Proceedings of the 18th Annual British Columbia Mine Reclamation Symposium in Vernon, BC, 1994. The Technical and Research Committee on Reclamation A FRAMEWORK FOR CONDUCTING HUMAN HEALTH RISK ASSESSMENTAT CONTAMINATED SITES

R. Zapf-Gilje, B. Boyle, W. Wright, W. Haerer (Colder Associates) M. Macfarlane (B.C. Environment)

Introduction

Colder Associates was commissioned by the B.C. Ministry of Environment, Lands & Parks (B.C. Environment), Environmental Protection Division, to conduct a "Phase 1: Review of Risk Assessment Methods for the Development of Human Health Risk Assessment Guidance for Contaminated Sites" in January 1993.

The purpose of the study was to initiate the process of developing provincial protocols for the application of quantitative human health risk assessment at contaminated sites. This was undertaken by way of a review of methodologies used by other jurisdictions in North America and overseas, and the development of a practical framework. The finalized framework is presently being used by Health and Welfare Canada as the basis for the development of a detailed guidance document for use by industry and regulators (Phase II). Production of the risk assessment guidance document is expected to be followed by the training of regulatory staff as to its use and application (Phase III). The development of such a guidance document will be of significant benefit to parties involved in the investigation, remediation, management and regulation of contaminated sites in B.C. and Canada.

This paper, which focusses on the outcome of the Phase I study, will present 1) a brief discussion of the present status of the use of risk assessment at contaminated sites; 2) the criteria used in developing the framework; 3) highlights of the recommended framework; and 4) a case study using relevant examples from a quantitative human health risk assessment for a town located on an old mine tailings site in northern British Columbia.

Definitions

Before continuing, a few definitions of terms used throughout this paper are provided below.

Correlation: A dependency that exists between model variables.

Correlation coefficient: A number between minus 1 and 1 that specifies mathematically the amount of positive or negative correlation between model variables. A correlation of 1 indicates a perfect positive correlation, minus 1 indicates a perfect negative correlation, and O indicates that there is no correlation.

Deterministic: Referring to a process that contains no, or ignores, random events or probability.

Risk (human health): The likelihood, or probability, that the toxic effects associated with a chemical will be produced in populations of individuals under their actual conditions of exposure. Risk is usually expressed as the probability of occurrence of an adverse effect, i.e., the expected ratio between the number of individuals that would

experience an adverse effect in a given time, and the total number of individuals exposed to the factor. Risk is expressed as a fraction, without units, and takes values from 0 (absolute certainty that the adverse effect will never occur, which can never be shown) to 1.0, where there is absolute certainty that an adverse affect will always occur.

Risk analysis: The process and techniques that are used to identify and evaluate the nature and magnitude of a risk, as well as methods to best use the resulting information. Risk analysis includes risk assessment, risk communication, and risk management.

Risk assessment (human health): The process whereby all available scientific information is brought together to produce a description of the nature and magnitude of the risk associated with exposure of human receptors to an environmental chemical.

Risk communication: The process of explaining the results of the risk assessment and the risk management decisions to concerned parties.

Risk estimation: The integration of the exposure assessment and toxicity assessment to evaluate the likelihood of the occurrance of adverse human health effects associated with exposure to an environmental contaminant or pollutant

Risk management: The managerial, decision-making and active hazard control process used to deal with those environmental agents for which risk assessment has indicated that the risk is too high.

Screening: The process of filtering implausible or unlikely exposure pathways, chemicals or substances, or populations from the risk assessment process in order to focus the analysis on the chemicals, pathways and populations of greatest or probable concern.

Stochastic: Referring to a process incorporating a random variable, or involving chance or probability.

B.C Environment Contaminated Site Management Policy

B.C. Environment currently intends to develop an integrated, coordinated and consistent approach to the identification, assessment and remediation of contaminated sites which presently impact or have the potential to impact on human health or the environment¹. As an initial step, B.C. Environment has established an interim set of environmental quality criteria², consisting of two complimentary but distinct approaches for establishing site-specific remedial objectives:

- 1) a criteria-based approach, which uses numerical contaminant concentration criteria to determine when detailed investigation or remediation is required, and to assess whether remediation has been properly completed; and,
- 2) a risk analysis approach, which involves site-specific risk assessment, accompanied by risk management. The potential human health risks posed by chemical substances are calculated and compared to levels of risk that are considered both technically achievable and publicly acceptable.

Proceedings of the 18th Annual British Columbia Mine Reclamation Symposium in Vernon, BC, 1994. The Technical and Research Committee on Reclamation

The risk analysis approach may be used in situations where there are potential health impacts, and exposure to contamination is reduced to acceptable levels by either containment or treatment (i.e., *in situ* management), or contaminant removal. Risk assessment may be applied in those situations where all contaminants cannot be removed, due, for example, to physical, technical or financial constraints. Where risk assessment is contemplated in the remédia don/management of a contaminated site, potential environmental impacts must also be addressed.

