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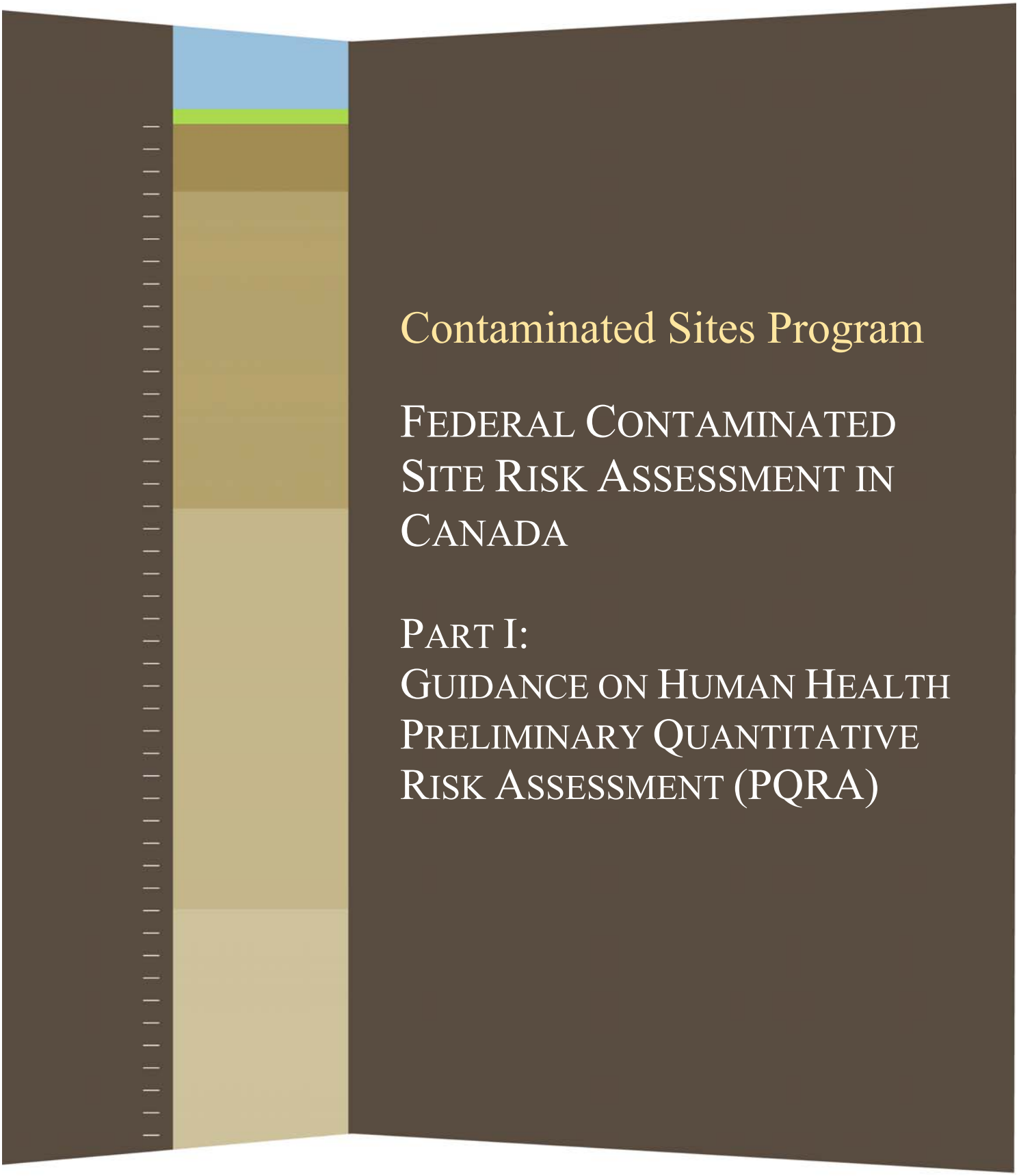

Contaminated Sites Program

Federal Contaminated Site Risk Assessment in Canada

Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA)

Canada

FEDERAL CONTAMINATED SITE RISK ASSESSMENT IN CANADA

PART I:
GUIDANCE ON HUMAN HEALTH PRELIMINARY QUANTITATIVE RISK ASSESSMENT (PQRA)

September 2004

Prepared by:

Environmental Health Assessment Services
Safe Environments Programme

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maintain and improve their health.
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PREFACE

This guidance document was prepared in support of the Federal Contaminated Sites Accelerated Action Plan (FCSAAP), a program designed to ensure improved and continuing federal environmental stewardship as it relates to contaminated sites located on federally owned or operated properties. As is common with national guidance, this document will not satisfy all of the requirements presented by contaminated sites or risk assessors in every case.

Federal Contaminated Site Risk Assessment in Canada: Part I was prepared by the Environmental Health Assessment Services Division, Safe Environments Programme, Health Canada. Both internal (federal government) and external peer reviews were undertaken to ensure, to the degree possible, that the broad requirements of contaminated sites' custodial departments and of contaminated site risk assessment in general were addressed. Following completion of Health Canada's and inter-departmental review, the document was submitted to the following external risk assessment practitioners:

- Kathryn E. Clark, P.Eng., Ph.D., BEC Technologies, Inc., Aurora, Ontario
- Brett Ibbotson, Angus Environmental Ltd., Don Mills, Ontario
- Ross Wilson, M.Sc., DABT, Wilson Scientific Consulting Inc., Vancouver, BC

Identification of peer reviewers should not be construed as endorsement of, approval of, or agreement with the risk assessment methods delineated herein. Comments were sought in an attempt to make the document as complete and defensible as possible, within the limitations presented by the federal contaminated sites program and Health Canada commitments, policies, and obligations with respect to health risk assessment and protection.

As the practice of risk assessment advances, and as the FCSAAP proceeds, new and updated information on soil quality guidelines, drinking water guidelines, toxicological reference values, contaminant bioavailability, human characteristics and exposure factors, and other aspects of risk assessment will be published. As a result, it is anticipated that revisions to this document will be necessary from time to time to reflect this new information. Health Canada should be consulted at the address below to confirm that the version of the document in your possession is the most recent edition and that the most recent assumptions, parameters, etc., are being used.

Questions, comments, criticisms, suggested additions or revisions to this document should be directed to:

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http://www.hc-sc.gc.ca/hecs-sesc/ehas/contaminated_sites.htm

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ABBREVIATIONS AND ACRONYMS

ADI	Acceptable daily intake
ATSDR	Agency for Toxic Substances and Disease Registry
CAAL	Canadian Association of Analytical Laboratories
CCME	Canadian Council of Ministers of the Environment
CMHC	Canada Mortgage and Housing Corporation
COPC	Contaminant of potential concern
CWS	Canada-Wide Standard
DNAPL	Dense non-aqueous phase liquid
DWQG	Drinking Water Quality Guidelines
ESA	Environmental site assessment
FCSAAP	Federal Contaminated Sites Accelerated Action Plan
HQ	Hazard Quotient
ILCR	Incremental lifetime Cancer risk
IRIS	Integrated Risk Information System
LNAPL	Light non-aqueous phase liquid
MRL	Minimum risk level
OMEE	Ontario Ministry of Environment and Energy
PHCs	Petroleum hydrocarbon compounds
PQRA	Preliminary quantitative risk assessment
PRG	Preliminary remediation goal
RAF	Relative absorption factor
RAIS	Risk Assessment Information System
RfC	Reference concentration
RfD	Reference dose
SF	Slope factor for carcinogenic potency
SSRA	Site-specific risk assessment
TC	Tolerable concentration
TC_{05}	Concentration (air, water) found to induce a 5% increase in the incidence of, or deaths due to, tumours considered to be associated with exposure
TD_{05}	Dose found to induce a 5% increase in the incidence of, or deaths due to, tumours considered to be associated with exposure
TDI	Tolerable daily intake
TRV	Toxicological reference value
UCL	Upper confidence limit
U.S. EPA	United States Environmental Protection Agency
WHO	World Health Organization

1. INTRODUCTION

Risk assessment, whether at the screening level (i.e., preliminary) or more complex, is not an exact science. A wide variety of advice and direction is offered by international, national and provincial/territorial environmental agencies regarding the conduct of risk assessments, and different risk assessors access and rely on the available regulatory advice and direction differently. This results in extensive variability in the estimates of chemical exposure and risk. For example, in 1997, the Canada Mortgage and Housing Corporation (CMHC) commissioned a study whereby nine consulting firms were contracted to estimate the risks posed by a contaminated residential property. The resulting estimates of exposure and risk produced by the different firms varied over nine orders of magnitude for non-cancer endpoints and over 10 orders of magnitude for cancer, despite being given the same site data set. The large variability related primarily to the differing receptors and exposure scenarios assumed by the different firms. Variability was also introduced by the selection of different toxicological reference values (TRVs) for risk characterization.

