Paper #PA-510
IAIA Conference, Vancouver, BC

Why Standardized Risk Assessment Guidance within a Health Impact Assessment is Essential to Effective Environmental Stewardship of Federal Contaminated Sites in Canada

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Abstract
Human health risk assessment is a valuable tool within the Health Impact Assessment toolkit. However, risk assessment, whether at the screening level or more complex, is not an exact science. A wide variety of advice and direction is offered by international, national and provincial environmental agencies regarding the conduct of risk assessment. Environmental regulatory agencies across Canada, and those abroad, offer differing guidance on many aspects of risk assessment as well as specifying different levels of risk that are defined as essentially negligible, tolerable or acceptable. Individual risk assessors, often within the same consulting firm, access and rely on the available regulatory advice and direction differently. The resulting variability prevents the effective comparison of risk assessment results from one site to another, complicating the task of identifying and remediating the highest risk sites first. We will review the available evidence on risk assessment variability, including studies conducted specifically for Health Canada, and demonstrate why Health Canada has formalized standard risk assessment procedures for the assessment of federal contaminated sites in Canada.

1.0 INTRODUCTION

Within the Canadian federal government, a new contaminated sites initiative has emerged. The Federal Contaminated Sites Accelerated Action Plan (FCSAAP) has been established to assist in identifying, assessing and managing the risks at contaminated properties under the custodial care of Canadian federal departments. A major emphasis of the FCSAAP program is to give priority for remediation or risk management to those sites/properties posing the greatest potential health risks.

Risk assessments of contaminated sites may be conducted when levels of chemicals in environmental media exceed regulatory guidelines for a particular site use. This includes residential/parkland, commercial/industrial or agricultural land use. Regulatory guidelines are designed to protect the most sensitive receptor within a hypothetical near-worst case exposure scenario, and it is possible that the most sensitive receptor is not present at the site, or that the duration and/or frequency of site use is lower than assumed for derivation of regulatory guidelines. Also, site characteristics such as ground surface cover (asphalt, snow and ice, etc.), building presence/absence, building design features, or other conditions are different from those assumed for the hypothetical scenario. For these reasons, risk assessments are routinely used to determine whether there is a human

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health risk associated with exposure to elevated chemicals in various media at a site, under more accurate assumptions of duration, frequency and site characteristics.

The process of a contaminated site risk assessment has several components. These include identification of contaminants of potential concern (e.g., chemicals that exceed regulatory guidelines), identification of potential receptors that may be present at the site, or affected off-site and determination of exposure pathways by which the receptors may come into contact with the contamination. The problem formulation stage of the risk assessment is a qualitative step that identifies whether there are operable exposure pathways at a site. If there are operable exposure pathways, a screening level risk assessment is used initially to quantify the potential health risk, assuming a worst case scenario for receptors to come into contact with maximum levels of contaminants at the site. If there are no risks identified at a screening level using a worst-case scenario, there is no requirement for additional work at the site. If there is a potential risk identified at a screening level, a complex risk assessment may be employed to derive more realistic estimates of exposure and risk associated with exposure to contaminants at a site or off-site to determine whether there is in fact a risk of exposure to contaminants. Data gaps identified in the screening level risk assessment are used to reduce uncertainty in the complex risk assessment. The complex risk assessment could include additional data collection from the site that allows better characterization of the contamination, and potentially address additional exposure pathways such as ingestion of foods from a site. A complex assessment generally provides more realistic exposure and risk estimates, rather than worst-case estimates that may not be reflective of actual site use.

Risk assessment, whether at the screening level or more complex, is not an exact science. A wide variety of advice and direction is offered by international, national and provincial regulatory agencies regarding the conduct of risk assessment, and different risk assessors access and rely on the available regulatory advice and direction differently. This results in wide variability in the estimates of chemical exposure and risk. For example, in 1997, the Canada Mortgage and Housing Corporation (CMHC, 1997) commissioned a study whereby 9 consulting firms conducted risk assessments to estimate potential human health risks posed by a contaminated residential property. The resulting estimates of exposure and risk produced by the different firms varied over 8 orders of magnitude for vinyl chloride (Figure 1). Variations of 9 orders of magnitude were observed for some non-carcinogenic substances. This variability in risk estimates between consultants occurred 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 regulatory exposure levels (RELs; or toxicity reference values – TRVs) for risk characterization.

