine), livestock water use or irrigation water use standards presented in CSR Schedule 3.2."	The ministry agrees and this change has been made.
28	4.4.1.2	first paragraph - what are the references for the Koc and Kd vs pH isotherms, specifically for arsenic since its calculated soil concentration prior to background adjustment is so insignificant?	The references are available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage.
28	4.4.3	"Soil standards are not calculated or provided for all pathways for the following substances in CSR Schedule 3.1, Part 1:" Are there other substances that should be added to the the list? For example, standards are not provided for all pathways for the following substances benzene, cyanide, ethyl benzene, manganese, methanol, PCBs, Polychlorinated Dioxins and Furans, and sodium ions, as well as others.	This has been changed in the protocol.
28	Table 4A-1	First note, should it refer to "A shaded <u>grey</u> cell ..." rather than just "A shaded cell..."?	The ministry agrees and this change has been made.
28	Table 4A-2	CAS # provided for Chromium differs from the CAS # presented in the CSR Schedule 3.1, Part 1. Xylenes, total are only referred to as Xylenes in the CSR Schedule 3.1, Part 1. Reference to Xylenes throughout the document as xylenes, total.	The ministry agrees and these substance-specific changes have been made in the protocol so it matches the CSR.

28	Table 4E-1 through to 4E-5	what source references were used for the listed chemical properties (H', Kd, Koc, isotherms, etc.)? "Reference source: Chapter 9 of Protocol 28..." does not appear correct as Chapter 9 is Background Adjusting Soil Standards.	The reference to Chapter 9 applies only to Table 4E-5. The other listed chemical properties in Tables 4E-1 to 4E-4 are available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage.
28	Table 4E-1	Does BC ENV plan on reconciling the solubility limit for PCE of 206 mg/L in this table with Protocol 16? (i.e. mobile DNAPL for PCE would be over 20,600 ug/L and 1% would be 2,060 ug/L).	Theoretical solubility limit values are not prescribed in Protocol 16 "Determining the Presence and Mobility of Nonaqueous Phase Liquids and Odorous Substances." For the purposes of assessment of dense non-aqueous phase liquid presence and mobility, the theoretical solubility limit values in the Groundwater Protection Model, provided as part of Technical Guidance 13 "Groundwater Protection Model," should be used. For further information, see the responses to Protocol 16 comments.
28	Table 4E-5	CAS # provided for Chromium differs from the CAS # presented in the CSR Schedule 3.1, Part 1.	This has been changed so the protocol matches the CSR.
28	Table 4H-1	The following parameters not included in table PCB and Polychlorinated Dioxins and Furans. No note at bottom table indicating that they have not been included.	This has been changed in the protocol.
28	5.2	Various sources of guidelines were used for the derivation of generic water standards. <i>Recommendations: (1) Provide a crystallization date or clarify if this included in Section 8 statement of crystallization date (2) provide a reference for each standard as to which source was used for the standard derivation (with the exception of drinking water standards as they are identified in footnotes in CSR Schedule 3.2).</i>	The following is found in Protocol 28, Chapter 8: "The crystallization date of TRVs and guidelines used to develop standards for amendments to the CSR was November 30, 2015." The ministry intends for this to be broadly applicable to all chapters of the protocol, which includes the CCME guidelines for derivation of water standards. Identification of each source of each aquatic life, irrigation water and/or livestock water use standards be considered in the future. As indicated, the source of each drinking water use standard is currently identified via a footnote in Schedule 3.2 of the CSR. For substance-specific information on sources used for derivations, an enquiry can be submitted through the Contact Us webpage.