Currently, within British Columbia, risk assessments are typically conducted following one or more phases of investigation, once substantial data collection has taken place. To date, most risk assessments have employed deterministic models, which ignore random events and do not provide sufficient information to quantify uncertainty: they use point-estimate inputs and generate point-estimates of risk. Because of the lack of knowledge regarding the degree of uncertainty associated with a deterministic risk assessment, input parameters are generally highly conservative, which can result in estimates of risk that are not likely to reflect reality.

While viewed as being a desirable approach for addressing site-specific objectives, risk assessment is also recognized as being complex and inter-disciplinary, typically requiring various levels of expertise in data collection, site characterization, statistics, contaminant fate and transport modelling, toxicology, environmental chemistry, and data analysis. Without guidelines that detail the human health risk assessment process to be followed, inconsistencies are likely to occur. In the absence of any formal provincial risk assessment guidance, B.C. Environment has adopted an interim risk assessment approach generally based on the United States Environmental Protection Agency's (U.S. EPA) *Risk Assessment Guidance for Superfund* (RAGS), and has provided default values and assumptions for calculations of exposure¹.

In 1992, B.C. Environment initiated the development of specific guidelance by commissioning the *Phase I: Review of Risk Assessment Methods for the Development of Human Health Risk Assessment Guidance for Contaminated Sites.* The Phase I study, conducted by Colder Associates, consisted of the following components:

- a compilation, classification and review of information on existing contaminated site risk assessment approaches used in North America, Europe and British Commonwealth nations;
- an evaluation and comparison of the existing risk assessment approaches and of the degree to which various components of these approaches may be appropriate to B.C.;
- the development of recommendations regarding an optimal risk assessment process, i.e., one meeting the criteria set out below, that can be used to establish a practical risk assessment guidance document (Phase H) for the Province; and,
- the preparation of a reports detailing the findings of the study and a recommended human health risk assessment framework. The report, entitled *Quantitative Human Health Risk* Assessment: Phase I Review of Methods and Framework Recommendation, is presently available and copies may be obtained from B.C. Environment.

The criteria used in the development of the framework, highlights of the recommended Phase I human health risk assessment process, and examples from a risk assessment conducted in a manner consistent with the recommended framework, are presented in the remaining sections of this paper.

Criteria for Framework Development

Based on input from B.C. Environment staff, it was determined that an optimal human health risk assessment framework should:

- be consistent in application and allow for integration with the existing and proposed environmental legislation and policies of British Columbia;
- provide a sound basis for the development of structured technical components that will facilitate the consistent application, implementation, reporting, and review of risk assessments for contaminated sites;
- facilitate communication of the risk assessment requirements, scope, and outcome amongst risk assessors, risk managers, regulators, and other stakeholders;
- provide flexibility to account for site-specific factors and needs;
- provide the means for documenting and tracking the risk assessment process such that the chosen path of application can be retraced;
- minimize paper flow between the regulator and party(ies) responsible for the site;
- provide direction for consideration of future land- water- and air-use scenarios; and,
- address the need to optimize costs, time, and expertise required to conduct and review varying levels of risk assessments.

No single risk assessment method reviewed by the study team was found to meet the B.C. Environment criteria. However, it was determined that a hybrid approach, incorporating various technical components from well-established methods, plus; allowances for stochastic modelling as described in more "emerging" methods, could be recommended.

Highlights of Recommended Framework

The resulting framework, which is largely based on elements of the U.S. EPA *Risk Assessment Guidance for Superfund* (RAGS)⁴ including some of the supplemental RAGS guidance, and incorporates the stochastic modelling enhancements of the Quebec Ministry of the Environment *Guidelines for Toxicological Risk Assessment*⁵, is comprised of three major components:

- problem formulation, which emphasizes contaminant, receptor and exposure pathway screening, and the development of a site-specific conceptual model;
- analysis, involving the completion of toxicity and exposure assessments; and,
- risk characterization, the integration of toxicity and exposure assessment results, the description and quantification of risk, and the analysis of uncertainty.

Proceedings of the 18th Annual British Columbia Mine Reclamation Symposium in Vernon, BC, 1994. The Technical and Research Committee on Reclamation

The framework allows for the use of risk assessment in an iterative manner and, where appropriate, in all phases of the investigation and remediation process (Figure 1). In addition, the provision of clear and concise phase-specific interim deliverables, documenting procedures and assumptions, is recommended. Such documentation and tracking will allow the chosen path of application to be retraced, and facilitate review and communication amongst risk assessors, risk managers, regulators and other stakeholders.

The value of developing a site-specific conceptual model at an early stage in the investigation/remediation process, to focus on the contaminants, pathways and receptors mat are truly of concern, is also emphasized. The conceptual model (elements shown in Figure 2) can be used to assist in the planning of all phases, and can be refined throughout the project as additional information is gathered. Such a site-specific focussing or screening effort will allow subsequent phases of the project to be completed in a more timely and cost-effective manner.