Likewise, a comparison of ten screening level risk assessments conducted on behalf of Fisheries and Oceans Canada (Risklogic, 2003) demonstrated widely differing approaches, assumptions and risk-related conclusions, despite the fact that all sites were similar in land use and public access. Lead was a contaminant that was evaluated at all ten sites. The toxicological reference value (TRV) alone, selected to characterize the risk

associated with lead exposure at those sites, varied by a factor of almost 5 between the different consulting firms.

Numerous other variables and assumptions also varied widely, both between consulting firms, and in one case within the same firm, making it virtually impossible to rely on (at face value) and compare the conclusions between sites with respect to the presence or absence of human health risk, without further analysis and recalculation. Re-estimation of exposures and risks, following a standard approach applied to all sites, demonstrated that the risk estimates provided by the different consulting firms could not be relied upon as an objective basis for deciding which site(s) presented the highest relative risk.

Provincial regulatory agencies across Canada offer differing guidance on many aspects of risk assessment (see Table 1). Not all provinces prefer to rely on Health Canada advice regarding RELs (including tolerable daily intakes, reference doses, reference air concentrations, as well as cancer slope factors). In some cases, provincial risk assessment guidance stipulates the US Environmental Protection Agency's Integrated Risk Information System (IRIS) as the preferred source of RELs. Health Canada's and US EPA's determination of what constitutes a tolerable daily intake, or the carcinogenic potency, of a substance can vary widely (see Table 2), due in part to policy issues relating to the interpretation and extrapolation of toxicological and dose-response data. Often different RELs are defined by these two agencies despite reliance on the same toxicological database for those determinations.

Definitions of acceptable risk also vary between the regulatory agencies of provinces within Canada. For carcinogen exposures, an incremental lifetime cancer risk of either 1 in 1 million (1×10^{-6}) or 1 in 100,000 (1×10^{-5}) may be defined as 'essentially negligible'. For exposure to non-carcinogenic substances, the acceptable Hazard Quotient (ratio of exposure to REL) varies between 0.2 and 1.0.

In a direct comparison of different provincial risk assessment methods applied to the same hypothetical contaminated site (Dillon, 2004), inter-provincial differences in the estimates of exposure and risk were realized (see Figure 2), with some suggesting significant, although variable, risk while others indicated that risks were negligible.

The results of the studies on variability within risk assessments of contaminated sites have identified that some consultants may conclude that a particular site does not pose a potential health risk, while other consultants may conclude that the same site does pose a risk. This discrepancy can have significant impacts on remediation costs, since the variable risk assessments will produce different risk based remediation criteria for contaminants at the same site. Custodial departments within the government that are responsible for managing the sites may not have the ability to identify whether the risk assessment and subsequent recommended remediation are acceptable. They may spend significant amounts of money to clean up sites that do not pose a health risk. Conversely, there are implications with liability for the federal government if a risk assessment does not adequately identify potential health risk, thereby leaving residual contamination at a site at levels that may constitute a human health risk.

Based on the above observations, it became apparent that the federal government in Canada required standardized guidance to assist with the consistent and objective identification of contaminated sites with the greatest potential health risk, and thereby deserving highest priority for remediation or risk management.

2.0 HEALTH CANADA'S STANDARDIZED SCREENING LEVEL RISK ASSESSMENT (SLRA) GUIDANCE

2.1 General

The purpose of a screening level risk assessment (SLRA) is to provide a preliminary quantitative estimate of potential human health risk posed by contamination at a subject site. The results of a SLRA for federal sites/properties are employed by Health Canada to rank and prioritize the subject site for remedial funding, relative to all other sites being considered for funding under the FCSAAP program. As a result, with the current disparity in risk assessment methods, the need was recognized for standardized risk assessment guidance to ensure that all federal sites are evaluated for that priority on an equitable and defensible basis.

