SUDBURY AREA RISK ASSESSMENT

VOLUME II – CHAPTER 1
INTRODUCTION AND GENERAL METHODOLOGY

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1.0 INTRODUCTION

1.1 Historical Background

The Sudbury Basin is an area rich in mineral deposits, particularly the nickel and copper ores that have drawn people to the region for the past 125 years. The soils of the area have naturally high levels of a number of metals, with recent studies demonstrating that there are areas in Sudbury with elevated metal levels in the soil. These areas are generally close to the historic smelting sites of Coniston, Falconbridge and Copper Cliff. Although these metals do occur naturally in all soils, the studies indicate that the higher amounts in surface soil (the top 5 cm of soil) are the result of local mining, smelting and refining operations (see Volume I, Sudbury Soils Study).

In 2001, the Ontario Ministry of the Environment (MOE) released a report that identified that the concentrations of nickel, cobalt, copper and arsenic in Sudbury soil exceeded the generic MOE soil quality guidelines. Under Ontario legislation, this triggers the need for more detailed study. Therefore, the MOE made two recommendations:

- That a more detailed soil study be undertaken to fill data gaps; and,
- That a human health and ecological risk assessment be undertaken.

Both Inco Limited (now Vale Inco) and Falconbridge Limited (now Xstrata Nickel) voluntarily accepted the recommendations and began working together to establish what is commonly referred to as the "Sudbury Soils Study". The full background and rationale for the Sudbury Soils Study (hereafter referred to as "the Study") was presented in Volume I of this report series.

The mining companies joined with four other major stakeholders in Sudbury to form a Technical Committee to oversee this rigorous study. These organizations included Vale Inco, Xstrata Nickel, the Ontario Ministry of the Environment (MOE), the Sudbury & District Health Unit (SDHU), the City of Greater Sudbury, and Health Canada's First Nation and Inuit Health Branch. A Public Advisory Committee (PAC) was also established to help address community questions and concerns about the potential impact of elevated metal levels on the local environment and on human health. As people who live and work in Sudbury, the members of this partnership share these questions and concerns.

As the first phase of the Study, a comprehensive soil sampling and analysis program was undertaken in 2001 by the MOE and the mining companies. Approximately 8,400 soil samples were collected from urban and remote areas and analyzed for 20 elements. These data form the basis for the current risk assessment.

Early in 2003, a consortium of consulting firms working together as the SARA (Sudbury Area Risk Assessment) Group was retained to undertake the risk assessment portion of the study. The main partners of the SARA Group were C. Wren & Associates Inc. (CWA), Cantox Environmental Inc. (CEI), Rowan Williams Davies and Irwin Inc. (RWDI), SGS Lakefield, and Goss Gilroy Inc. CWA was subsequently acquired by Gartner Lee Limited in 2006, and CEI became Intrinsik Environmental Sciences Inc. in 2007.

This document is Volume II of the overall Study report, and represent the methods, results, and conclusions of the human health risk assessment (HHRA) conducted in the Greater Sudbury Area (GSA).

1.2 Human Health Risk Assessment

An HHRA is a scientific study that evaluates the potential for the occurrence of adverse health effects from exposures of people (receptors) to chemicals of concern (COC) present in surrounding environmental media (*e.g.*, air, soil, sediment, surface water, groundwater, food and biota, *etc*.), under existing or predicted exposure conditions. HHRA procedures are based on the fundamental dose-response principle of toxicology. The response of an individual to a chemical exposure increases in proportion to the chemical concentration in critical target tissues where adverse effects may occur. The concentrations of chemicals in the target tissues (the dose) are determined by the degree of exposure, which is proportional to the chemical concentrations in the environment where the receptor resides, works or visits.

The Sudbury HHRA has been conducted in accordance with the regulatory guidance provided by the MOE (*O. Reg.* 153/04; MOEE, 1997 and related documents) and Health Canada (1993; 2004), and is primarily based upon guidance developed as part of the U.S. EPA Superfund program (U.S. EPA, 1989; 1992; 1997; 1999; 2001a,b; 2002; 2004). The current study is considered an area-wide risk assessment, as it is evaluating a large geographical area, rather than an individual property (that would be considered a site-specific risk assessment or SSRA). The main advantage to this approach is that it allows the estimation of potential health risks across a broad area, and can evaluate potential exposures from a variety of input sources (*e.g.*, smelter emissions, locally grown foods, regional drinking water, *etc*.). However, this approach also requires considerably greater amounts of data specific to the study area.