By allowing for a high degree of site specificity and for more realistic modelling in the form of stochastic analysis and quantitive uncertainty analysis, where appropriate, the recommended framework is expected to result in risk assessments that more closely approach reality than those using highly conservative deterministic default assumptions. Stochastic models incorporate random variables and uncertainty and allow uncertainty in the results to be quantified; such models use probability distributions as inputs and generate am output in the form of a probability distribution. The use of stochastic modelling, where appropriate, is: expected to be especially useful in communicating me meaning and certainty of assessment results and enhance the subsequent risk management process. 'Issues to consider in the selection of a deterministic or stochastic method of analysis are presented in Table 1.

The following is a phase-by-phase checklist of the essential elements of the recommended contaminated site human health risk assessment framework. The elements are illustrated in Figure 3.

Step 1; Problem Formulation

- i) Screen contaminants, pathways, and receptors, documenting both the process and the rationale used, to assist in development of a site-specific conceptual model:
 - Screen contaminants against applicable regulatory criteria, sitespecific background concentrations, and site-specific risk-based objectives to determine contaminants of potential concern.
 - Screen receptors based on current and future land, water, and air uses to identify those receptor populations or subpopulations of potential concern.
 - Screen exposure pathways to identify those likely to be significantly operative and of potential concern. (A depiction of the pathway screening process for air is shown in Figure 4).
- ii) Develop a site-specific conceptual model and document the model, the screening procedures and results, in the form of a technical memorandum, for use in communicating 1) the risk assessor's understanding of the site, and 2) the focus of subsequent detailed risk assessment phases, to regulatory authorities and other relevant stakeholders.

Proceedings of the 18th Annual British Columbia Mine Reclamation Symposium in Vernon, BC, 1994. The Technical and Research Committee on Reclamation FIGURE 1. CONTAMINATED SITE REMEDIATION PROCESS



FIGURE 2. CONCEPTUAL MODEL ELEMENTS



Adapted from the report to B.C. Environment: *Quantitative Human Health Risk Assessment: Phase 1 - Review of Methods and Framework Recommendation*

Peterministic	Stochastic
Low degree of public interest Relatively low degree of site-specific uncertainty Deterministic result is far (rom action level Small-scale project (scope, budget, schedule) Routine application	High degree of public interest Relatively high degree of site-specific uncertainty Deterministic result is close to action level Large-scale project (scope, budget, schedule) Non-routine application
and/or pathways (rapid screening or triggering tool) Initial model development	and/or pathways Model refinement Quantification of uncertainty Detailed value-of-information analysis (project planning)

Adapted from the report to B.C. Environment: *Quantitative Human Health Risk Assessment: Phase 1 - Review of Methods and framework Recommendation*

Proceedings of the 18th Annual British Columbia Mine Reclamation Symposium in Vernon, BC, 1994. The Technical and Research Committee on Reclamation FIGURE 3. ELEMENTS OF RECOMMENDED HUMAN HEALTH RISK ASSESSMENT FRAMEWORK



Adapted from the report to B.C. Environment: Quantitative Human Health Risk Assessment: Phase 1 - Review of Methods and Framework Recommendation



Adapted from the report to B.C. Environment: *Quantitative Human Health Risk Assessment: Phase 1 - Review of Methods and Framework Recommendation*

Step 2: Analysis

i) Exposure Assessment

- Characterize contaminants of potential concern in terms of their environmental distributions in both space and time; evaluate bioavailability of such contaminants.
- Characterize receptors based on existing or future land, water, and air use, which govern such factors as age, weight, contact rate, exposure frequency and exposure duration.
- Conduct exposure analysis to combine contact rate, frequency, and duration with physical receptor characteristics to determine dose estimates.
- Document, in the form of a technical memorandum, results of the initial exposure assessment, including procedures and assumptions used, for use in communicating interim status of the assessment to regulatory authorities and other relevant stakeholders.

ii) Toxicity Assessment

- Classify toxicants as carcinogens, non-carcinogens, or both, as appropriate.
- Access toxicity databcises, develop surrogate toxicity values or distributions if required, or, in rare instances, conduct site-specific toxicological studies,
- Conduct dose-response analysis, taking high-dose-to-low-dose and animal-to-human extrapolations into account as required; evaluate bioavailability of contaminants of potential concern (unless taken into consideration during the exposure assessment).
- Document, in the form of a technical memorandum, results of the initial toxicity assessment, including procedures and assumptions used, for use in communicating interim status of the assessment to regulatory authorities and other relevant stakeholders.