Screening level risk assessments generally prescribe methods and assumptions that ensure that exposures and risks are not under-estimated. 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 and no further action may be required at the site. Additionally, if there is contamination at a site, but no operable exposure pathways by which receptors may come into contact with the contamination, then there is no exposure and therefore, no health risk.

First and foremost, the conservative assumptions employed for exposure assessment generally over-estimate the true or likely case. Generally, the exposure scenarios defined within SLRAs are for 'reasonable maximum exposure' (plausible but upper bound and of exceptional or rare occurrence) or worst case. Secondly, a Regulatory Exposure Level, used to characterize the 'potential' for risk, does not distinguish between the potential for disease and the absence thereof. For example, although RELs for non-cancer effects are defined as "the intake or concentration to which it is believed that a person can be exposed daily over a lifetime without deleterious effect" (HC, 1994), a slight or short term exceedence is seldom a cause for concern. This is due to the fact that such RELs are, for the most part, derived from No-Observed-Adverse-Effect-Levels (NOAELs) that are further reduced by the application of uncertainty factors to account for inter-species extrapolation (if required), inter-individual variability in toxic susceptibility (to consider 'sensitive' individuals), and other factors.

Where SLRA suggests a potential for unacceptable risks, this does not immediately indicate that actual site conditions are unacceptable. As indicated above, the SLRA is designed specifically to address worst-case scenarios. Often, further assessment may be necessary to resolve conservatism and uncertainty in the SLRA process before the actual extent of health risk can be fully quantified and defined. The SLRA can identify potential

data gaps associated with site characterization, that include the presence of contaminants in media that were not adequately sampled in previous environmental investigations or identify additional data regarding receptor characteristics for particular site use. These uncertainties can be quantified in a complex site-specific risk assessment.

2.2 Federal Contaminated Site Risk Assessment in Canada

Health Canada has now prepared three parts in an evolving series of guidance documents on human health risk assessment for contaminated sites in Canada:

1. Federal Contaminated Sites Risk Assessment in Canada, Part 1: Guidance on Human Health Screening Level Risk Assessment (SLRA). Version 1.1, Environmental Health Assessment Services, Health Canada, Ottawa. October 3, 2003.

2. Federal Contaminated Sites Risk Assessment in Canada, Part 2: Health Canada Toxicological Reference Values (TRVs). Version 1.0, Environmental Health Assessment Services, Health Canada, Ottawa. October 3, 2003.

3. Federal Contaminated Sites Risk Assessment in Canada, Part 3: Guidance on Peer Review of Human Health Risk Assessments. Version 1.0, Environmental Health Assessment Services, Health Canada, Ottawa. January 5, 2004.

A variety of additional guidance documents are now in development, including guidance on conducting detailed, comprehensive, site-specific risk assessments for chemical, radiological and biological contamination.

Figure 3 presents a simple schematic of Health Canada's SLRA guidance. The document offers guidance on the general conduct of risk assessments and information that is required for the assessment. The SLRA guidance provides standard assumptions for receptor characteristics, including, but not limited to body weight, inhalation rate, and soil ingestion rates for various age groups. Additionally, there are recommendations for exposure duration and frequency for various receptors at different types of sites, including agricultural, residential/parkland and commercial/industrial land uses. Health Canada has also provided standard equations for estimating exposure and potential risk for a variety of exposure pathways that occur at contaminated sites. Professional judgement is still required for the interpretation of site characteristics from environmental site investigations, as well as other site-specific characteristics. However, numerous recommendations are provided in the SLRA guidance document to attempt to reduce contractor variability in the application of risk assessment at federal contaminated sites.