Likewise, a comparison of 10 preliminary quantitative risk assessments conducted on behalf of Fisheries and Oceans Canada (Risklogic, 2003) revealed widely differing approaches, assumptions, and risk-related conclusions, despite the fact that all 10 sites were similar in land use and public access. The toxicological reference value for just one contaminant, evaluated at all 10 sites, varied by a factor of five among different consulting firms. Numerous other variables and assumptions also varied widely, both among consulting firms, and in one case within the same firm, making it virtually impossible to rely on (at face value) and compare the conclusions among sites and reports with respect to the presence or absence of human health risk, without further analysis and recalculation.

Provincial regulatory agencies across Canada offer differing guidance on many aspects of risk assessment. For example, definitions of acceptable cancer risk vary (BC, Alberta and the Atlantic provinces accept an incremental lifetime cancer risk of 1×10^{-5}, while Ontario targets 1×10^{-6}). When characterizing the risks posed by exposure to non-carcinogenic substances, British Columbia accepts a Hazard Quotient of 1, while Alberta and Ontario target 0.2. Provinces also differ in their preferred statistics for exposure calculations, varyingly prescribing the maximum contaminant concentration, the 95% upper confidence limit of the mean concentration, or the 90^{th} percentile or 95^{th} percentile of the concentration data distribution.

Based on the above observations, it became apparent that standardized guidance was required at the federal level to assist with the consistent assessment of risks posed by contaminated sites under federal custodianship across the country.

1.1 Background

In 2003 the federal government established the Federal Contaminated Sites Accelerated Action Plan (FCSAAP), a new contaminated sites initiative to assist in identifying, assessing and managing the risks at contaminated properties under the custodial care of Canadian federal government departments.

A major emphasis of the FCSAAP is to give priority for remediation or risk management to those sites and properties posing the greatest risks. The purpose of a preliminary quantitative risk assessment (PQRA) is to quantify the degree of potential human health risk posed by the presence of contamination at a subject site. The results of a PQRA for federal sites/properties may be used by Health Canada to rank and prioritize the subject site for remedial funding under the FCSAAP. As a result, with the current disparity in risk assessment methods, there is a need for standardized risk assessment guidance that will ensure that all federal sites are evaluated for that priority on an equal and defensible basis.

Preliminary quantitative risk assessments generally prescribe methods and assumptions that ensure that exposures and risks are not underestimated. In this way, if negligible or acceptable risks are indicated using these conservative methods, then actual site use patterns and conditions will almost certainly present negligible or acceptable risks. However, the converse is not necessarily true; where PQRA suggests a potential for unacceptable risks, this does not immediately indicate that actual site conditions are unacceptable. Often, further assessment may be necessary to resolve conservatism and uncertainty in the PQRA process before the actual extent of the health risk can be fully quantified and defined.

When risk management strategies are implemented on the basis of the results of a PQRA, the remediated or managed site conditions will almost certainly achieve a reduction in health risk that was greater than might have otherwise been necessary if the on-site risks had been more extensively and accurately ascertained. It becomes a question of cost and feasibility of risk management action when deciding whether to implement remediation on the basis of a PQRA or to further reduce risk assessment uncertainties at a given site before defining the most suitable risk management strategy.

1.2 Purpose

The purpose of this guidance document is to prescribe, to the degree possible, standard exposure pathways, receptor characteristics, toxicological reference values, and other parameters required to quantitatively assess the potential chemical exposures and risks at federal contaminated sites.

The standard PQRA approach presented herein is designed specifically for the assessment of sites that are to remain the properties of federal agencies, properties for which greater consistency in risk assessment methods and interpretation of results is required. For properties being divested to a private party or to provincial governments, or for assessments that address risks from off-site migration of contamination (to an adjacent provincial water body or neighbouring private property, for example), risk assessments may have to be completed in accordance with local provincial/territorial regulatory requirements. Local regulatory requirements may differ from the standardized methods described in this guidance document. When the methods being employed in such cases differ significantly from those presented in this document, risk assessors should identify those assumptions, methods, and interpretations required by provincial agencies that differ from this method, and discuss the implications for the custodial department.

At first glance this guidance may seem overly demanding. However, the length of this document stems predominantly from the inclusion of explanatory text to ensure that the guidance is understood. In other words, an attempt has been made to describe *why* the methods are requested, not just to delineate those methods.

Most risk assessors have standard spreadsheets containing the various equations, assumptions, TRVs, etc., that they routinely use for risk assessments. The primary requirement for federal sites is to ensure that those spreadsheets comply with the prescribed equations, assumptions, TRVs, etc., outlined herein. Health Canada is flexible on the format and presentation of data and results, as long as the key components described below are included.

Although the guidance offered here is prescriptive in nature, it is not designed or intended as a substitute for the sound professional judgement of a qualified and experienced risk assessment practitioner. It is recognized that many sites will present unique situations not specifically addressed here. Risk assessors are encouraged to ensure that their assessments are complete and that they address all relevant risks. The methods delineated below should not be viewed as a "black box" of equations and assumptions that negate the need for sound professional judgement. However, where possible and appropriate, the guidance provided here should be used. Where alternate or unique approaches have been determined to be necessary, these must be sufficiently documented and described to enable peer review, and must be evaluated for their impact on risk estimates relative to the application of the standard methods prescribed below.

The guidance that follows is organized according to subject areas that Health Canada wants included in the final report. However, it is recognized that different writing styles or corporate standard formats may differ somewhat from those of the outline presented below. Alternate formats are acceptable as long as all of the requested information is presented.

1.3 Preliminary Quantitative Risk Assessment versus More Complex Site-Specific Risk Assessment

Preliminary quantitative risk assessments (PQRAs) and the more complex site-specific risk assessment (SSRA) are not independent but represent opposite ends of a continuum of complexity in risk assessment. The general characteristics of SSRA versus PQRA are outlined in Table 1. PQRA is not intended as a substitute for SSRA. A complex SSRA may be particularly appropriate in those situations where there is a large degree of variability across the site in terms of land use, contaminant types and concentrations, soil quality and other site characteristics, and receptors and their interaction with the site.

The increased detail and complexity of SSRA will generally reduce the degree of uncertainty associated with PQRA, resulting in the more accurate, precise, realistic, reliable, and defensible quantification of risks, as well as serving as a critical tool in the identification of complex remedial and risk management alternatives. When PQRA determines that, for maximal exposures, potentially unacceptable human health risks may exist, it may be appropriate to undertake a more detailed and complex SSRA prior to defining remedial or risk management options.

Guidance on conducting complex site-specific risk assessments is currently being formulated by Health Canada and will be published when work on it is completed.

1.4 Petroleum Hydrocarbons and Radiological Contaminants

The guidance presented below focuses exclusively on chemical contaminants other than petroleum hydrocarbon compounds (PHCs) or radiological contaminants. For PHCs, a Canada-Wide Standard (CWS) has been established and published by the Canadian Council of Ministers of the Environment (CCME) (2000, 2001), including spreadsheets to assist in the derivation of modified generic (Tier 2) soil quality guidelines incorporating limited site-specific data. Those methods should be employed where PHCs are encountered.

For sites presenting radiological risks, Health Canada should be consulted for advice on the most appropriate methods and approach to risk assessment for the type of contaminant and site in question.