Step 3: Risk Characterization

- Integrate exposure and toxicity assessment results.
- Estimate non-carcinogenic risks by comparison to threshold toxic effects values or distributions.
- Estimate carcinogenic risks on the basis of incremental probabilities of developing cancer.
- Analyze, quantify (where appropriate) and discuss uncertainty in the overall risk assessment process.
- Describe the risks in terms of magnitudes, types, and uncertainties involved (as opposed to evaluating risk significance).

Case Study - Stochastic Risk Assessment

The following sections illustrate a risk assessment which follows the framework presented above. In particular, the case study demonstrates: 1) the iterative nature of the risk assessment; 2) the value of developing a conceptual site model; and, 3) the benefits of applying stochastic analysis, in terms of gaining a better understanding of the site, quantifying uncertainty, assessing the value of information and focussing subsequent phases of investigation. For simplicity, the case study focusses on:

- one exposure scenario (residential)
- one exposure pathway (inhalation of fugitive dust); and ,
- non carcinogenic risk.

The case study pertains to a mining town located in northern B.C., which, during 50 years of gold mining and ore processing, had become contaminated with arsenic. Mine tailings containing arsenic had been used as fill within the town itself, and extensive tailings deposits are now present on the outskirts of the town. Following a number of site investigations, a decision was made to remediate (by way of excavation or containment) all residential properties having soil with arsenic concentrations in excess of 150 milligrams per kilogram (mg/kg). A quantitative human health risk assessment was conducted to determine whether additional remediation would be required at those properties having arsenic concentrations in the range of 30 to 150 mg/kg.

Overview of the Risk Assessment Process

Although the risk assessment process was initiaited following the completion of extensive site investigations, the risk assessment itself was conducted iteratively, with technical memoranda documenting the problem formulation phase (exposure scenarios, conceptual model development) and analysis phases (toxicity, bioavailability and exposure assessments) being submitted separately to B.C. Environment for review. Following the receipt of B.C. Environment and internal review comments, the technical memoranda were revised appropriately and eventually included as appendices in the risk assessment report, in order to provide a means of documenting the process and retracing the decision-making route.

Both deterministic and stochastic models were used to estimate the health risks associated with exposure to arsenic. As a safety measure, conservative assumptions were used in both methods, a practice which tends to result in an overestimate of the risk to human health. The risk assessment was concerned with any increased risk to human health which results from anthropogenic releases of arsenic (i.e., arsenic originating from the mine and mine tailings). For this study, arsenic found in the environment at site was assumed to be in the more toxic inorganic form, except in food, where it was assumed to be in the less toxic, non-carcinogenic organic form. The full risk assessment presented an estimate of the carcinogenic and non-carcinogenic risks associated with arsenic exposure to a random individual within this population.

Problem Formulation

Exposure Scenarios

Arsenic had been explicitly defined as the sole contaminant of concern on the basis of earlier assessments, hence the problem formulation phase focused on definition of the potential receptors and exposure pathways. Three distinct contaminated areas within and adjacent to the town had been defined and identified:

- soils within the town;
- lake-side tailings; and,
- river-bank tailings.

Six receptor populations of potential concern were identified, including: residents of the town (present-day and future); potential future resident populations of the lake-side and river-bank tailings areas; and, current and future recreational users of the lake-side tailings area.

Conceptual Model

A conceptual site exposure pathway model, identifying contaminant sources and release mechanisms, environmental transport and residency media, exposure routes, and receptors, was defined (Figure 5). Although pathways would normally be screened at this stage in the risk assessment, it was decided by the project team that all pathways would be evaluated to the extent feasible. This was made possible by the focus on a single contaminant; it was deemed desirable because, as likely the first probabilitistic contaminated site risk assessment conducted for B.C. Environment, it would provide a good overall pathway template for future assessment to serve as a comprehensive value-of-information analysis to guide any further site characterization efforts.

Prior to proceeding with the analysis phase, pathways expected to contribute the most to the total risk (i.e., primary pathways) were postulated, as shown in Figure 5. This in no way affected the performance of the risk assessment; rather, the risk assessment served to test this hypothesis.

Analysis

Components of Analysis Phase

The analysis phase of the risk assessment was comprised of three subphases:

- an arsenic bioavailability assessment;
- a toxicity assessment; and,
- and exposure assessment.

The purpose of the analysis phase was to identify toxicity and exposure equations to be used in the assessment and to document stochastic and deterministic assumptions for each of the independent variables (input parameters) in these equations.

Proceedings of the 18th Annual British Columbia Mine Reclamation Symposium in Vernon, BC, 1994. The Technical and Research Committee on Reclamation FIGURE 5. CONCEPTUAL PATHWAY MODEL FOR ARSENIC EXPOSURE -CASE STUDY



Primary Pathways

Secondary Pathways

Examples of the toxicity and exposure equations, relevant to the inhalation of fugitive dust pathway, are presented in the following sub-sections. These equations are accompanied by examples of graphical representations of the stochastic (distributional) and deterministic (point estimate) assumptions for several of the input parameters (Figure 6); examples of the supporting rationale for some of these assumptions are listed in Table 2.