The SLRA guidance received wide application in the fall of 2003, during which 89 federally-owned or operated contaminated sites were submitted to screening level risk assessment following that guidance, for the 2003-04 round of funding submissions under the FCSAAP program. The provision of standardized guidance resulted in a significant reduction in risk assessment variability (see Figure 4). Of 89 contaminated sites

assessed, >90% of the assessments conducted by contractors agreed with the risk estimates determined by Health Canada for those same sites. However, some significant discrepancies remained for some sites. As a result, a workshop was held in March 2004 with those consultants that had applied the SLRA guidance, in order to identify and define necessary revisions to further reduce misinterpretation of the guidance and other causes of observed variability. Version 2 of the SLRA guidance will be released by Health Canada in 2004.

3.0 SUMMARY AND CONCLUSIONS

The practice of risk assessment, for contaminated sites or other environmental issues, is the subject of considerable variability with respect to methods, equations and assumptions for exposure estimation, as well as in the selection of regulatory exposure levels for risk characterization. That variability results both from the inconsistency in guidance available from different levels of government, and from the continuing requirement for professional judgment in the interpretation of that guidance.

There are practical examples where that variability can range over several orders of magnitude in terms of estimated exposures and risks. The subsequent interpretation of the presence or absence of potential risks becomes difficult, if not impossible. Concomitantly, variations in definitions of 'acceptable', 'tolerable' or 'essentially negligible' risk across different levels of government or different jurisdictions further complicate the risk assessment process for federal agencies in Canada, that own contaminated sites in all regions of the country.

Health Canada has chosen to define standardized, quantitative guidance for the assessment of risks posed by contaminated federal properties. Such standardized guidance has been shown to reduce the variability in risk estimates from site to site, those assessments conducted of necessity by multiple consulting firms and individuals. This improved consistency ensures that risk assessment results from one site can be directly compared to others so that final determinations as to which sites constitute the greatest potential risk, and should thereby receive funding for remediation and improved environmental stewardship, can be made in an equitable and defensible manner.

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Table 1. Variations in Provincial Risk Assessment Guidance for Contaminated Sites.

Province	Risk Characterization		Preferred Source for RELs	General Guidance
	Hazard Quotient	Essentially Negligible Cancer Risk		
Atlantic provinces	1.0	10^{-5}	Health Canada	Atlantic-specific
Ontario	0.2	10^{-6}	US EPA	EPA RAGS [1]
BC	1.0	10^{-5}	Not specified	Some BC-specific Other not specified
Quebec	1.0	10^{-6}	US EPA	Quebec-specific

1. see US EPA (1992)

Table 2. Comparison of Some RELs from Health Canada and US EPA

Substance	Health Canada [1]	US EPA [2]	REL Type
Arsenic	2.8 $(mg/kg\text{-}d)^{-1}$	1.5 $(mg/kg\text{-}d)^{-1}$	Oral cancer slope factor
Benzo(a)pyrene	2.3 $(mg/kg\text{-}d)^{-1}$	7.3 $(mg/kg\text{-}d)^{-1}$	Oral cancer slope factor
Dichloromethane	0.05 mg/kg-d	0.06 mg/kg-d	TDI/RfD [3]
Hexachlorobenzene	0.0005 mg/kg-d	0.0008 mg/kg-d	TDI/RfD [3]
Methyl methacrylate	0.05 mg/kg-d	1.4 mg/kg-d	TDI/RfD [3]
Tetrachloroethylene	0.014 mg/kg-d	0.01 mg/kg-d	TDI/RfD [3]
Toluene	0.22 mg/kg-d	0.2 mg/kg-d	TDI/RfD [3]
Vinyl chloride	0.26 $(mg/kg\text{-}d)^{-1}$	0.72 $(mg/kg\text{-}d)^{-1}$	Oral cancer slope factor
Xylenes	1.5 mg/kg-d	0.2 mg/kg-d	TDI/RfD [3]

1. from HC (2003b)
2. from US EPA IRIS (http://www.epa.gov/iris/)
3. TDI = tolerable daily intake (Health Canada terminology);
   RfD = reference dose (EPA terminology)