TABLE 1
Specific Characteristics of Preliminary Quantitative Risk Assessments (PQRAs) vs Site-Specific Risk Assessments (SSRAs)

	Preliminary Quantitative Risk Assessment (PQRA)	Tier 2/3 Site-Specific Risk Assessment (SSRA)
Environmental Media Sampled	Generally, soil only; occasionally groundwater, if a concern	Generally, will include soil, groundwater, vegetation, indoor air, outdoor air (volatiles and/or particulate), indoor dust, other environmental media as required
Quantity of Data	Limited; generally restricted to data collected during ESA 2/3 for confirmation of contamination and very limited delineation of hot spots	Extensive; Tier 2/3 SSRA generally includes a sampling plan designed to provide reliable and representative quantification of the contaminant(s) in each environmental medium/pathway
Statistic Used to Represent COPC Level(s)	Generally, the maximum measured concentration	Generally, the arithmetic average or the upper 95% confidence limit on the arithmetic average.
Use of Modelling	Extensive, since COPC concentrations in all media but soil (and perhaps groundwater) are usually estimated with the use of models.	Limited; generally direct data will be collected for all environmental media that are expected to be contaminated and/or contribute significantly to exposure.
Characterization of Site	Limited to measurement of COPCs in soil (and perhaps groundwater)	Extensive; physical (soil grain size, depth to groundwater, etc.) and chemical (pH, organic carbon content, buffering capacity, etc.) characterization of on-site soils and groundwater; precise measurement of distance from on-site structures (house, etc.) to contamination sources (hot spots); other characteristics as required
Characterization of Receptors	Limited to standard, conservative assumptions available from published sources	May be site-specific, particularly with respect to the nature and extent of land use as well as time-activity patterns (when and how the land is used by receptors); quantification of receptor characteristics tends toward greater precision and less conservatism
Risk Characterization	For non-carcinogens, based on 20% of the tolerable daily intake since exposure from background sources (unrelated to the site) is not quantified For carcinogens, based on 100% of the acceptable risk value of 1×10^{-5} since the incremental lifetime cancer risk (ILCR) is independent of background sources	Based on 100% of the tolerable daily intake since exposure from background sources is quantified For carcinogens, based on 100% of the acceptable risk value of 1×10^{-5} since the ILCR is independent of background sources

2. SCOPE OF WORK / PQRA REPORT CONTENT

The human health preliminary quantitative risk assessment (PQRA) report should include the chapters/sections listed below. It is important for risk communication purposes that each PQRA report be able to "stand alone". Therefore, all relevant equations, assumptions, models, etc., required for the PQRA must be presented in each report.

2.1 Executive Summary

A brief synopsis of the site, the definition of the problem, the results and conclusions of the PQRA, and any recommendations stemming from the analysis must be presented.

2.2 Introduction

This section should briefly identify the client department, the project manager/departmental contact, and the assessor undertaking the risk assessment.

2.3 Description of the Property/Site

A brief but complete description of the site should be provided, including all site characteristics that may be pertinent to the understanding and/or quantification of potential exposures and risks on-site. Subsections may include but not necessarily be limited to:

- site location;
- current site use;
- topography;
- geology;
- hydrogeology, including the use of groundwater as a source of drinking water;
- identification of current land uses and potential receptors on neighbouring properties;
- distance to the nearest community (village, town, city, etc.); if the site is within municipal boundaries, this should be mentioned;
- an estimate of the size of the population of the nearest community;
- proximity to local surface water;
- summary of on-site contamination, including identification and description of any plumes, dense non-aqueous phase liquid (DNAPL), light non-aqueous phase liquid (LNAPL), etc.;
- local or regional background concentrations of contaminants (as available and appropriate); and
- reference to appropriate reports that provide a detailed description of the property.

2.3.1 Concentrations of Contaminants in Environmental Media

The data on concentrations of contaminants measured on-site should be adequately summarized. At the least, for all sampled media (soil, groundwater, surface water, vegetation, etc.) the

minimum, maximum, and arithmetic average concentrations should be reported, along with the number of samples analyzed. For soil samples, the depth at which samples were collected should be indicated. A map depicting sampling locations is often helpful in demonstrating or determining if the sampling plan has been adequate to reflect the distribution of contaminants across the property.

Direct pathways of exposure to soil contaminants (i.e., ingestion, dermal absorption, inhalation of suspended particulate matter) will relate predominantly to "surface" soil. The precise definition of surface soil will vary from site to site, depending on the depth of sample collection and may be represented by depths ranging from ≤ 5 cm to 1.5 m. The CCME (1996) defines surface soil from "grade" to 1.5 m below grade. Barring sampling from shallower depths, the CCME definition should be used to define surface versus subsurface soils.

The laboratory performing chemical analyses should be certified by the Canadian Association of Analytical Laboratories (CAAL) or similar organization. Further information on sample collection, analysis, and data management is offered by the CCME (1993a, 1993b).

2.4 Problem Formulation

It is essential that a brief but thorough problem formulation be provided. Specifically, report subsections will likely include but not necessarily be limited to:

- screening and identification of contaminants of potential concern (COPCs);
- identification and description of potential receptors;
- identification of operable exposure pathways;
- a brief summary paragraph describing the COPCs, critical receptor(s), and exposure pathways; and
- presentation of the Problem Formulation Checklist (see section 2.4.4, Table 2).

2.4.1 Screening and Identification of Contaminants of Potential Concern

For soil-borne contaminants, COPCs should be identified (screened) employing CCME *Environmental Quality Guidelines* for protection of human health, where possible. Where CCME human health guidelines are not available, human health-based provincial guidelines may be used, provided those for non-carcinogens are derived on the basis of 20% of the toxicological reference value (TRV). The CCME applies 20% of the tolerable daily intake (TDI; also termed a reference dose (RfD) or acceptable daily intake (ADI)) when setting guidelines for soil and other media. Where no Canadian jurisdiction has established a human health-based environmental quality guideline for a particular contaminant, the U.S. Environmental Protection Agency's preliminary remediation goals (PRGs) (U.S. Environmental Protection Agency [U.S. EPA],

2002) may be used, again adjusting those for non-carcinogens to reflect 20% of the U.S. EPA RfD.

In the event that a contaminant has no corresponding health-based soil quality guideline, the contaminant should be included as a COPC for further risk assessment, unless the measured concentrations are consistent with natural or background concentrations (see below).

For contaminants in groundwater, the Health Canada Guidelines for Canadian Drinking Water Quality (http://www.hc-sc.gc.ca/hecs-sesc/water/index.htm) should be used for screening of COPCs if the groundwater is potable. If it is non-potable, available provincial guidelines should be reviewed and employed as appropriate in the professional judgement of the risk assessor.

Before a site is considered contaminated, on-site concentrations of contaminants, particularly natural elements, should also be compared to data from local or regional surveys of background soil quality and groundwater quality (and surface water quality if relevant) in uncontaminated areas, if data are available. If it is found that concentrations of contaminants of potential concern at the site are representative of background levels, then the site may not be contaminated despite the fact that generic guidelines are exceeded. A further discussion of background levels is presented in Appendix A.

Various sampling procedures will have been applied to the site to collect samples of contaminated environmental media that could include soil, indoor dust, drinking water, indoor or ambient air, vegetation and/or other biota. A variety of methods could have been used to select sampling locations, including random, systematic (grid), or targeted (at known or suspected "hot spots" or in locations of frequent/continuous receptor occupation), etc. The soil sampling conducted at contaminated sites during typical environmental site assessments (ESAs) is usually targeted at zones of known or suspected contamination. As a result, the sampling is not random, and areas with elevated concentrations will typically be subject to more frequent sampling than are areas without contamination. Therefore, the maximum concentration determined from such targeted sampling will in all probability exceed the true average, on-site soil concentration of contaminants.

Depending on the quantity and quality of available data for a given site, and on professional judgment, a variety of possible statistics may be used to represent the on-site contaminant concentration in appropriate media (air, water, soil, etc.) for screening purposes. The statistic could be the maximum concentration, the arithmetic average, the 95% upper confidence limit (UCL) of the mean, or the 90^{th} or 95^{th} percentile value of the available data, etc.

In most cases, it is anticipated that the maximum measured concentration of a contaminant will be used to characterize its concentration at the site under investigation. However, where in the opinion of the risk assessor the data are sufficiently rigorous, the arithmetic average concentration should be used for screening purposes. In any case, a brief justification for the statistic selected should be provided (for example, only 20 samples were collected and, therefore, the maximum concentration was most appropriate).

2.4.2 Identification of Potential Receptors

The receptors likely to visit or inhabit a site will depend on land use and may include members of the general public, departmental personnel, members of specific population subgroups, etc. Exposure calculations may be done for all potential receptors/receptor age groups or only for those critical receptors that are confirmed to have the greatest exposure per unit of body weight per day. Due to the nature of federally owned and operated properties, receptors will often include employees of the custodial department and members of the general public. Members of specific population subgroups (Native Canadians, for example) may also access the site. Critical receptors in all such subgroups should be evaluated if it is anticipated that these groups would be exposed to on-site contaminants.