Bioavailability Assessment

Seven bioavailability factors were identified for the three types of exposure routes identified in Figure 5 and are listed below:

- ingestion of soil, tailings, water (BF_W) and food;
- dermal contact with solid and aqueous media; and,
- inhalation (BF_i).

These factors (unitless) were applied to normalize toxicity and exposure to an absorbed-dose basis.

Toxicity assessment

Toxicity factors were identified for the two types of toxicity mechanisms relevant to arsenic exposure (carcinogenic and non-carcinogenic). The factor pertaining to the inhalation of fugitive dust, for the non-carcinogenic toxicity mechanism, derived on the basis of water consumption studies, is:

• Non-carcinogenic toxicity reference dose - oral ingestion of inorganic arsenic (RfD_{o,i}) in mg/kg-day.

The above toxicity variable was modified according to the following equation to yield an absorbed-dose-basis effective toxicity factor:

Effective Reference Dose (non-carcinogenic toxicity factor) in mg/kg-day:

$$ERfD_{o,i} = RfD_{o,i} \times BF_w$$
 (Equation 1)

Exposure assessment

A total of 55 exposure factors were identified for the 16 arsenic exposure pathways shown on Figure 5. The applicable equation for the calculation of non-carcinogenic absorbed arsenic dose for the fugitive dust inhalation pathway is as follows:

Non-carcinogenic absorbed dose (mg/kg-day):

$$D_{n,fd,inh} = InhR \times RPSF \times RF \times C_{fd} \times EF_0 \times BF_i \times BW^{-1} \times UCF_t^{-1}$$

(Equation 2)

Proceedings of the 18th Annual British Columbia Mine Reclamation Symposium in Vernon, BC, 1994. The Technical and Research Committee on Reclamation FIGURE 6. STOCHASTIC AND DETERMINISTIC ASSUMPTIONS FOR INPUT PARAMETERS

Toxicity Variable Assumption

0.00027

0.00077 0.0014

0.0003

Assumption: RfDoi (mg/kg-d) Non-Carcinogenic Toxicity Reference Dose

Triangular distribution with parameters: Minimum Likeliest Maximum Deterministic estimate:



Exposure and Bioavailability Variable Assumptions





Lognormal distribution with parameters:		RPSFw	
Mean	0.72		
Standard Dev.	0.16		
Maximum	1		
Selected range is from 0.00 to 1.00			
Mean value in simulation was 0.70			
Deterministic estimate:	0.25	0.36 0.61 0.86 1.11	

FIGURE 6. (CONTINUED) STOCHASTIC AND DETERMINISTIC ASSUMPTIONS FOR INPUT PARAMETERS

Exposure and Bioavaitability Variable Assumptions

Assumption: Cfd (mg/m3) Arsenic Concentration in Fugitive Dust



Assumption: Bfi (unitless) Arsenic Bioavailability Factor for Inhalation

Uniform distribution with parameters:		Bfi	
Minimum	0.75		
Maximum	0.85		
Selected range is from 0.75 to 0.85			
Mean value in simulation was 0.80			0.12
Deterministic estimate:	1	0.75 0.77 0.80	0.82 0.1

Assumption: RF (unitless) Fraction of Respired particulates retained in the lungs

Exponential distribution with parameters:		RF
Rate	20	
Maximum	0.35	
Selected range is from 0.00 to 0.35		
Mean value in simulation was 0.05		
Deterministic estimate:	1	
		0.00 0.06 0.12 0.13 0.23

Proceedings of the 18th Annual British Columbia Mine Reclamation Symposium in Vernon, BC, 1994. The Technical and Research Committee on Reclamation TABLE 2. EXAMPLES OF RATIONALE FOR INPUT PARAMETER ASSUMPTIONS

Assumption: BW (kg) Body Weight

Distribution — Custom bimodal distribution with a mean of 62 kg and a standard deviation of 23 kg, with minimum and maximum values of 9.2 and 110 kg, respectively.

Distribution rationale – Derived from truncated normal distributions developed from GCA (1985) for female and male children, youths, and adults that were sampled in proportion to the demographic profile for ϕ_{OWFN} (R. Fisk, BCH [Memorandum to J. Lugsdin, J. Smith, and J. Ward, BCE] April 23, 1990) to derive a balanced distribution for the overall population.

Correlates — On the basis of subjective judgement: $IngR_{w/d}$ at r = -0.50 (children generally eat more dirt), $IngR_{tw}$ at r = 0.50 (large people generally consume more tap water), EvD_s at r = -0.50 (young people generally swim longer), EF_s at r = -0.50 (young people generally swim longer), $IngR_t$ at r = 0.50 (large people generally eat more fish), $IngR_s$ at r = 0.25 (large people generally eat more fish), $IngR_s$ at r = 0.25 (large people generally eat more fish), $IngR_s$ at r = 0.25 (large people generally eat more fish), $LngR_s$ at r = 0.25 (large people generally eat more skin surface area), and SE at r = -0.50 (young people generally wear less clothing).