While many of the elements of an area-wide assessment have their roots in the approaches used to evaluate risk on a site-specific basis, it is important to note that there is no specific regulatory guidance available governing area-wide risk assessment in Canada. The differences between an area-wide risk assessment and a site-specific risk assessment are discussed in greater detail in Chapter 2.0 of this report.

It must also be recognized that a human health risk assessment is not the same as a community health study. Community health studies may involve such tasks as questionnaires, interviews, medical records review and collection of biological tissue or fluid samples (*e.g.*, blood, urine, hair) to directly measure human exposures. While these types of information can be valuable supplementary information for a human health risk assessment, they are not components of the established HHRA framework that is described below.

The following sections describe the human health risk assessment framework and methodology used in the HHRA for the Greater Sudbury Area.

1.3 The Human Health Risk Assessment Framework

The fundamental purpose of a HHRA is to estimate whether people working, living or visiting a given location are being exposed, or will be exposed to concentrations of chemicals that have the potential to result in adverse health effects. The assessment of potential occurrences of adverse health effects from chemical exposure is based on the dose-response concept that is fundamental to the responses of biological systems to chemicals, whether they are therapeutic drugs, naturally-occurring substances, or man-made chemicals in the environment. Thus, an HHRA evaluates the likelihood (or risk) of health effects following chemical exposures. It requires consideration of the toxic properties of the chemicals, the presence of receptors, and the existence of exposure pathways to the receptors. When all three factors are present (*i.e.,* chemicals, receptors and exposure pathways), there is a potential for adverse health effects to occur if exposures to the chemicals are elevated above acceptable levels (See Figure 1-1).

Figure 1-1 Factors Required for a Risk of Health Effects

The current framework used to evaluate potential environmental and human health risks has evolved considerably from its roots in the 1983 regulatory document, "Risk assessment in the federal government: Managing the process", released by the United States National Research Council (NRC, 1983). Although there are slight variations between different jurisdictions with respect to how HHRAs are conducted, the key elements of the human health risk assessment framework are highly consistent across most agencies in their respective jurisdictions.

The current HHRA follows the standard human health risk assessment framework (see Figure 1-2) that is composed of the following steps:

i) Problem formulation;

ii) Exposure assessment;

iii) Hazard assessment; and

iv) Risk characterization.

Typically, where potential adverse impacts are predicted through risk characterization, an additional step providing risk management recommendations to address these concerns can be added, if necessary. However, this report (Volume II) addresses the assessment of health risk, but does not provide risk management options. Proposed risk management approaches to any issues raised in this assessment are addressed in a separate document.