Age groups to be addressed are those specified by Health Canada (1994) and the CCME (1996): infants (0 to 6 months of age); toddlers (7 months to 4 years of age); children (5 to 11 years); teens (12 to 19 years); and adults (20+ years of age).

In the case of industrial properties, there may be concern regarding risks posed to construction workers during occasional short-term work on-site, particularly work involving soil excavation. If, in the opinion of the risk assessor, soil excavation may present significant risks to these construction workers, even over short time periods, this receptor should also be included in the risk assessment.

2.4.3 Identification of Operable Exposure Pathways

One or more exposure pathways may not be functional at a given site. Operable and inoperable exposure pathways should be identified and a rationale provided for pathways deemed inoperable (i.e., to be excluded from exposure calculations) at the subject site.

2.4.4 Problem Formulation Checklist

Table 2 presents an example checklist to aid in, and summarize, the problem formulation for the subject site. It identifies land use, receptors, and operable/inoperable exposure pathways. This or a similar checklist should be included with the risk assessment report.

TABLE 2
Problem Formulation Checklist

	Land Uses (check [√] as appropriate)		Receptor Group(s) (check [√] as appropriate)		Critical Receptors (check [√] as appropriate)		Exposure Pathways (check [√] as appropriate)
	Agricultural		General public		Infant		Soil ingestion
	Residential/ urban parkland		Employees		Toddler		Soil dermal absorption
	Commercial with daycare		Construction workers		Child		Particulate inhalation
	Commercial without daycare		Canadian Native communities		Teen		Vapour inhalation
	Industrial		Other (specify)		Adult		Groundwater ingestion
	Other (specify)				Other (specify)		Water dermal absorption
							Produce ingestion
							Fish ingestion
							Wild game ingestion
							Other (specify)
							Other (specify)
							Other (specify)
							Other (specify)

2.5 Exposure Assessment

This section should include all exposure equations, chemical-specific characteristics, any necessary assumptions, the concentration (maximum, arithmetic average) used to represent the concentrations of COPCs in applicable media (air, water, soil, vegetation, etc.), and identification of and the results from the application of any methods or models required to estimate concentrations in one environmental medium based on those in another medium. Models may include those that employ measured soil-borne concentrations to estimate concentrations in groundwater, in surface water, in indoor air (volatile contaminants only), in ambient air, in agricultural produce, in vegetation used as country foods, in wildlife or fish that serve as food, etc.

In some cases, assessors may believe that the assumptions and equations presented in this guidance document are inadequate or inappropriate for the site in question. In these cases, the assessor should discuss his/her concerns with the client department and, where deemed appropriate, alternate assumptions and/or equations may be employed. However, it is imperative that the PQRA report contain a clear description of the inadequacies of the guidance presented here as it relates to the issue at hand, and that a convincing rationale (with citations) to support the use of alternate methods or assumptions is provided. For these cases, exposures should be estimated using the prescribed methods and assumptions ***and*** employing the assessor's preferred approach so that the impact on risk estimates is obvious and transparent.

2.5.1 Characterization of Potential Receptors

The physical characteristics (required for exposure calculations) for a variety of common receptor groups are presented in Table 3. When considering exposure pathways and circumstances beyond those encompassed by the equations and assumptions outlined in this document, additional receptor characterization assumptions should be drawn from Richardson (1997), if available. Where Canadian data on required receptor characteristics have not been published, alternate sources such as the U.S. EPA *Exposure Factors Manual* (U.S. EPA, 1997) should be used. Where alternate data sources are consulted, they must be clearly cited and fully referenced.

A table of the specific values employed in the PQRA should be included in the report.

2.5.2 Exposure Frequency and Duration

Most assumptions concerning exposure frequency and duration are arbitrary in nature, being based on best professional judgment. While it is not the intent to question such professional judgment, a less arbitrary basis for these assumptions is desirable. For purposes of preliminary quantitative risk assessments, the frequency of site visits (days per year) and duration of such visits (hours per day) should be based on the guidance presented in Table 4 unless, in the opinion of the risk assessor, alternate assumptions are more defensible. Justification for alternate assumptions must be provided and fully referenced.

TABLE 3: Recommended Human Receptors and Their Characteristics for Preliminary Quantitative Risk Assessments

Canadian General Population							
Receptor Characteristic	**Infant**	**Toddler**	**Child**	**Teen**	**Adult**	**Construction Worker**	**Source**
Age	0 – 6 mo.	7 mo.- 4 yr	5 – 11 yr	12 – 19 yr	≥ 20 yr	>20 yr	Health Canada, 1994
Body weight (kg)	8.2	16.5	32.9	59.7	70.7	70.7	Richardson, 1997
Soil ingestion rate (g/d)	0.02	0.08	0.02	0.02	0.02	0.1	CCME, 1996 MADEP, 2002
Inhalation rate (m^3/d)	2.1	9.3	14.5	15.8	15.8	15.8	Richardson, 1997; Allan and Richardson,1998
Water ingestion rate (L/d)	0.3	0.6	0.8	1.0	1.5	1.5	Richardson, 1997
Time spent outdoors (hr/d)	-- [1]	-- [1]	-- [1]	1.5	1.5	8	Richardson, 1997
Skin surface area (cm^2)							Richardson, 1997
Hands	320	430	590	800	890	890	
Arms (upper and lower)	550	890	1480	2230	2500	2500	
Legs (upper and lower)	910	1690	3070	4970	5720	5720	
TOTAL	1780	3010	5140	8000	9110	9110	
Soil loading to exposed skin (g/cm^2/event							Kissel et al., 1996, 1998
Hands	1×10^{-4}	1×10^{-4}	1×10^{-4}	1×10^{-4}	1×10^{-4}	1×10^{-3}	
Surfaces other than hands	1×10^{-5}	1×10^{-5}	1×10^{-5}	1×10^{-5}	1×10^{-5}	1×10^{-4}	
Food ingestion[2] (g/day)							Richardson, 1997
Root vegetables	83	105	161	227	188		
Other vegetables	72	67	98	120	137	NA	
Fish	0	56	90	104	111		
Canadian Native Populations (characteristics not listed should be assumed to be equivalent to those for the general population)							
Receptor characteristic	**Infant**	**Toddler**	**Child**	**Teen**	**Adult**		**Source**
Age	0 – 6 mo.	7 mo.- 4 yr	5 – 11 yr	12 – 19 yr	≥ 20 yr		Health Canada, 1994
Food ingestion[2] (g/day)							Richardson, 1997
Fish	0	95	170	200	220		
Wild game	0	85	125	175	270		

[In Table 3 above:

1 – Data not available; however, time spent outdoors may be assumed to be equivalent to that of adults if the infant, toddler or child is assumed to be accompanied by a parent or guardian during outdoor activity.

2 – Data are for "eaters only"; those reporting zero (0) intake were excluded from the estimate.]

TABLE 4
Exposure Duration and Frequency Assumptions for Preliminary Quantitative Risk Assessments

	Agricultural Land	Residential Land	Commercial Land	Industrial Land	Construction Worker
Hours per day on site	24	24	8	8	8
Days per week on site	7	7	5	5	5
Weeks per year on site	52	52	52	48	2
Dermal exposure events per day	1	1	1	1	1
Meals of contaminated foods consumed per day	1	1	1	1	NA[1]
Life expectancy (years) for amortization of carcinogen exposures[2]	56/75	56/75	56/75	56/75	56/75

1 – Not applicable

2 – If cancer risks are estimated for adults only, the 56-year duration of adulthood (20 to 75 years, inclusive) should be used; if cancer risks are estimated on the basis of lifetime average daily intake, then average life expectancy of 75 years should be used.

2.5.3 Exposure Equations

The preferred exposure equations to be employed for a limited number of exposure pathways are presented in Table 5. Additional equations may also be included where the assessor determines that other exposure pathways beyond those listed in Table 5 are required. In those cases, the Problem Formulation section of the PQRA report should provide an adequate explanation of the need to include those additional pathways. The source of any additional equations must be fully referenced.

Inhalation exposures will be derived on the basis of the time spent in the contaminated environment (1.5 hours per day if outdoors; 22.5 hours per day if indoors; see Table 3). However, soil ingestion exposures are considered to be independent of the time spent outdoors. Although it is unlikely that ingested soil would be delivered as a single bolus dose, it is equally

unlikely that intake would be distributed uniformly throughout the day. Therefore, for purposes of conservatism, 100% of the daily unintentional intake of contaminated soil should be assumed.