Deterministic estimate - 61 kg.

Deterministic rationale - Age-weighted average of default values specified under BCE policy.

Assumption: InhR (m3/d) Inhalation Rate

Distribution — Lognormal with an arithmetic mean of 19 m^3/d and an arithmetic standard deviation of 13 m^3/d , truncated at the 99.9th percentile or 110 m^3/d .

Distribution rationale -- Derived from truncated lognormal distributions developed from GCA (1985) for light, moderate, and heavy breathing rate activities; these distributions were sampled in proportion to the average amount of time spent in the three activity categories to derive a balanced distribution for all activities.

Correlates - None.

Deterministic estimate -- 18 m³/d.

Deterministic rationale - Weighted average of activity- and age-specific default values specified under BCE policy.





The independent variables in the above exposure equations (which include parameters related to physical and behavioural characteristics of the exposed population as well as bioavailability and concentration-related parameters), in the order that they first appear, are:

- InhR inhalation rate (m³/day);
- RPSF respirable-particulate size fraction in the town (unitless);
- RF fraction of respired particulates retained in lungs (unitless);
- Cfd arsenic concentration in fugitive dust (mg/m³);
- EF₀ outdoor exposure frequency (days/yr);
- ED exposure duration (yr);
- BF_i arsenic bioavailability factor for inhalation (unitless);
- BW body weight (kg); and,
- UCF_t time unit conversion factor (days/yr).

It should be noted at this point that the distribution for arsenic concentration in fugitive dust, Qd, was based on a data set comprised entirely of non-detectable values. The assumption that the concentration of arsenic in fugitive dust is uniformly distributed between zero and the detection limit, as shown in Figure 6, was felt to be conservative, and likely to result in a conservative estimate of risk from this pathway.

Risk Characterization

The risk characterization phase of the risk assessment consisted of three sub-phases:

- risk estimation;
- uncertainty analysis; and,
- risk description.

Risk Estimation

Risk estimation was undertaken by combining the toxicity and exposure assessment equations to calculate both deterministic and stochastic estimates of risk. Carcinogenic risks were reported as incremental (above-background) lifetime cancer incidence risks, or ILCRs, and non-carcinogenic risks were reported as pathway-specific hazard quotients, or HQs, or as a total site hazard index, or HI, which is the sum of all pathway-specific HQs. Both HQ and HI are unitless.

Risk estimation equations for each of the 16 exposure pathways were developed. The applicable equation for calculation of the non-carcinogenic fugitive dust inhalation risk is as follows:

$$HQ_{fd,inh} = D_{n,fd,inh} / ERfD_{o,i}$$
 (Equation 3)

The effective toxicity factor is as defined for Equation 1, and the absorbed dose is as defined for Equation 2.

The deterministic analysis was conducted by solving the risk estimation equations on an Excel® spreadsheet. The stochastic analysis was conducted by solving the same equations on the same spreadsheet using the Crystal Ball® Monte Carlo simulation program (10,000 trials). The total risks were calculated by summing the deterministic risk estimates and stochastic risk distribution estimates for each of the 16 exposure pathways.

Deterministic Risk Estimation Result

The deterministic hazard quotient for the fugitive dust inhalation pathway, $HQ_{fd,inh}$, was estimated to be 0.012. The deterministic total non-carcinogenic risk (HI) for the town residential scenario, including background contributions, was estimated to be 7.

Stochastic Risk Estimation Result

The distributions for $HQ_{fd,inh}$ and for HI, resulting from the stochastic analysis, are shown in Figures 7 and 8, respectively.

Deterministic Uncertainty Analysis

Quantitative analysis of uncertainty is not possible in a purely deterministic risk assessment Deterministic assessments thus tend to be conservatively biased to ensure that results are consistent with the jurisdictional environmental iregulatory agency's mandate to protect human health and the environment However, as the results of the stochastic analysis were available for comparison, the level of conservatism associated with the deterministic results was quantified.

As can be seen in Figure 8, the deterministic result for the HI (7) exceeded by almost an order of magnitude the 99.9th percentile of the estimate of the corresponding stochastic risk distribution (1.2).

The U.S. EPA has recently defined any deterministic estimate in excess of the 99.9th percentile of the distribution as a bounding estimate⁶. Under such an operational definition, the deterministic estimate of HI is regarded as invalid for the purpose of making subsequent remedial action decisions. A conservative bounding estimate does, however, have utility as a screening tool.

The U.S. EPA⁶ requires mat decisions regarding the need for site remediation be made on the basis of a high-end risk estimate, which is defined as an estimate lying between the 90th and 99.9th percentile of the risk distribution. Conceptually, U.S. EPA's goal in deterministic modelling is to estimate the 95th percentile of the risk distribution, which is referred to within the agency as the risk corresponding to a "reasonable maximum exposure".