28	5.2.1	ENV derived de novo aquatic life use standards for VPHw, LEPhw and EPHw10-19. These are common parameters that require a risk based remediation. <i>Recommendation (1) provide the equations, exposure factors and TRVs used in the derivation of VPHw, and LEPhw.</i>	This may be considered for inclusion in a future version of Protocol 28.
28	5.2.3.1	it is not clear why a 20% apportionment has been applied to the USEPA Tapwater RSLs? Further, select RSLs (e.g., lithium) are based on provisional TRVs and result in standards that are below background concentrations. Could interim standards be recommended for these substances to avoid unnecessary costs and delays?	The ministry considers the drinking water pathway to be 1 of 5 routes of exposure; hence the apportionment of 20% to this pathway. Protocol 9 "Background Concentrations in Groundwater" has addressed the lithium in groundwater topic. The ministry may consider issuing "Director's Interim Standards" as they are described in EMA and the CSR.
28	5.2.3.1	considering that HC updated the DW guideline for B(a)P in Jan. 2016 to 0.04 ug/L and that B(a)P is a common concern in groundwater when the CSR standard, based on the old HC guideline, is 0.01 ug/L, would a director considering implementing an interim guideline for B(a)P? EPA MCL is 0.2 ug/L, BC ENV approved water quality guidelines also adopted HC's guideline of 0.04 ug/L and WHO used 0.7 ug/L.	Changes to TRVs used in standards development can be considered during the 5 year standards updating cycle (per CSR 68). Until a regulatory amendment is made by the government of BC, the CSR standard is in-force as indicated in the law. The ministry may consider issuing "Director's Interim Standards" as they are described in the EMA and the CSR.
28	5.2.3.1, 5.2.3.2	The second bullet on page 65 states " <i>All standards adopted from the USE EPA RSL are adjusted for 20% apportionment to the drinking water route of exposure. Carcinogenic substances are additionally adjusted to reflect the CSR 18 (3)(a) human lifetime exposure cancer risk of less than or equal to one in 100,000. US EPA Regional Screening Levels that are adopted and subsequently adjusted are rounded as per the rounding rule (see Chapter 10).</i> " This is reflected in Footnote 4 of CSR Schedule 3.2. The third bullet on page 65 states " <i>Drinking water guidelines adopted from Health Canada, the Province of B.C., the US EPA and the World Health Organization as standards are not rounded or adjusted.</i> " On page 66, items c. and d. state:  "c. <i>The most stringent of the calculated carcinogenic or non-carcinogenic standard is developed as the drinking water standard for the substance.</i>	This question is outside the scope of Protocol 28, which is for calculating CSR numerical standards, but the ministry's position will be included in the final posted Protocol 1. Follow the requirements of conducting detailed risk assessment in BC at contaminated sites as legally required in Protocol 1.  The ministry's position on acceptable risk for substances that share the same route of exposure has been updated in Protocol 1.

		<p><i>d. In detailed risk assessment, risk-based drinking water standards must also follow this selection of the most stringent standard as a requirement."</i> (This item seems better suited for Protocol 1)</p> <p>The 20% apportionment to the drinking water route of exposure has only been applied to drinking water values adopted from the US EPA RSLs (and not to guidelines adopted from Health Canada, the Province of B.C., the US EPA or the WHO). CSR 18 (1)(3) states the following:</p> <p><i>"...a director must consider a contaminated site to have been satisfactorily remediated without review and recommendation by a medical health officer if</i></p> <p><i>(a) for each non-threshold carcinogenic substance, the calculated human lifetime cancer risk due to exposure to that substance at the site is less than or equal to one in 100 000, and</i></p> <p><i>(b) for each substance for which a hazard index is calculated, the hazard index due to exposure of a human to that substance at the site is less than or equal to one."</i></p> <p>CSR 18 (3) refers "exposure of a human to that substance at the site" (which to some extent is contradictory to the definitions of cancer risk and hazard quotient in CSR Section 1, as neither of these two definitions refers to exposure to a substance "<i>at the site</i>" - however, in practice this has been supported by ENV as the default). Assuming additivity is taken into account where toxic modes of action are the same (e.g., hazard quotients and cancer risks are additive for the soil ingestion and water ingestion pathways when the same toxic effect occurs via these routes of exposure), Will ENV support exclusion/alteration of the 20% apportionment default assumption in HHRA risk quantification for the drinking water (and soil ingestion) pathway?</p>	
--	--	--	--