2.5.4 Airborne Respirable Dust Levels

It is anticipated that this pathway of exposure will generally be insignificant relative to direct ingestion of soil and water, and to dermal absorption. However, exposures corresponding to this pathway should be calculated if deemed appropriate by the assessor. When included, the concentration of a specific contaminant in the respirable airborne dust should be assumed to be equal to the concentration in surface soil (maximum or average, as appropriate).

When this pathway is included, an average airborne concentration of respirable ($\leq$ 10 μm aerodynamic diameter) particulate matter should be assumed to be 0.76 $\mu g/m^3$ (based on U.S. EPA, 1992). For situations where significant vehicle traffic on contaminated unpaved surfaces is a concern, such traffic can generate considerably greater suspended dust levels. Dust levels from unpaved roads vary according to climatic conditions, traffic levels, and the texture and nature of the road surface material (Claiborn et al., 1995). A reasonable dust level created by vehicle traffic on unpaved roads is 250 $\mu g/m^3$ (down-wind side of the road; Claiborn et al., 1995).

2.5.5 Models

Models may be necessary to estimate the concentrations of contaminants of potential concern in groundwater, surface water, indoor or ambient air, produce and vegetation, fish, wild game or other environmental media through which receptors may potentially be exposed. Necessary modelling should be kept to a level of complexity consistent with the "screening" nature of the risk assessment. Estimates of the concentrations of volatile COPCs in indoor air should be derived from the methods presented by Williams et al. (1996) and the CCME (1996 - Appendix G). Likewise, estimating COPC concentrations in groundwater and in surface water may be obtained from the methods described by the CCME (1996). For estimating COPC concentrations in vegetation, methods presented by the CCME (1996 – produce check) or the Oak Ridge National Laboratory (ORNL) (1998) may be used. For estimating COPC concentrations in fish and wildlife, simple bioaccumulation/biomagnification factors may be employed where available on a chemical-by-chemical basis, or more sophisticated modelling may be used, as deemed appropriate by the risk assessor.

Not withstanding the guidance above, other modelling methods may be used as long as they are generally accepted. Any models employed should be fully referenced to permit peer review, including a rationale for the specific model selected.

TABLE 5
Recommended General Equations to Be Used to Estimate Doses

Note: Presented below are generalized equations; actual equations presented by individual contractors may vary according to the manner in which different variables are presented, the units used, and the precise presentation of exposure frequency, exposure duration and averaging times.

INADVERTENT INGESTION OF CONTAMINATED SOIL

The predicted intake of each contaminant via soil ingestion is calculated as:

$$Dose \quad (mg/kg \quad / day) \; = \; \frac{C_S \times IR_S \times AF_{GIT} \times D_1 \times D_2 \times D_3}{BW \quad \times LE}$$

Where:

C_S	=	concentration of contaminant in soil (mg/kg)	D_2	=	weeks per year exposed/52 weeks
IR_S	=	receptor soil ingestion rate (kg/d)	D_3	=	total years exposed to site (to be employed for assessment of carcinogens only)
AF_{GIT}	=	absorption factor from the gastrointestinal tract (unitless)	BW	=	body weight (kg)
D_1	=	days per week exposed/7 days	LE	=	life expectancy (yr) (to be employed for assessment of carcinogens only)

INHALATION OF CONTAMINATED SOIL PARTICLES

The predicted intake of each contaminant via inhalation of dust entrained into the air is calculated as:

$$Dose\,(mg/kg\,/\,day) = \frac{C_S \times P_{Air} \times IR_A \times AF_{Inh} \times D_1 \times D_2 \times D_3 \times D_4}{BW \times LE}$$

Where:

C_S	=	concentration of contaminant in soil (mg/kg)	D_2	=	days per week exposed/7 days
P_{Air}	=	particulate concentration in air (kg/m^3)	D_3	=	weeks per year exposed/52 weeks
IR_A	=	receptor air intake (inhalation) rate (m^3/h)	D_4	=	total years exposed to site (to be employed for assessment of carcinogens only)
AF_{Inh}	=	inhalation absorption factor (unitless)	BW	=	body weight (kg)
D_1	=	hours per day exposed (h/day)	LE	=	life expectancy (yr) (to be employed for assessment of carcinogens only)

TABLE 5 (continued)
Recommended General Equations to Be Used to Estimate Doses

INHALATION OF CONTAMINANT VAPOURS

The predicted intake of each contaminant via inhalation of vapours is calculated as:

$$Dose\ (mg/kg/day) = \frac{C_a \times IR_A \times AF_{Inh} \times D_1 \times D_2 \times D_3 \times D_4}{BW \times LE}$$

Where:

C_a	=	concentration of contaminant in air (mg/m^3)	D_3	=	weeks per year exposed/52 weeks
IR_A	=	receptor air intake (inhalation) rate (m^3/h)	D_4	=	total years exposed to site (to be employed for assessment of carcinogens only)
AF_{Inh}	=	inhalation absorption factor (unitless)	BW	=	body weight (kg)
D_1	=	hours per day exposed (h/day)	LE	=	life expectancy (yr) (to be employed for assessment of carcinogens only)
D_2	=	days per week exposed/7 days			

Note: C_a may be directly measured or may be estimated from soil-borne or groundwater-borne concentrations of volatile COPCs using methods discussed in the text.

INGESTION OF CONTAMINATED DRINKING WATER

The predicted intake of each contaminant via ingestion of contaminated drinking water is calculated as:

$$Dose\ (mg/kg/day) = \frac{C_W \times IR_S \times AF_{GIT} \times D_1 \times D_2 \times D_3}{BW \times LE}$$

Where:

C_W	=	concentration of contaminant in drinking water (mg/L)	D_2	=	weeks per year exposed/52 weeks
IR_S	=	receptor water intake rate (L/d)	D_3	=	total years exposed to site (to be employed for assessment of carcinogens only
AF_{GIT}	=	absorption factor from the gastrointestinal tract (unitless)	BW	=	body weight (kg)
D_1	=	days per week exposed/7 days	LE	=	life expectancy (yr) (to be employed for assessment of carcinogens only)

TABLE 5 (continued)
Recommended General Equations to Be Used to Estimate Doses

DERMAL CONTACT WITH CONTAMINATED SOIL

The predicted intake of each contaminant via dermal contact with soil is calculated as:

$$Dose\,(mg/kg/day) = \frac{(C_S \times SA_H \times SL_H) \times AF_{Skin} \times EF \times D_1 \times D_2 \times D_3}{BW \times LE}$$

Where:

C_S	=	concentration of contaminant in soil (mg/kg)	D_1	=	days per week exposed/7 days
SA_H	=	skin surface area exposed (cm^2)	D_2	=	weeks per year exposed/52 weeks
SL_H	=	soil loading to exposed skin (kg/cm^2-event)	D_3	=	total years exposed to site (to be employed for assessment of carcinogens only)
AF_{Skin}	=	dermal absorption factor (unitless)	BW	=	body weight (kg)
EF	=	exposure frequency (events/d)	LE	=	life expectancy (yr) (to be employed for assessment of carcinogens only)

INGESTION OF CONTAMINATED PRODUCE, FISH, GAME OR OTHER FOOD

The predicted intake of each contaminant via ingestion of contaminated produce, fish and/or game is calculated as:

$$Dose\ (mg/kg/day) = \frac{[\sum [C_{FoodI} \times IR_{Food\ i} \times RAF_{GIT} \times D_i]] \times D_2}{BW \times 365 \times LE}$$

Where:

C_{Food} I	=	concentration of contaminant in food I (mg/kg)	D_2	=	total years exposed to site (to be employed for assessment of carcinogens only)
IR_{Food} i	=	receptor ingestion rate for food i (kg/d)	BW	=	body weight (kg)
RAF_{GITi}	=	relative absorption factor from the gastrointestinal tract for contaminant *i* (unitless)	365	=	total days per year (d/yr)
D_i	=	days per year during which consumption of food *i* will occur (d/yr)	LE	=	life expectancy (yr) (to be employed for assessment of carcinogens only)

2.5.6 Relative Absorption Factors and Exposure via Multiple Pathways

Few, if any, toxicological reference values (TRVs) exist specifically for the dermal exposure pathway. Therefore, dermal exposures will routinely be added to the oral dose, following adjustment for relative bioavailability or absorption, for subsequent comparison to the oral TRV.