Forecast: HQ: fd,inh

Cell: E275

Statistics:	Value
Trials	10000
Mean	4.64E-02
Median (approx.)	1.83E-02
Mode (approx.)	1.02E-02
Standard Deviation	9.72E-02
Variance Skewness	9.45E-03
Kurtosis	7.34
Coeff. of Variability	87.87
Range Minimum	2.10
Range Maximum	1.17E-06
Range Width Mean	2.03E+ 00
Std. Error	2.03E + 00
	9 72F-04



Percentiles:

Percentile	Value (approx.)
0%	1.17E-06
5%	1.27E-03
25%	6.35E-03
50%	1.83E-02
75%	4.65E-02
95%	1.79E-01
100%	2.03E+ 00

Golder Associates

Proceedings of the 18th Annual British Columbia Mine Reclamation Symposium in Vernon, BC, 1994. The Technical and Research Committee on Reclamation FIGURE 8. DISTRIBUTION FOR HI (HAZARD INDEX) TOWN RESIDENTIAL SCENARIO

Mean	

Value

Mean	
	0.7E-02
Median (approx.)	3.5E-02
Mode (approx.)	1.3E-02
Standard Deviation	1.1E-01
Variance	1.2E-02
Skewness	6.7E + 00
Kurtosis	7.8E + 01
Coeff. of Variability	1.6E + 00
Range Minimum	2.0E-03
Range Maximum	2.2E + 00
Range Width	2.2E + 00
Mean Std. Error	1.1E-03



Total Non-Cancer Risk Estimate

Percentiles:

Percentile	<u>Value (approx.)</u>
0%	0.00
5%	0.01
25%	0.02
50%	0.04
75%	0.07
90%	0.15
95%	0.24
99%	0.50
99.9%	1.20
100%	2.16
Deterministic Estimate	7.00

Proceedings of the 18th Annual British Columbia Mine Reclamation Symposium in Vernon, BC, 1994. The Technical and Research Committee on Reclamation Stochastic Uncertainty Analysis

Quantitative analysis of uncertainty can be performed in two parts with the results of a stochastic risk assessment: 1) an evaluation of the overall uncertainty; and, 2) a sensitivity analysis.

• Evaluation of Overall Uncertainty

The overall uncertainty (i.e., uncertainty due to both stochastic environmental variability and to lack of knowledge) in the risk distribution can be evaluated by means of the range of the distribution and its coefficient of variation. The range is merely the maximum value minus the minimum value in the distribution, while the coefficient of variation is the standard deviation divided by the mean. A large range or coefficient of variation indicates a large amount of overall uncertainty in the distribution.

Figure 8 illustrates that the HI for a random individual in the town was approximately lognormally distributed, with an arithmetic mean of 0.07, and an arithmetic standard deviation of 0.11. The HI was found to range from 0.002 to 2 (three orders of magnitude between the 0.01th and 99.99th percentiles), while the coefficient of variation was determined to be 1.6.

Sensitivity Analysis

The second part of the quantitative uncertainty analysis for a stochastic result consists of a relative comparison of rank correlation coefficients of each of the independent variables against the corresponding dependent risk variable. This type of analysis provides information as to which of the numerous input parameters the resulting distribution is most sensitive. In other words, those independent variables that are highly correlated with the dependent variable have the most influence on the result.

Each highly correlated independent variable can then be examined in light of whether its overall uncertainty is due to stochastic variability (an irreducible form of uncertainty) or lack of knowledge (a reducible form of uncertainty). Such analysis can be useful in assisting in making decisions regarding what, if any, additional site investigation activities should be undetaken to improve the confidence in the risk assessment results.

One method of plotting the rank correlation coefficients for the input variables in the non-cancer risk modelling results is depicted in Figure 9, which presents this information in a percent-contribution-to-overall-uncertainty format.

Figures 9 illustrates that RF, the fraction of respired particulates retained in the lungs, is the variable to which the HI estimate is, by far, the most sensitive (with 19% contribution to the overall uncertainty of the HI estimate). There is likely to be a substantial lack of knowledge (reducible uncertainty) contributing to the overall uncertainty in the RF variable.

Proceedings of the 18th Annual British Columbia Mine Reclamation Symposium in Vernon, BC, 1994. The Technical and Research Committee on Reclamation FIGURE 9. PERCENT CONTRIBUTIONS TO OVERALL UNCERTAINTY FOR TOP FIVE NON-CANCER RISK MODEL VARIABLES



Risk Description

The risk description for the town residential scenario is provided below in two sections. First, the relative contributions of the various exposure pathways are analyzed, based upon both the deterministic and stochastic results. Second, the significance of the deterministic and stochastic estimates are evaluated by comparison to B.C. Environment's policy guidelines.