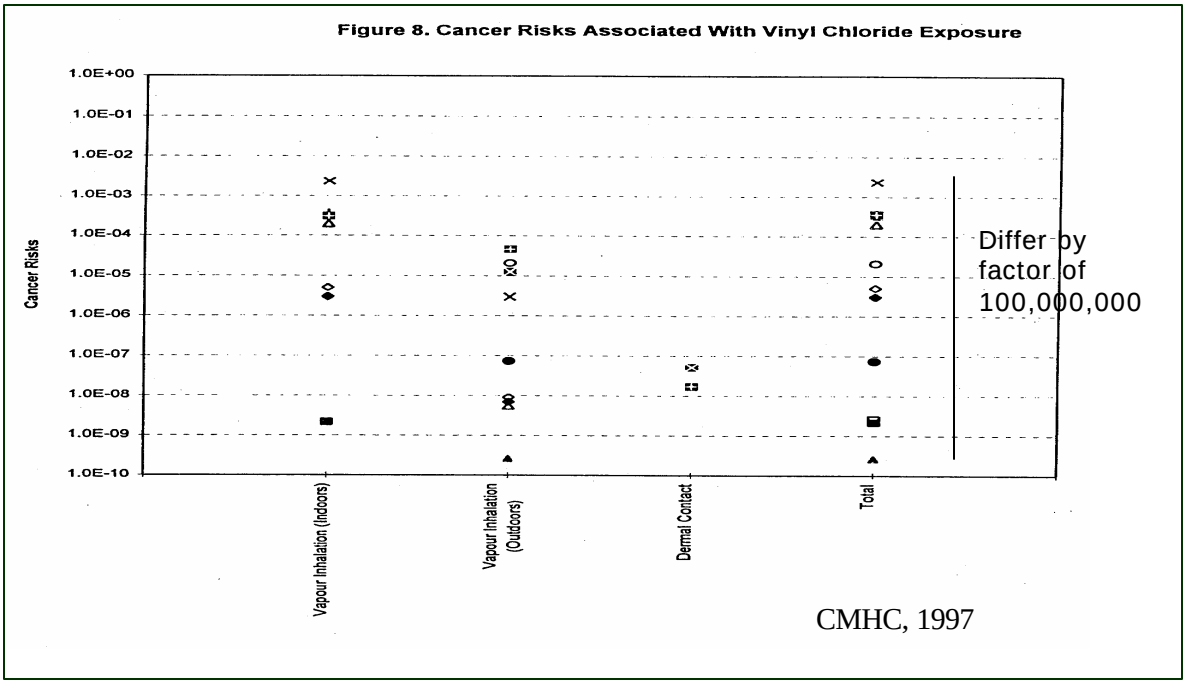

Figure 1. Variability in vinyl chloride risk estimated by multiple contractors for the same residential contaminated site. From CMHC (1997)