For some contaminants of potential concern, separate TRVs are available for oral and inhalation exposures. In these cases, the exposures via these pathways should be determined separately for comparison to pathway-specific TRVs.

In cases where only an oral TRV is available, exposures by all routes (oral, dermal, inhalation) should be summed for comparison to the oral TRV.

For COPCs where multiple exposure pathways will be summed for comparison to a single TRV, it will be necessary to apply relative absorption factors (RAFs) in exposure calculations. Oral exposures should always be assumed to have a relative absorption of 100% (RAF = 1). Where inhalation exposures are being summed with oral exposures, the inhalation RAF will generally default to 1 unless there is good evidence that respiratory absorption is significantly less that 100%.

Where dermal exposures are being summed with oral exposures, the RAF values presented in Table 6 should be applied, unless more appropriate information has been identified and justified (with proper citations). For contaminants not listed in Table 6, other sources such as the Risk Assessment Information System (RAIS; http://risk.lsd.ornl.gov/rap_hp.shtml), Toxicological Profiles published by the Agency for Toxic Substances and Disease Registry (ATSDR; http://www.atsdr.cdc.gov/toxpro2.html), or other authoritative sources should be consulted. Where alternate data sources are consulted, they must be clearly cited and fully referenced.

For other forms of dermal exposures, such as those involving submersion in water, dermal absorption in units of $\mu g/cm^2$-hour may be required. The source of such equations and assumptions, if required, should be clearly cited and fully referenced.

TABLE 6
Relative Dermal Absorption Factors (RAF_{Dermal}) Recommended for Preliminary Quantitative Risk Assessments
(after Ontario Ministry of Environment and Energy (OMEE), 1996b)

CHEMICAL	AF_{DERMAL}	CHEMICAL	AF_{DERMAL}
ACENAPHTHENE	0.2	DICHLOROETHYLENE, CIS-1,2-	0.1
ACENAPHTHYLENE	0.18	DICHLOROETHYLENE, TRANS-1,2-	0.1
ACETONE	0.1	DICHLOROPHENOL, 2,4-	0.4
ALDRIN	0.25	DICHLOROPROPANE, 1,2-	0.2
ANTHRACENE	0.29	DICHLOROPROPENE, 1,3-	0.2
ANTIMONY	0.1	DIELDRIN	0.25
ARSENIC	0.03	DIETHYL PHTHALATE	0.02
BARIUM	0.1	DIMETHYL PHTHALATE	0.07
BENZENE	0.08	DIMETHYLPHENOL, 2,4-	0.26
BENZO(A)ANTHRACENE	0.2	DINITROPHENOL, 2,4-	0.26
BENZO(A)PYRENE	0.2	DINITROTOLUENE, 2,4-	0.13
BENZO(B)FLUORANTHENE	0.2	ENDOSULFAN	0.2
BENZO(G,H,I)PERYLENE	0.18	ENDRIN	0.25
BENZO(K)FLUORANTHENE	0.2	ETHYLBENZENE	0.2
BERYLLIUM	0.03	ETHYLENE DIBROMIDE (DIBROMOETHANE, 1,2-)	0.1
BIPHENYL, 1,1-	0.08	FLUORANTHENE	0.2
BIS(2-CHLOROETHYL)ETHER	1	FLUORENE	0.2
BIS(2-CHLOROISOPROPYL)ETHER	1	HEPTACHLOR	0.2
BIS(2-ETHYLHEXYL)PHTHALATE	0.02	HEPTACHLOR EPOXIDE	0.2
BROMODICHLOROMETHANE	0.1	HEXACHLOROBENZENE	0.13
BROMOFORM (TRIBROMOMETHANE)	0.11	HEXACHLOROBUTADIENE	0.2
BROMOMETHANE	0.1	HEXACHLOROCYCLOHEXANE, GAMMA (GAMMA-HCH)	0.2
CADMIUM	0.14	HEXACHLOROETHANE	1
CARBON TETRACHLORIDE	0.1	INDENO(1,2,3-CD)PYRENE	0.2
CHLORDANE	0.05	LEAD	0.006
CHLOROANILINE, P-	0.1	MERCURY	0.05
CHLOROBENZENE	0.1	METHOXYCHLOR	0.2
CHLOROFORM	0.1	METHYL ETHYL KETONE	0.1
CHLOROPHENOL, 2-	0.26	METHYL ISOBUTYL KETONE	0.1
CHROMIUM(III)	0.04	METHYL MERCURY	0.2
CHROMIUM(VI)	0.09	METHYL TERT BUTYL ETHER	0.1

CHEMICAL	AF_{DERMAL}	CHEMICAL	AF_{DERMAL}
CHRYSENE	0.2	METHYLENE CHLORIDE (DICHLORMETHANE)	0.1
COBALT	0.1	METHYLNAPHTHALENE, 2-	0.1
COPPER	0.1	MOLYBDENUM	0.1
CYANIDE	0.3	NAPHTHALENE	0.1
DIBENZO(A,H)ANTHRACENE	0.09	NICKEL	0.35
DIBROMOCHLOROMETHANE	0.1	P,P'-DDD	0.2
DICHLOROBENZENE, 1,2- (O-DCB)	0.1	P,P'-DDE	0.2
DICHLOROBENZENE, 1,3- (M-DCB)	0.1	P,P'-DDT	0.2
DICHLOROBENZENE, 1,4- (P-DCB)	0.1	PENTACHLOROPHENOL	0.11
DICHLOROBENZIDINE, 3,3'-	0.54	PETROLEUM HYDROCARBONS (PHC; CCME F1 – F4)	0.2 [a]
DICHLOROETHANE, 1,1-	0.13	PHENANTHRENE	0.18
DICHLOROETHANE, 1,2-	0.1	PHENOL	0.26
DICHLOROETHYLENE, 1,1-	0.1	PYRENE	0.2
SELENIUM	0.002	TRICHLOROETHANE, 1,1,2-	1
SILVER	0.25	TRICHLOROETHYLENE	0.1
STYRENE	0.2	TRICHLOROPHENOL 2,4,6-	0.26
TETRACHLOROETHYLENE	0.1	TRICHLOROPHENOL, 2,4,5-	0.26
THALLIUM	0.01	VANADIUM	0.1
TOLUENE	0.12	VINYL CHLORIDE (CHLOROETHYLENE)	0.16
TRICHLOROBENZENE, 1,2,4-	0.08	XYLENES (MIXED ISOMERS)	0.12
TRICHLOROETHANE, 1,1,1-	0.1	ZINC	0.02

a – see CCME, 2000

2.5.7 Carcinogens

For carcinogenic substances, only exposure in adult receptors need be determined, consistent with the methods employed by the CCME (1996) and Health Canada (1995) to derive soil quality guidelines for carcinogenic substances. The variability between adult exposure and lifelong average exposure is much smaller than the uncertainty inherent in the derivation of cancer slope factors. Therefore, the more complex lifelong average daily intake need not be determined for a preliminary quantitative risk assessment, unless preferred by the assessor.

When establishing health-based guidelines for soil quality, neither the CCME (1999) nor Health Canada (1995, for example) amortized shorter-than-lifetime exposures over average life expectancy. During the derivation of guidelines for industrial properties, for example, exposure was averaged to account for anticipated occupational exposures of 8 hours per day, 5 days per

week, 48 weeks per year (CCME, 1996), but career-long exposure (say, 35 years) was not averaged over life expectancy. However, it is generally assumed that exposure to low doses or concentrations of a carcinogenic substance – i.e., relatively low environmental levels -- require a concurrent increase in exposure duration to initiate cancer. Also, cancer potency values (TD_{05}, TC_{05}, slope factor, unit risk) are typically derived on the assumption of lifelong exposure.

The validity and defensibility of exposure amortization for carcinogenic substances is under review by Health Canada. Until that review is complete, shorter-than-lifetime carcinogen exposures should be amortized over the average life expectancy (75 years) if the cancer risk is based on lifetime average daily exposure, or over 56 years (the duration of adulthood) if cancer risk is based on estimates in adults only. Recommended exposure durations for various land uses are presented in Table 4.