• <u>Pathway Exposure Contribution Analysis</u>

Deterministic Analysis:

The 16 non-carcinogenic exposure pathways assessed under the town residential scenario were tabulated in descending order of the magnitude of risk contribution, as estimated by deterministic analysis. The list indicated that the inhalation of fugitive dust pathway (HQ_{fd,inh}) was, relatively speaking, an insignificant contributor (less than 0.2%) to the HI estimate, and that about 43% of the HI estimate for town residents was attributable to dermal contact with lakeside tailings.

Stochastic Analysis:

The medians and 95th percentiles of the pathway-specific non-cancer risk estimates, resulting from stochastic modelling, were tabulated and ranked in descending order of the magnitude of risk contribution. The stochastic evaluation showed that inhalation of fugitive dust (HQ_{fd,inh}) is a primary contributor to the HI. The 95th percentile of HQ_{fd,inh} was estimated to be 0.18; that of the HI was estimated to be 0.20.

Comparison Against Regulatory Action Levels

Deterministic Analysis:

The deterministic estimate of non-carcinogenic HI for the town residential scenario, 7, is well above the B.C. Environment action level of unity (1.0). The pathways responsible for this value were primarily dermal contact with lakeside tailings, ingestion of home-grown produce, dermal contact with river-bank tailings and ingestion of lake-side tailings. The remaining 12 pathways, including inhalation of fugitive dust, were insignificant relative to B.C. Environment's HI guideline, accounting for less than 1% of the total non-carcinogenic risk when summed.

Stochastic Analysis:

An HI of 1.0 corresponded,, according to the Monte Carlo simulation output, to the 99.8th percentile of the distribution, or the upper bound estimate. The "reasonable maximum exposure", represented by the 95th percentile of the hazard index ($HI_{0.95}$) was 0.2, which is less than the HI action level. In other words, we are 95% certain that the hazard index for non-carcinogenic risks related to arsenic for town residents is 0.2 or less, and therefore that the site does not pose an unacceptable non-carcinogenic risk.

Discussion

Given that the deterministic risk estimate of HI for the town residential scenario was shown to be a bounding estimate (well beyond the 99.9th percentile), it was felt that it should be disregarded with respect to any decisions !regarding further remedial action. As the deterministic process was proven to have been adequately conservative, however, it was determined that the estimates could be used for pathway screening purposes, to focus any additional investigation or modelling efforts.

That the $HQ_{fd,inh}$ estimate (the largest contributor to the stochastic estimate of HI) was considered conservative provided for a meaningful value-of-information analysis: even though arsenic was not detected in the fugitive dust, there would be little, if any, benefit associated with obtaining additional and better quality data, as the conservative analysis indicated that the site does not pose an unacceptable non-carcinogenic risk.

Summary

The recommended human health risk assessment framework allows for the consideration of site-specific factors, such as the screening of exposure pathways, contaminants and receptors, and encourages the development of a conceptual site model, which will enable the risk assessor to focus on matters of potential significance or concern. The need to provide interim deliverables, in the form of technical memoranda documenting assumptions made and procedures used in the the problem formulation, toxicity assessment and exposure assessment phases, is emphasized. As demonstrated above, provisions made for the use of stochastic modelling, where appropriate, will likely result in estimates of risk mat more closely reflect reality, and allow uncertainty to be quantified; value-of-information analysis can then be performed to determine where additional (if any) investigation or modelling efforts should be focussed.

Acknowledgements

The authors gratefully acknowledge the other members of the team who have worked on components of or provided input to various aspects of this paper. Particular thanks are extended to R. Lee, L. Swenson, Dr. G. Fox (BCE) and Mr. J. Negraeff (BCE-WL).

References

- 1. Fox, G.R. and Macfarlane, M., 1992, *Human Health Risk Assessment Considerations for Contaminated Sites in British Columbia*, Draft 2, B.C. Environment, Victoria.
- 2. British Columbia Ministry of Environment, November 1989, *Criteria for Managing Contaminated Sites in British Columbia,* Draft 6, Victoria.

Proceedings of the 18th Annual British Columbia Mine Reclamation Symposium in Vernon, BC, 1994. The Technical and Research Committee on Reclamation

- 3. Colder Associates Ltd., June 1993, *Quantitative Human Health Risk Assessment: Phase I Review of Methods and Framework Recommendation*, Prepared for B.C. Ministry of Environment, Lands & Parks, Environmental Protection Division.
- 4. United States Environmental Protection Agency, 1989, *Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual,* RAGS, OSWER 9285.7-Ola and b, U.S. Environmental Protection Agency, Washington, D.C.
- 5. Quebec Ministry of the Environment, June 1991, *Guidelines for Toxicological Risk Assessment: Summary and Supporting Documents*, Quebec Ministry of the Environment, Risk Assessment Service.
- 6. United States Environmental Protection Agency, 1992, "Guidelines for Exposure Assessment", *Federal Register 57* (104):22888-22938