28	5.2.3.2	<p>Point a. states "The carcinogenicity classification of the US EPA Regional Screening Levels is used for substances with drinking water standards adopted from the US EPA Regional Screening Levels. Otherwise, Protocol 30 "Classifying Substances as Carcinogenic" is used." This is confusing as some substances may or may not be included as carcinogenic under P30 rules. Also, it is unclear which carcinogenic criteria was used of each substances.</p> <p><i>Recommendations: (1) have P30 rules followed (2) note which method of classification was used for each standard.</i></p>	<p>Protocol 28 describes the legal requirements for deriving CSR numerical standards. Protocol 30 provides requirements for practitioners to classify substances as carcinogenic, particularly for use in risk assessment under Protocol 1. The ministry is not unaware of the inconsistencies between Protocol 28 and Protocol 30; however, practitioners in contaminated sites work are required to use Protocol 30 and Protocol 1 for classifying carcinogenic substances and conducting detailed risk assessment, respectively.</p>
28	5.2.3.2	<p>Last paragraph on page 66 states how risk-based standards must be calculated and how to select an appropriate TRV.</p> <p><i>Recommendation: These statements may be better located in P1.</i></p>	<p>The ministry agrees this statement would be better suited to Protocol 1, and it was removed from Protocol 28.</p>
28	Table 6-1	<p>Parkade use exposure term. The equation appears to missing some brackets.</p> <p><i>Recommendation: extra brackets should be placed around the exposure terms added prior to multiplying by 70/70. This is only important if the exposure term is modified.</i></p> <p><i><math>((1\text{hr}/24\text{hr} \times 5\text{d}/7\text{d} \times 52\text{wk}/52\text{wk}) + (8\text{hr}/24\text{hr} \times 2\text{d}/7\text{d} \times 52\text{wk}/52\text{wk})) \times 70\text{y}/70\text{yr}</math></i></p>	<p>The ministry agrees and this change has been made.</p>
28	Table 6-1	<p>Exposure durations have not been presented for Wildlands, although in Section 2.5 it was considered possible for a human receptor to reside in a wildlands land use setting. Wildlands are also not considered in the CSR Schedule 3.2. Should a footnote be added regarding applicable vapour standards in a Wildlands setting, where human receptors may reside?</p>	<p>Derivation of human health vapour standards for wildlands was deferred from the last cycle of standards amendments, and are therefore not included in this chapter.</p> <p>Applicability of vapour standards in a wildlands setting is outside the scope of Protocol 28 but inside the scope of conducting detailed risk assessment in BC at contaminated sites (e.g. relates to identifying complete exposure pathways), as described in Protocol 1.</p>

28	6.3	<p>In Section 6.3, it is stated "<i>An adult lifespan in the derivation of generic numerical vapour standards is 70 years.</i>" It would seem prudent to include additional rationale for this assumption in Section 6.3.</p> <p>In Table 6-1 in Section 6.4 "Exposure Durations", the 70 year lifespan only affects IL vapour use (35 years/70 years) in the derivation of vapour standards since all other vapour uses have an exposure term that includes 70 years/70 years. This results in slightly higher (less stringent) vapour standards for IL use (35 years/70 years = 0.5, vs. 35 years/60 years = 0.583).</p> <p>Based on the wording in Section 6.3, does/will ENV support the use of a 70 year adult lifespan in risk assessments submitted in support of recommendations made by risk assessment approved professionals under Protocol 6, or as direct submissions made to and reviewed by ENV? If yes, would this be for IL use only, or for other vapour uses (e.g., commercial)?</p>	<p>The 70 year lifespan will be considered during the next cycle of CSR standards amendments (see section 68). The parameters identified in this protocol are the legal requirement for calculating the numerical standards of the CSR. Follow the requirements of conducting detailed risk assessment in BC at contaminated sites as legally required in Protocol 1.</p>
28	6.3	<p>The 70 year lifespan is inconsistent with HC guidance.</p>	<p>The ministry's default parameters (e.g. exposure terms) are not necessarily adopted outright from another jurisdiction. The 70 year lifespan will be considered during the next cycle of CSR standards amendments (see section 68). The parameters identified in this protocol are the legal requirement for calculating numerical standards in the Schedules of the CSR.</p>
28	6.4	<p>It appears that the IL human health standards for inhalation of air/vapour (e.g. 1,2,4 trimethylbenzene, xylenes were checked) were back-calculated using ET exposure terms based on the equation shown in Table 6-1. This includes years/lifetime exposure dose averaging. Such an approach would rarely be used for non-carcinogens, whereby threshold effects would typically occur after chronic exposure of months to years, rather than lifetime. Why was such an approach used?</p>	<p>The ministry cannot concur with this concept of back-calculation. The derivation method for human health vapour standards is the same for all substances, unless indicated in Protocol 28 or the CSR. The vapour standards derivation method was consulted on during Stage 10 regulatory amendment and included in final proposal papers issued in February 2016. By publishing these exposure terms and equations in Protocol 28, these become BC's legally enforceable standards derivation methodology. Further details could be provided in an</p>