2.6 Hazard Assessment

Health Canada TRVs should be applied where available (these are presented in a companion document [Health Canada, 2003]). For substances with no Health Canada TRVs, reference doses (RfDs), reference concentrations (RfCs), acceptable daily intakes (ADIs), or minimum risk levels (MRLs) should be obtained from the following agencies, in order of preference:

1) U.S. EPA Integrated Risk Information System (IRIS);
   http://www.epa.gov/iriswebp/iris/index.html
2) World Health Organization (WHO); various sources including:
   http://www.inchem.org/;
   http://jecfa.ilsi.org/index.htm;
   http://www.who.dk/air/activities/20020620_1)
3) Netherlands National Institute of public Health and the Environment (RIVM);
   http://www.rivm.nl/bibliotheek/rapporten/711701025.pdf
4) Agency for Toxic Substances and Disease Registry (ATSDR) (U.S.);
   http://www.atsdr.cdc.gov/toxpro2.html

For each contaminant of potential concern, the source of each TRV and the pathway(s) to which it is being applied should be identified.

In some cases, assessors may believe that the TRVs presented by Health Canada (2003) are inadequate or inappropriate for application at the site in question. In these cases, the assessor should discuss his/her concerns with the Client and, where deemed appropriate, alternate TRVs may be employed. However, it is imperative that the PQRA report contain a clear description of the inadequacies of the TRVs presented by Health Canada, along with a convincing rationale

(with citations) to support the use of an alternate value. For these cases, risks should be characterized using the prescribed TRV ***and*** the assessor's preferred value.

2.7 Risk Characterization

2.7.1 Non-carcinogens: Single-Substance Exposures

For substances presenting risks other than cancer, a Hazard Quotient (HQ; analogous terms include "exposure ratio" and "hazard ratio") will be derived as the ratio of the estimated exposure (for each critical receptor) to the tolerable daily intake (TDI) or tolerable concentration (TC), as follows:

$$\textit{Hazard Quotient} = \frac{\textit{Estimated Exposure (}\mu\textit{g/kg/day)}}{\textit{Tolerable Daily Intake (}\mu\textit{g/kg/day)}}$$

OR, in the case of air-borne contaminants with a tolerable air concentration in $(\mu g/m^3)^{-1}$:

$$\textit{Hazard Quotient} = \frac{\textit{Air Concentration (}\mu\textit{g/m}^3\textit{)} \times \textit{Fraction of Time Exposed}}{\textit{Tolerable Air Concentration (}\mu\textit{g/m}^3\textit{)}}$$

Hazard Quotients for individual exposure pathways should be presented where there are pathway-specific TRVs. Where exposures via multiple pathways are being summed for comparison to a single TRV (for example, it is common to sum oral and dermal exposures for comparison to the oral TDI), it is necessary only to display the HQ for the summed exposure.

For purposes of preliminary quantitative risk assessment, exposures associated with a HQ $\leq$ 0.2 will be deemed negligible. This is consistent with the CCME (1996) and the OMEE (1996a), and has become accepted common practice.

2.7.2 Carcinogens: Single-Substance Exposures

For substances deemed to be carcinogenic, the estimated exposure (amortized as appropriate) will be multiplied by the appropriate slope factor or unit risk to derive a conservative estimate of the potential incremental lifetime cancer risk (ILCR) associated with that exposure. The ILCR is derived as:

$$\textit{ILCR} = \textit{Exposure (}\mu\textit{g/kg/d)} \times \textit{Cancer Slope Factor (}\mu\textit{g/kg/d)}^{-1}$$

OR, in the case of air-borne contaminants with a unit risk value in $(\mu g/m^3)^{-1}$:

$$\textit{ILCR} = \textit{Air Concentration (}\mu\textit{g/m}^3\textit{)} \times \textit{Fraction of Time Exposed} \times \textit{Cancer Unit Risk (}\mu\textit{g/m}^3\textit{)}^{-1}$$

Where pathway-specific slope factors or unit risks exist, the risks via inhalation and the risks via oral + dermal exposure should be estimated separately. In other cases, the cancer risks posed by simultaneous inhalation/dermal/oral exposure will be estimated.

Cancer risks will be deemed to be "essentially negligible" (*de minimus*) where the estimated ILCR is ≤ 1-in-100,000 ($\leq 1 \times 10^{-5}$). The rationale for this essentially negligible risk level is presented in Appendix B.

2.7.3 Exposure to Mixtures

For simultaneous exposure to multiple chemicals of potential concern, non-cancer Hazard Quotients should be assumed to be additive, and should be summed for those substances determined by the risk assessor to have similar target organs/effects/mechanisms of action. For the purposes of PQRAs, exposures associated with this total HQ ≤ 0.2 will be deemed negligible.

For carcinogens with the same target organ and form of cancer, the risks should be assumed to be additive and thus should be summed. The total cancer risk in such cases will be deemed to be "essentially negligible" where the estimated total ILCR is ≤ 1-in-100,000 (1×10^{-5}).

2.8 Non-standard Assumptions and Toxicological Reference Values

In those situations where assessors have introduced exposure pathways, equations, assumptions and/or TRVs that are different from, or in addition to, those presented in this guidance document, the implications for exposure and risk estimates must be summarized and discussed.

- Were exposures increased, decreased, or essentially unchanged compared to the prescribed procedures?
- Were the resulting risks increased, decreased, or essentially unchanged compared to the prescribed procedures?
- Do the prescribed methods predict negligible risks while the alternate methods suggest that a risk exists? Or vice versa?

2.9 Uncertainties

The uncertainties in the exposure and risk estimates should be discussed. Issues to be addressed should include, but not be limited to:

- the quality and quantity of data;
- use of maximum COPC concentrations (where appropriate);
- factors, assumptions, and models that would likely lead to an overestimation of exposures and risks; and

- factors, assumptions, and models that might lead to an underestimation of risks.

2.10 Conclusions and Discussion

The overall conclusions with respect to the risks posed by the contaminated site should be summarized in this section of the PQRA report. Any other issues that, in the opinion of the assessor, require discussion but have not been presented in other sections, should also be included here.

2.11 Recommendations

List all recommendations that may stem from the results of the PQRA.

2.12 References

The report should be thoroughly referenced to enable peer reviewers to identify and obtain all documents and authoritative sources cited in the report. A complete list of those references is required.

3. REFERENCES

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APPENDIX A
Screening Contaminants of Potential Concern for Local or Regional Background (Natural) Soil, Groundwater and Surface Water Concentrations

Before a site is considered contaminated, on-site concentrations of contaminants, particularly natural elements, should be compared to data from local or regional surveys of soil quality, groundwater quality, or surface water quality in uncontaminated areas. If possible, such surveys should be conducted at the time of the site environmental assessment, although the collection of background samples at that time is generally a rare occurrence. However, the results of many regional soil surveys are available in the open scientific literature. Soil survey data are also available from provincial ministries of natural resources, which have conducted surveys and compiled soil survey data for purposes of mineral exploration and mineral mapping. Similarly, the Geological Survey of Canada (GSC) has compiled data from numerous large-scale and small-scale soil surveys for purposes of mineral exploration and mapping across Canada. These GSC surveys are publicly available as GSC Open Files, which can be searched and reviewed with the assistance of the local GSC office or library.

If it is found that concentrations of contaminants of potential concern at the site are representative of background levels, the site may not be considered contaminated despite the fact that generic guidelines are exceeded.

Many contaminants, particularly metals, are naturally occurring, and natural levels can exceed Canadian Council of Ministers of the Environment (CCME) guidelines and other generic guidelines without representing industrial or anthropogenic contamination. A prime example is arsenic. The CCME soil quality guideline for arsenic is 12 ppm. This guideline was derived on the basis of a "national" natural background concentration of 10 ppm arsenic in agricultural soils from southern Ontario and the Prairies, with an additional 2 ppm which represented the additional contamination (above background) associated with a 1-in-1-million cancer risk (Health Canada, 1995). Although natural levels of arsenic in those agricultural soils are only 10 ppm, the regional background of arsenic established for Ontario is 17 ppm (Ontario Ministry of Environment and Energy (OMEE), 1997b), and in various regions of British Columbia it ranges up to 25 ppm (British Columbia Ministry of Water, Land and Air Protection (BCMWLAP), undated). In Sydney, Nova Scotia, local sampling determined that the local urban background concentration of arsenic ranged up to 200 ppm (JDAC Environment Ltd., 2002). In Yellowknife, NWT, the natural soil-borne levels of arsenic average approximately 150 ppm, with natural levels occasionally exceeding 1500 ppm (Richardson, 2002).