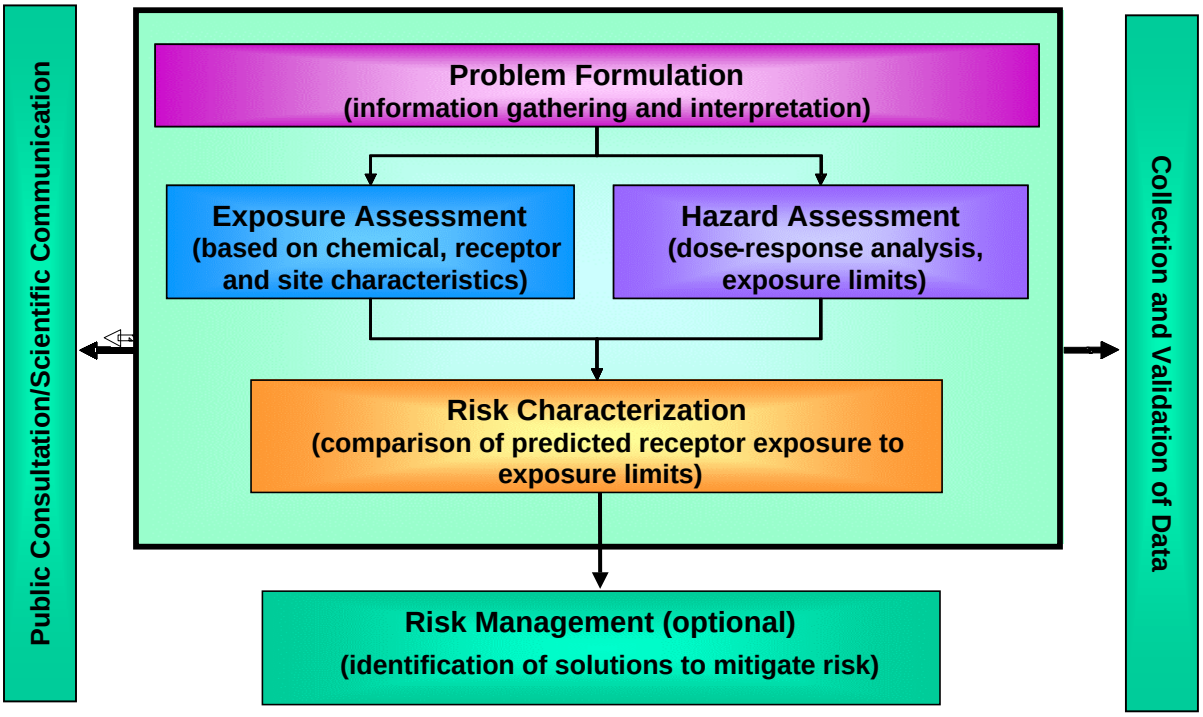

Figure 1-2 Overview of the Risk Assessment Framework

Within these four steps, human health risk assessments typically include the following key components and concepts:

- A multimedia approach which considers total exposure from all relevant environmental media. This approach recognizes that contaminants may be present simultaneously in food, air, water, consumer products, soil or dust;
- Exposure pathway identification and analysis;
- Receptor identification and characterization;
- Assessment of the bioaccessibility/bioavailability of COC;
- Toxicological assessment of COC; and
- Should they be required, the development of health-based site-specific intervention levels and/or other risk management activities (*e.g.*, decreasing bioavailability of metals, blocking exposure pathways), which can be used to establish remedial action levels or other risk management goals

on a community and area-wide basis that will be protective of human health, now and in the future.

Based upon the proposed Scope of Work, as outlined in the Request for Proposals (RFP) issued by the Technical Committee, issued by the following were identified as key objectives for the Sudbury HHRA:

1. Address health risk attributable to present environmental conditions and levels of COC in the Sudbury area;
2. Assess potential exposure pathways *via* all relevant media (*e.g.*, air, food, water, soil, *etc*.) and routes of entry (*e.g.*, dermal absorption, ingestion and inhalation) for individuals living in the Sudbury community;
3. Quantify the intake of each chemical of concern (COC) from each exposure pathway;
4. Compare each integrated COC intake with suitable acceptable or safe intakes (*i.e.*, toxicity reference values);
5. Document the literature sources of the acceptable intakes and their method of use for each COC;
6. Evaluate the dietary source of COC specific to the Sudbury area;
7. Utilize results of the Sudbury-specific COC speciation and bioaccessibility analyses to better understand the toxicity and bioavailability of the COC;
8. Evaluate the HHRA results with respect to land use in the Sudbury area;
9. Determine the levels of background exposure (non-related to smelting operations) of COC in the Sudbury area for comparison with exposures related to environmental levels of COC attributed to smelting operations;
10. Determine a range of soil intervention levels that may be used as a management option to reduce risk (if applicable); and
11. Address the issue of potential future impacts from ongoing COC deposition from the active emission sources in the Sudbury area to determine whether there is a need for the development of site specific health risk-based objectives for COC in environmental media.

Each of these objectives was integrated into the current HHRA, where possible, to respond to the specific concerns and issues raised as part of the Study.

1.4 A Phased Approach to Human Health Risk Assessment

The HHRA framework was applied in three distinct phases:

Phase 1 – Problem Formulation and Screening Level Risk Assessment;

Phase 2 – Sampling and Analyses to fill Identified Data Gaps; and

Phase 3 – Detailed Human Health Risk Assessment (HHRA).

The phased approach allowed the HHRA to proceed in a logical and sequential manner, and allowed for unresolved issues or major uncertainties to be addressed as they were identified. A phased approach also allowed for multiple iterations of the HHRA, such that various components of the HHRA were efficiently revisited and re-evaluated as new information became available.

A brief introduction to and list of key activities within each phase is provided below. Subsequent chapters (*i.e.*, Chapters 2 through 4) describe each phase in detail.

1.4.1 Phase 1 – Problem Formulation and Screening Level Risk Assessment (SLRA)

The first phase of the HHRA functioned as a scoping study, and used available data and exposure parameters to provide preliminary point estimates of exposure and potential risk. The majority of the screening of COC had been completed by analyses conducted during the initial stages of the Study, and was outlined in the RFP on which the current risk assessment was built. From the beginning of this Study, it was the expectation of the Technical Committee, and members of the Sudbury community at large that a full detailed HHRA would be conducted for each of the COC. Therefore, a formal quantitative screening level risk assessment (SLRA) was not undertaken by the study team. Rather, components of an SLRA were qualitatively conducted internally, prior to undertaking the detailed HHRA, to help guide the detailed risk assessment, to determine which chemicals required further detailed analysis (see Section 2.1.3), which exposure pathways required analyses (see Section 2.1.5), and also to identify key potential data gaps that needed to be filled (see Chapter 3).