			enquiry through the ministry's Contact Us webpage.
28	6.4	Is ENV endorsing use of the exposure dose averaging (ET equation) shown in Table 2-3 for calculation of Industrial Worker HQs. Or should risk calculations be performed per Health Canada's guidance on dose averaging. Note, Protocol 1 (page 15) indicates " <i>human health exposure assessment must consider Protocol 28 as the default source of human health risk exposure parameters and scenarios</i> ".	The equations and assumptions for standards derivation are inherently conservative and should therefore be considered the default. Modifications to these parameters may be appropriate, which would be determined on a site-specific basis. Protocol 28 is provided to describe how the ministry derives toxicologically-based CSR numerical standards, whereas Protocol 1 describes how to conduct risk assessment for contaminated sites in BC.
28	6.6	ENV derived vapour standards for VPHv. This is a common parameter that requires risk based remediation. <i>Recommendation (1) provide the equations, exposure factors and TRVs used in the derivation of VPHv.</i>	This may be considered for inclusion in a future version of Protocol 28.
28	7.2	Section 7.2 states " <i>Sediment Quality Criteria are derived by multiplying a probable effect level from the Canadian Council of Ministers of the Environment, 1999, Environmental Quality Guidelines, for a substance by a defined probability of observing an EC<sub>20</sub> in selected toxicity tests.</i> " While this may be the case for most substances in Schedule 3.4, it is not the case for pentachlorophenol or for total PAHs as there are no CCME Environment Quality Guidelines for these substances in sediment. In CSR Schedule 3.4, footnotes 7 and 8 are specific to pentachlorophenol - Footnote 7 refers to 1994 New York State Department of Environmental Conservation criteria (freshwater), while Footnote 8 refers to 1991 Washington State Department of Ecology criteria (marine). For polycyclic aromatic hydrocarbons, total, Footnote 9 lists the thirteen individual PAHs that comprise the regulated substance "PAHs, total", but there is no indication where the values of 10 µg/g for sensitive sediment use, and 20 µg/g for typical sediment use came from. If they represent the cumulative sums of the individual PAH sensitive and typical standards, these sums are below the standards for "polycyclic aromatic hydrocarbons, total" - this likely reflects application of the "rounding rule" (in this case rounding up) and results in at least	Footnotes 7 and 8 of CSR Schedule 3.4 describe the pentachlorophenol exception, therefore it is not included in the protocol. This, along with the polycyclic aromatic hydrocarbons topic may be considered for inclusion in a future version of Protocol 28.

		<p>one individual PAH always exceeding its applicable standard before total PAHs would exceed an applicable standard.</p> <p>Section 7.2 should reflect that PCP was an exception to the use of CMCE PELs in the derivation of sediment standards.</p> <p>For PAHs, total, in a future update of Schedule 3.4 it would seem useful to include a footnote referring to the "rounded standard" if the sensitive and typical standards are indeed based on the sums of individual PAHs, with the "rounding rule" applied. Alternatively, ENV should consider whether there is sufficient toxicity information to develop a PEL-like TRV for PAHs, total, to better represent the toxicity of the mixture (e.g., to capture other PAHs such as alkylated PAHs), or consider removing PAHs, total from Schedule 3.4 as it serves no useful purpose if it only represents the sum of individual PAHs which already have sediment standards (and which are not subject to rounding).</p>	
28	Section 7.2	Words "sediment quality criteria" should be replaced with "generic sediment standards".	The ministry agrees and this change has been made.
28	Section 7.2	If the Typical sediment standards "theoretically" represent a 50% probability of EC20 (or worse?) to amphipods which are considered to be a sensitive organism, may the typical standards be used as TRVs for benthic invertebrates at sensitive sites, given EC20 is the accepted effects level?	It is not possible to answer such a specific question via a response to stakeholder comment forum. This appears to be a specific question best addressed by Protocol 1 and/or submitting an email request for response to the ministry's Contact Us webpage.