Yellowknife is situated on a geologic anomaly known as a greenstone belt. Greenstone belts and other geologic deposits are rich in mineral deposits, of which arsenic is a natural contaminant.

Soils derived from such geologic deposits will have naturally high concentrations of those elements. In fact, prospecting for mineral deposits is often accomplished by surveying soils for anomalously high arsenic levels (see Richardson, 2002). Therefore, arsenic and other metals can be present in soils at levels far in excess of national or provincial guideline values, but such levels do not represent anthropogenic or industrial pollution.

When setting national guidelines, the CCME derives guideline values by determining the tolerable or essentially negligible concentration of a contaminant above the background (natural) level (CCME, 1996a). The CCME also recognizes that natural levels in soil vary spatially, and recommends that local soil quality objectives be established that incorporate local or regional background concentrations if they are significantly different from the background value used in the derivation of the national generic guideline for a particular contaminant (CCME, 1996b).

In some cases, it may be appropriate to use "urban" background concentrations, rather than those associated with more rural areas. This may be particularly true for carcinogens where risk assessment and risk management are targeted at *incremental* risks above background levels. If the local urban environment and/or adjacent properties have elevated concentrations from sources other than the subject property, and those elevated concentrations are accepted and not slated for remediation or risk management, then these urban background levels may constitute the appropriate background concentrations for risk assessment and risk management purposes. However, professional judgment will be required to determine the most suitable basis for defining background concentrations.

The Ontario Ministry of Environment and Energy presents the main elements of a background approach and Ontario-specific criteria (OMEE, 1997 – Table F). Similar guidance is also provided by the BC Ministry of Water, Land and Air Protection (BCMWLAP, undated).

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APPENDIX B
Essentially Negligible Cancer Risk for Contaminated Site Risk Assessment

When assessing risks posed by exposure to carcinogenic substances, regulatory agencies such as Health Canada and the United States Environmental Protection Agency (U.S. EPA) assume that any level of exposure (other than zero) is associated with some hypothetical cancer risk. As a result, it is necessary for regulatory agencies to specify a level of carcinogenic risk that is considered acceptable, tolerable, or essentially negligible.

In the 1970s, the U.S. Food and Drug Agency (FDA) was the first agency to address this issue, adopting a risk level of 1-in-1-million (10^{-6}) as the incremental cancer risk for carcinogenic residues in foods that was considered to be "essentially zero" (Kelly, 1991). The origin of this "essentially zero" risk level was purely arbitrary. Since then, the 10^{-6} risk level has become commonplace in the regulation and management of environmental contaminants, with the strongest endorsement coming from the U.S. EPA, which employs 10^{-6} as its primary risk benchmark for "acceptable" exposure to carcinogens within the general population.

Although a 1-in-1-million (10^{-6}) cancer risk is the most frequently used risk level for the management of risks posed by environmental (including soil) contamination, many agencies and provinces, including the U.S. EPA, identify a range of increased cancer incidence risks; generally, from 1-in-10,000 (or 1×10^{-4}) to 1-in-1,000,000 (or 1×10^{-6}) is considered an acceptable risk range depending on the situation and circumstances of exposure (Graham, 1993; Kelly, 1991; Lohner, 1997; Travis, 1987; U.S. Environmental Protection Agency (U.S. EPA), 1991).

In contrast, many industrial standards for workplace environments (such as those of the American Conference of Governmental Industrial Hygienists [ACGIH], 2002) offer a protection to only the 1×10^{-3} level or higher of risk (e.g., a risk of 1×10^{-2}, or 1-in-100, is a 1 percent chance). This higher cancer risk is "accepted" in workplace environments because it is often technologically or financially infeasible to reduce exposures to even lower levels, and the nature of exposure is generally deemed to be informed and "voluntary" in the workplace. The U.S. Supreme Court has upheld the industry basis for such standards (Graham, 1993).

In establishing generic Canadian soil quality guidelines, the Canadian Council of Ministers of the Environment (CCME) (1996) prescribed the 10^{-6} level of risk as being essentially negligible. This was established as the lowest common denominator amongst provincial and federal agencies participating in the CCME guidelines derivation process. However, the CCME (1996) acknowledges that the designation of negligible cancer risk is an issue of policy rather than of science, allowing different agencies to establish such a policy consistent with their respective

environmental regulatory agendas. To that end, Health Canada, when publishing human health soil quality guidelines in support of the CCME process, applied the concentration of carcinogenic substances in soil associated with risks ranging from 1-in-10,000 (10^{-4}) to 1-in-10,000,000 (10^{-7}) (see Health Canada, 1995, for example).

Health Canada (formerly Health and Welfare Canada [HWC], 1989), as the federal advisor on environmental health issues, has established that a cancer risk in the range of 1-in-1-100,000 (10^{-5}) to 1-in-1-1,000,000 (10^{-6}) is "essentially negligible" for carcinogenic substances in drinking water. Although published Health Canada advice on this issue has been restricted to exposures via drinking water, the 10^{-5} risk level has been widely accepted by federal agencies and others involved with contaminated site risk assessment. This level of risk was deemed essentially negligible for risk assessments being conducted in Sydney, Nova Scotia, for soil-borne carcinogenic contaminants associated with the Sydney Tar Ponds, for example (JDAC Environment Ltd., 2002).

The Atlantic Provinces (NS, NB, PEI, and Nfld./Lab.) have implemented a common approach to contaminated site risk assessment known as Atlantic Risk-Based Corrective Action (RBCA) (Atlantic Partnership in RBCA Implementation [Atlantic PIRI], 1999). Within that common risk assessment / risk management framework, an acceptable or essentially negligible cancer risk level of 10^{-5} has been adopted.

The background incidence of cancer in Canada and the U.S. is high, relative to a 10^{-5} or 10^{-6} risk level. The lifetime probability of developing cancer in the U.S. and Canada is approximately 0.4, or 40% (National Cancer Institute of Canada [NCIC], 2001; National Cancer Institute [NCI], 1999). Thus, an excess or incremental cancer risk of 1×10^{-5} increases a person's lifetime cancer risk from 0.40000 to 0.40001.

Some unknown proportion of this "background" cancer incidence is believed to be associated with exposure to environmental pollutants. However, a 10^{-5} incremental (i.e., over and above background) cancer risk represents only a 0.0025% increase over background cancer incidence; an increase that would be undetectable using available epidemiological data and statistics, particularly in smaller populations that may reside near contaminated sites.

Hypothetical incremental cancer rates associated with carcinogenic substances at contaminated sites are estimated from cancer "slope factors" or "unit risks" derived from human epidemiological studies and animal cancer bioassays. Generally, the incidence of cancer for occupationally exposed adults or laboratory animals (both of which are exposed to dose levels far in excess of exposure levels in the general population or in populations residing near contaminated sites) is plotted against the exposure dose (often standardized for exposure

duration, particularly for occupational studies), and a dose-response curve is fitted to those data. This dose-response curve is then extrapolated from the study exposure range down to a dose of zero, with the assumption that there is no threshold below which cancer will not occur. In the U.S. (Crump, 1996), low-dose extrapolation is achieved through application of the linearized multistage model, a statistical model that can describe both linear and non-linear dose-response patterns, and that produces an upper confidence bound on the linear low-dose slope of the dose-response curve. Health Canada often applies this same methodology for the derivation of the TC_{05} (the concentration in air or water found to induce a 5% increase in the incidence of, or deaths due to, tumours considered to be associated with exposure; see Health Canada [1996]) or the TD_{05} (the dose found to induce a 5% increase in the incidence of, or deaths due to, tumours considered to be associated with exposure). Health Canada may also apply a model-free low-dose extrapolation method (Krewski et al., 1989), making no *a priori* judgments regarding the shape of the dose-response curve in the low-dose range. The model-free approach can also provide an upper bound estimate on the slope of the dose-response curve in the low-dose range. These upper bounds on the dose-response curve become the slope factors or unit risks employed for the estimation of hypothetical cancer rates. As such, it is believed (but not proven) that the slope factor or unit risk for carcinogenic substances will overestimate the true cancer incidence associated with low-dose exposure to environmental pollutants, such as from contaminated sites (Kelly, 1991).

Given the conservatism (safety) margin associated with the derivation of cancer slope factors and unit risks, and the negligible impact of a 1-in-100,000 incremental risk level for contaminated site exposures, a cancer risk level of 1-in-100,000 (1×10^{-5}) is recommended for the purposes of assessing and managing federal sites contaminated with carcinogenic substances.

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