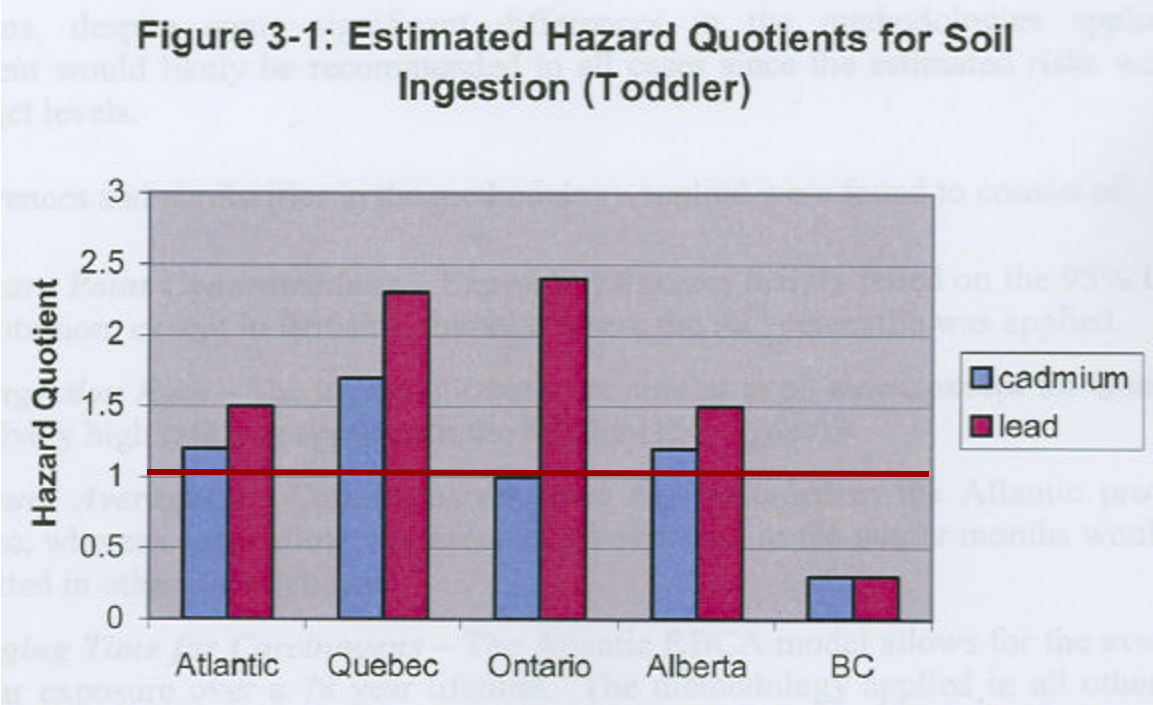

Figure 2: Inter-provincial variation in estimated hazard quotients (HQ = dose ÷ Regulatory Exposure Level) for Pb and Cd, for a toddler ingesting contaminated soil at a hypothetical site. A HQ = 1.0 is generally interpreted as negligible risk, except for Ontario where negligible risk is HQ = 0.2. From Dillon (2004).

