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Requirements for Human Health and Ecological Risk Assessment Reports

Purpose

This bulletin provides supplemental direction to that provided in [Procedure 10, "Requirements for Service Application Resubmissions, Withdrawals and Amendments"](#) regarding expectations for human health and ecological detailed risk assessment reports submitted for review under the *Environmental Management Act* and Contaminated Sites Regulation (the Regulation).

Bulletin

To ensure that the quality of risk assessments is sufficient for timely review and for the evaluation of quantified risks and associated risk controls, risk assessment reports must be returned under subsection 9 (10) of the Regulation if the Director considers the report to be incomplete or that the report contains errors. This Technical Bulletin provides criteria and examples relevant to determining if a risk assessment report is incomplete or contains errors of sufficient magnitude to require the return of the report for correction and/or resubmission. Note that the authority of the Director to return a submission on the basis of completeness or errors is not limited to the items specifically listed in this technical bulletin.

Requirements for completeness

To be considered complete, risk assessment reports must conform to the following minimum requirements:

1. Takes the form of a stand-alone document that provides all results pertinent to the risk assessment performed. If the results of previous investigations, reports or assessments are referenced, a complete summary of the previous results must be included.
2. Confirms that the detailed site investigation^{1,2} completed for the site asserts:
 - (a) that for each potential contaminant of concern (PCOC), the horizontal and vertical extent of contamination has been delineated, and
 - (b) that the contamination present at the site is stable or decreasing in concentration and extent³

¹ A risk assessor is not responsible for ensuring that a detailed site investigation was completed according to the requirements of the Regulation. However, a risk assessment that does not meet criteria 2(a) and (b) above is incomplete.

² A Numerical Standards Approved Professional is responsible for ensuring that a detailed site investigation is complete. Requirements for detailed site investigation reports are described in detail in Technical Guidance 11.

³ Sites affected by contaminant migration are excluded from the requirement to show that the extent (but not the concentration) of the contamination is stable or decreasing.

in accordance with subsection 59(2) of the Regulation.

3. Is sufficiently comprehensive and sufficiently recent to reflect current site contaminants, conditions, receptors, exposures, and risks (see Protocol 20).
4. Is organized in consideration of, and includes pertinent and comprehensive information related to, the following risk assessment components (see Protocol 20):
 - (a) problem formulation
 - (b) conceptual site model for current and/or future land use
 - (c) exposure assessment
 - (d) toxicity/effects assessment
 - (e) risk characterization
 - (f) uncertainty analysis, and
 - (g) conclusions.
5. Follows, as applicable, ministry risk assessment protocols, policy and associated guidance (see “Associated contaminated sites documents” box below).
6. Confirms that if the risk assessment is submitted in support of an application for an Approval in Principle or a Certificate of Compliance, it contains the Protocol 20 checklist as well as the professional statement in Appendix 1 of this Bulletin; is duly signed and where applicable bears the Professional Society stamp of the risk assessor(s) who completed the risk assessment report.

Errors and omissions

In addition to the more generally applicable documentary and technical errors and omissions considered under Procedure 10, Table 1 lists the most frequently noted errors and omissions specific to risk assessment reports.

Table 1. Most frequently noted examples of errors and omissions in contaminated site risk assessment reports submitted to the ministry

Common examples of major errors or omissions	Common examples of minor errors or omissions
<ul style="list-style-type: none"> • Risk assessment does not include or evaluate all contaminant: sources, PCOCs, transport or exposure pathways • Vapours addressed in the detailed site investigation with attenuation factors other than those described in Technical Guidance 4 were not included in the risk assessment • Risk assessment lacks a conceptual model or the conceptual model provided does not evaluate all site exposure pathways and/or site receptors • Risk assessment does not evaluate the potential for biomagnification • Risk assessment does not assess credible exposure scenarios and/or uses unrealistic exposure assumptions, resulting in risk estimates that are either excessively simplistic or unreasonably over-conservative for use in risk management decisions • Exposures are not summed for all contaminants of concern (1) that share an identical mechanism of toxicity and target organ, (2) across exposure pathways and/or (3) across environmental media 	<ul style="list-style-type: none"> • Risk assessment lacks an analytical data summary including: minimum, maximum, median, mode, average, 90th percentile and 95% UCL estimates • Conceptual site model for current and/or future land use(s) contains minor errors or omissions • TRVs are not supported by a rationale for their selection • TRVs are not provided with a valid citation • Risk estimates are calculated incorrectly • A worked example for all types of calculations performed to produce risk estimates is not provided

Decision process

Risk assessments found to be incomplete or which are found to contain a major error will be returned for resubmission in accordance with the general provisions of Procedure 10. The Director also reserves the ability to return any risk assessment containing multiple minor errors that in combination would act to substantively change the conclusions of the risk assessment.

References

1. British Columbia. (2014). *Environmental Management Act – Contaminated Sites Regulation*. B.C. Reg. 375/96 O.C. 1480/96 and M271/2004. Includes amendments up to B.C. Reg. 4/2014, January 31, 2014. Victoria, British Columbia.

Associated contaminated site documents:

[Protocol 1, "Recommended Guidance and Checklist for Tier 1 Ecological Risk Assessment of Contaminated Sites in British Columbia"](#)

[Protocol 20, "Detailed Ecological Risk Assessment Requirements"](#)

[Procedure 10, "Requirements for Service Application Resubmissions, Withdrawals and Amendments"](#)

[Tier 1 "Ecological Risk Assessment Policy Decision Summary"](#)

[Administrative Guidance 10, "Site Risk Classification"](#)

[Administrative Guidance 14, "Performance Verification Plans, Contingency Plans and Operations and Maintenance Plans"](#)

[Technical Guidance 4, "Vapour Investigation and Remediation"](#)

[Technical Guidance 6, "Water Use Determination"](#)

[Technical Guidance 7, "Supplemental Guidance for Risk Assessment"](#)

[Technical Guidance 15, "Concentration Limits for the Protection of Aquatic Receiving Environments"](#)

Keywords: risk assessment, reporting requirements, omissions and errors, resubmission

Definitions: Terms used in this bulletin are defined in the ministry's [Procedure 8, "Definitions and Acronyms for Contaminated Sites."](#) Readers are advised to review definitions for the following terms before using this document:

conceptual model	receptor
ecological risk assessment	Regulation
exposure pathway	risk assessment
human health risk assessment	toxicity reference value [TRV]
potential contaminant of concern [PCOC]	upper confidence limit [UCL]

For more information, contact the Environmental Emergencies and Land Remediation Branch at site@gov.bc.ca.

Appendix 1

Professional Statement and Signature of Risk Assessor Completing the Risk Assessment Report

Professional statement and signature:

1. In accordance with Section 63 of the Contaminated Sites Regulation, I confirm that I have demonstrable experience in conducting human health and/or ecological risk assessment pertinent to the purposes of the Contaminated Sites Regulation.
2. I also confirm that:
 - (a) the risk assessment performed by me, and reported herein, has been performed to the best of my ability in accordance with ministry approved protocols, guidance, procedures, policies, methods and standards of professional practice, and
 - (b) the information used in the performance of the risk assessment and the conclusions of the risk assessment reported herein are true and accurate based on my current knowledge as of the date completed.

Print Name

Signature

Date completed



<Apply Professional Society stamp (if applicable)>

< If multiple signatories add additional signature blocks as required.>

Note

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