28	8.2.1	<p>At the bottom of page 71, the following is stated:</p> <p><i>"The following sources were used to classify substances as carcinogenic: United States Environmental Protection Agency, <u>Integrated Risk Information System</u>; International Agency for Research on Cancer; Health Canada, <u>Federal Contaminated Site Risk Assessment in Canada Part II: Health Canada Toxicological Reference Values (TRVs)</u>.</i></p> <p>In Protocol 30 "Classifying Substances as Carcinogenic" (Version 1.0, Effective Date November 1, 2017), Section 4.0 states the following: <i>"Substances not classified as carcinogenic substances under Section 3 of this protocol are considered to be non-carcinogenic substances under the Regulation."</i></p> <p>In Protocol 30, Section 3.1 (US EPA IRIS), Section 3.2 (IARC), and Section 3.3 (CCME carcinogenic PAHs) define the substances considered to be carcinogens. There is no reference in Protocol 30 to Health Canada TRVs. CSR Section 1 provides the following definition: <b>"carcinogenic substance"</b> means any chemical classified as carcinogenic in accordance with a director's protocol". Protocol 28 (once finalized) and Protocol 30 are both director's protocols, and have legal standing. Therefore, this inconsistency in classifying substances as carcinogens needs to be resolved.</p>	<p>Protocol 28 describes the legal requirements for deriving CSR numerical standards. Protocol 30 provides requirements for practitioners to classify substances as carcinogenic, particularly for use in risk assessment under Protocol 1. The ministry is not unaware of the inconsistencies between Protocol 28 and Protocol 30; however, practitioners in contaminated sites work are required to use Protocol 30 and Protocol 1 for classifying carcinogenic substances and conducting detailed risk assessment, respectively.</p>
28	Appendix 8	<p>There are no references as to the sources of toxicity reference values listed in Appendix 8. This could lead to frequent requests to ENV for provision of TRV references.</p> <p>It is recommended that TRV sources be provided in some form to increase transparency and avoid frequent request to ENV.</p>	<p>The source information will not be included in this protocol but remains available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage.</p>
28	Appendix 8	<p>References should be provided for the TRVs.</p>	<p>The source information will not be included in this protocol but remains available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage.</p>

28	Appendix 8A	The references to the TRV source for each substance are not provided. <i>Recommendation: (1) Provide TRV references in table Appendix 8A.</i>	The source information will not be included in this protocol but remains available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage.
28	Appendix 8A	References for TRVs not provided. Recommend references be provided.	The source information will not be included in this protocol at this time, but remains available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage.
28	Appendix 8A	There are no TRVs, or combinations and apportionment of TRVs for HEPHs, LEPHs, or HEPHs in Appendix 8A. Therefore, the means by which ENV derived the HEPHs, LEPHs, and HEPHs soil standards are not readily available to risk assessment practitioners.  Will ENV provide the TRV values and the derivation methodology (including worked example calculations) for HEPH, LEPHs, and VPHs (as would be required if risk-based standards were applied for these substance in a risk assessment submission made to ENV)? Alternatively, please confirm that the former 80% aliphatic and 20% aromatic apportionment, and the 1994 Staats Creativ Statistics TRV values were used in the derivations for HEPHs, LEPHs and VPHs, and hence, the standards did not change.	This may be considered for inclusion in a future version of Protocol 28.
28	Appendix 8A	An oral slope factor of $7.30 \text{ (mg/kg/d)}^{-1}$ is listed for benzo(a)pyrene. While this value was up to date in accordance with Protocol 28 "2016 Standards Derivation Methods" (Section 8.1 states " <i>The crystallization date of TRVs and guidelines used to develop standards for amendments to the CSR was November 30, 2015</i> "), US EPA IRIS subsequently issued an updated oral slope factor of $1 \text{ (mg/kg/d)}^{-1}$ in January of 2017, at least nine months prior to the CSR Omnibus standards coming into force on November 1, 2017. This has resulted in lower numerical standards being derived (and promulgated) than would be the case if the less potent slope factor was used. This is only mentioned because benzo(a)pyrene is a common contaminant and its slope factor is used to represent other carcinogenic PAHs (as listed in Section 3.3 of Protocol 30); thus, risk-based standards may be used more frequently for carcinogenic PAHs to address the existing	Changes to TRVs used in the derivation of CSR standards may be considered during the 5 year standards updating cycle (per CSR section 68). Until a regulatory amendment is made by the government of BC, the CSR standard is in-force as indicated in the law. The ministry may consider issuing "Director's Interim Standards" as they are described in the EMA and the CSR.