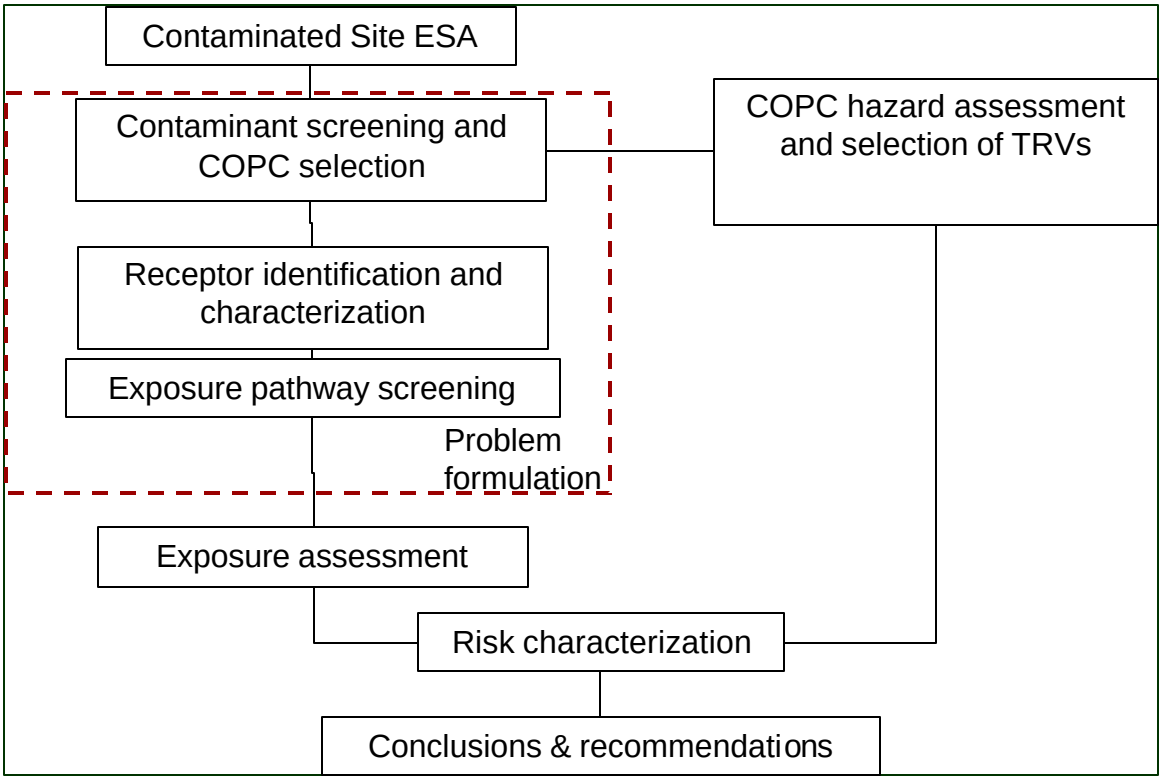

Figure 3. Schematic of Health Canada's SLRA Guidance (see HC, 2003a). COPC = contaminant of potential concern.

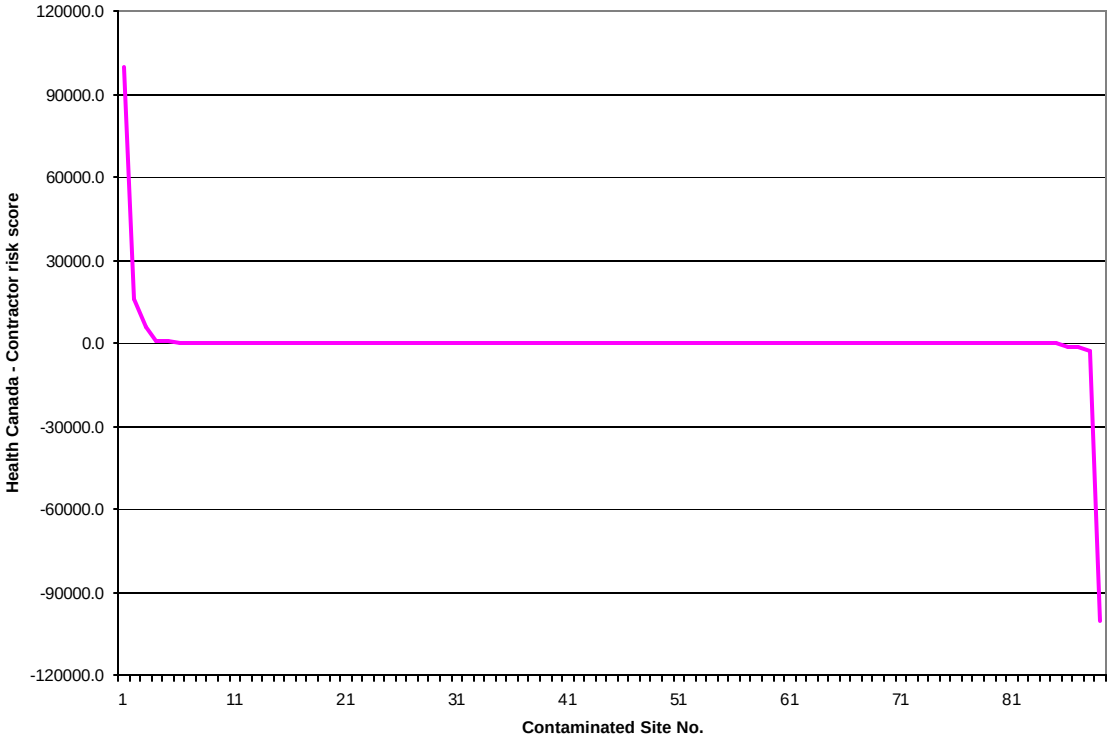

Figure 4. Comparison of overall contaminated site risk scores determined by Health Canada versus those determined by contractors following the SLRA guidance. Line depicts Health Canada scores minus contractors' scores for each of a total on 89 federal contaminated sites. A value of zero (0) indicates those sites where the Health Canada standard calculations matched the calculations of the consultants.