		<p>lower numerical standards than would be derived using the current IRIS slope factor.</p> <p>ENV may wish to consider an update to the human health-based standards for benzo(a)pyrene and related carcinogenic PAHs during the next opportunity for amendments to the CSR numerical standards, or by issuing "Interim Director's Standards" for benzo(a)pyrene and other carcinogenic PAHs.</p>	
28	Appendix 8A	<p>Trichloroethylene is listed with an IARC classification of 1 (i.e., carcinogenic to humans). However, only a reference dose (Rfd = 5.00E-04 mg/kg/d) is listed in Appendix 8A. US EPA IRIS provides an oral slope factor of <math>4.6 \times 10^{-2}</math> per mg/kg-day, and a weight of evidence classification of "carcinogenic to humans", which was last updated on September 28, 2011. Per Section 3.1.1 of Protocol 30, trichloroethylene would be classified as carcinogenic. Since Section 2.7 provides equations to derive standards for both non-carcinogenic and carcinogenic substances, Section 2.7.3 item 2b. states <i>"If a substance is a carcinogenic substance and appropriate TRVs are available, calculate both non-carcinogenic and carcinogenic effect endpoint-based standards..."</i>, and the oral slope factor predates the Protocol 28 TRV crystallization date of Nov. 30, 2015.</p> <p>Please clarify why the IRIS oral slope factor for trichloroethylene is not listed in Appendix 8A (i.e., even if the derived standard is lower based on non-carcinogenic effects).</p> <p>Section 2.6 of draft Protocol 28 states <i>"Selecting a TRV not found in the ministry approved appendix must have a technical rationale be justified within a risk assessment."</i> This seems like an unnecessary step for trichloroethylene unless ENV provides rationale for why they did not include the IRIS oral slope factor in Appendix 8A.</p>	<p>Calculation with the oral reference dose (RfD) resulted in a more stringent standard than the oral slope factor, and was therefore selected for standards derivation. Only the final TRVs for standards derivation were included in Appendix 8. As section 2.7.3 of the protocol states, the lowest of the derived standard for carcinogenic and non-carcinogenic endpoints is selected and set as the CSR numerical standard.</p>

28	Appendix 8A	for substances with two TRV values listed, which one was used for standard derivation, specifically for arsenic, benzene, DDT, lead where they vary by orders of magnitude?	If two TRVs are listed, they would both have been used in standards development, depending on which TRV provided the most stringent standard for each land use and the respective critical receptor. Substance-specific TRV selection is available upon request, by submitting an enquiry to the appropriate email address on the ministry's Contact Us webpage
28	Appendix 8C	<p>Trichloroethylene is listed with an IARC classification of 1 (i.e., carcinogenic to humans). However, only a reference concentration (RfC = 2.00 µg/m<sup>3</sup>) is listed in Appendix 8C. US EPA IRIS provides an inhalation unit risk of 4.1 x 10<sup>-6</sup> per ug/m<sup>3</sup>, and a weight of evidence classification of "carcinogenic to humans", which was last updated on September 28, 2011. Per Section 3.1.1 of Protocol 30, trichloroethylene would be classified as carcinogenic. Section 6 of Protocol 28 provides equations to derive standards for both non-carcinogenic and carcinogenic substances, and the unit risk value for trichloroethylene predates Nov. 30, 2015.</p> <p>Please clarify why the IRIS inhalation unit risk value is not listed in Appendix 8C (i.e., even if the derived standard is lower based on non-carcinogenic effects).</p>	Calculation with the oral RfD resulted in a more stringent standard than the oral slope factor, and was therefore selected as the CSR standard. Only the final TRVs for standards derivation were included in Appendix 8. As section 2.7.3 of the protocol states, the lowest of the derived standard for carcinogenic and non-carcinogenic endpoints is selected and set as the CSR numerical standard.
28	Appendix 8C	<p>There is no TRV or combination and apportionment of TRVs for VPHv. The means by which ENV derived the VPHv standards is not readily available to risk assessment practitioners.</p> <p>Will ENV provide the vapour standards derivation methodology (including worked example calculation) for VPHv (as would be required for VPHv if risk-based standards were applied in a risk assessment submission made to ENV)?</p>	This may be considered for inclusion in a future version of Protocol 28.
28	Chapter 9.0, Section 9.1	<p>Collected samples are analysed using the provincially accepted method, the "British Columbia Environmental Laboratory Manual, Section C, Strong Acid Leachable Metals (SALM) in Soil".</p> <p>In Section D of BCLM 2020 (page 20), SALM in soil indicates "The BC CSR includes Water and Soil as matrix types, but Soil is only broadly</p>	The ministry considers discussion about the definition of soil to be outside the scope of Protocol 28 at this time.



		defined (CSR, Section 1). Carter's definition of Soil (Reference: Carter) as being 'less than 2 mm' material is used for this method". Does BC ENV plan to reconcile this discrepancy with the definition of soil in the CSR which includes rock?	
28	9.1	"Background Concentrations Databases" - what is this, TG17? If not, when will it be available?	Technical Guidance 17 "Background Soil Quality Database" was migrated to a new Background Concentrations Database webpage.
28	9.2	In accordance with P4, should "site" be referred to as "locale" instead?	The ministry agrees and this change will be made.
28	9.2.3	second bullet: States that previous estimates were retained for antimony, boron, selenium, silver, thallium and zirconium. ENV should indicate what the previous estimates were based on (i.e., different analytical method)? Also, why is zirconium listed since there are no soil standards for it?	The previous estimates are based on an outdated laboratory method - aqua regia extraction. There was available data to derive a provincial background estimate for zirconium, therefore it was included. Soil standards may be derived for zirconium in the future, and an estimate will thus be available for background adjustment.
28	9.2.3	last bullet: Should chloride be mentioned as well as sodium or was chloride not analyzed/in the database?	Chloride was not analyzed and is therefore not included in the database.
28	Table 9-1	why are calcium, magnesium, sulfur and zirconium listed when there are no soil standards for these parameters anyway?	There was available data to derive a provincial background estimate for these substances, therefore, the information has been provided for those interested. Soil standards may be derived for those substances in the future, and an estimate will thus be available for background adjustment. Sulfur does have one or more soil standards in Schedule 3.1.
28	Table 9-1	thallium and zirconium are listed as not being analyzed by SALM but other four parameters are not (Sb, B, Se and Ag). Those four have the note $n < 10$ along with tin. Does that mean the values listed for those four parameters were not SALM results or not as per bullet in section 9.2.3? were previous results used for tin as well (i.e., not SALM results)?	Antimony, boron, selenium, silver and tin were analyzed by strong acid leachable metals but the resulting dataset had an insufficient number of detectable results ( $n < 10$ ), therefore the earlier estimates with a different analytical method were retained.

28	Table 9-1	why are calcium, magnesium, sulfur and zirconium listed when there are no soil standards for these parameters anyway?	There was available data to derive a provincial background estimate for these substances, therefore, the information has been provided for those interested. Soil standards may be derived for those substances in the future, and an estimate will thus be available for background adjustment. Sulfur does have one or more soil standards in Schedule 3.1.
----	-----------	---	---