Key activities in Phase 1 included the following:

- Identification of the Communities of Interest (COI) through a Stakeholder consultation process;
- Definition of the initial study area;
- Development of an approach for the selection of COC;

- Development of the overall HHRA methodology;
- Selection of toxicological criteria (*i.e.*, exposure limits) for each COC;
- Identification of the priority exposure pathways;
- Completion of a thorough review of existing data for the Greater Sudbury Area (GSA);
- Completion of components of a screening level risk assessment (SLRA); and
- Identification and prioritization of data gaps and information requirements for Phases 2 and 3.

Detailed methodologies for Phase 1 activities are provided in Chapter 2.

1.4.2 Phase 2 – Sampling and Analyses to Fill Identified Data Gaps

The purpose of Phase 2 of the HHRA was to collect the data necessary to fill the data gaps identified in Phase 1 (if feasible), and to decrease the level of uncertainty in the risk assessment. Using Phase 1 findings as a guide, Phase 2 included the development of sampling plans, sample collection and analyses, review of the new sampling data, and incorporation of new information into the spatial analysis or related databases. Based upon previous assessments and a review of the available data, the following issues were addressed in Phase 2:

- Speciation of nickel and arsenic in soil, dust and air to enable species-specific exposure and toxicity issues to be addressed;
- Data indicating the bioavailability of nickel (and other COC) from various exposure media (*e.g.*, investigation of nickel bioavailability/bioaccessibility in soil using both simulated stomach acid leach and bioaccessibility test data);
- A comprehensive air monitoring program for the GSA;
- Detailed dietary (*i.e.*, food consumption survey) and behavioural data on each Community of Interest, particularly the unique First Nation communities;
- Concentrations of COC in local fish and livestock;
- Concentrations of COC in local wildlife (*e.g.*, moose);
- Concentrations of COC in private potable water sources;
- Concentrations of COC in indoor environments (indoor dust); and
- Concentrations of COC in garden produce.

Detailed methodologies for Phase 2 activities are provided in Chapter 3.

1.4.3 Phase 3: Detailed Human Health Risk Assessment (HHRA)

Once all identified data gaps were addressed, the detailed HHRA was conducted, employing both deterministic and probabilistic exposure analysis approaches to characterize the exposure, predicted risks, and overall uncertainty inherent within the assessment methodology and results. A detailed discussion of exposure assessment techniques is provided in the HHRA Methodology (see Chapter 2). The following are some of the major items that were incorporated into the detailed Sudbury HHRA:

- A quantitative exposure analysis that incorporated data gathered during earlier phases of the assessment;
- A multi-pathway risk assessment model, based on published or peer reviewed literature. The model can provide both deterministic and probabilistic results for all COC, receptors and scenarios evaluated;
- A comprehensive toxicological profile for each COC;
- Selection of toxicological criteria (*i.e.,* toxicity reference values or exposure limits);
- The use of exposure and hazard data to characterize potential health risks, under all plausible exposure scenarios, for all receptors and all COC;
- An evaluation of the contribution to risk from each pathway and the cumulative risk from all pathways; potential interactions between any COC that may act *via* similar toxicological mechanisms were also considered, where appropriate;
- A quantitative uncertainty and sensitivity analysis to identify those assumptions and exposure pathways which significantly contribute to the overall uncertainty inherent within the predicted risk estimates;
- Development of area-specific, health-based, risk management objectives, if required. These objectives consider ongoing emissions, historical releases and impacts, fate and transport from sources to potentially impacted areas, natural levels in the Sudbury environment, and other sources of background exposure (*i.e.,* food); and
- Consultation with key stakeholders (*e.g.,* Technical Committee, Public Advisory Committee, First Nation and the general public) throughout the entire detailed HHRA process.

Detailed methodologies for Phase 3 activities are provided in Chapter 4.

1.5 References

Health Canada. 1993. Health Risk Determination. The Challenge of Health Protection. ISBN 0-662-20842-0.

Health Canada. 2004. Contaminated Sites Program. Federal Contaminated Site Risk Assessment in Canada. Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA). September, 2004.

MOEE. 1997. Guidelines for Use at Contaminated Sites in Ontario. Ontario Ministry of Environment and Energy. February ,1997.

NRC. 1983. Risk Assessment in the Federal Government: Managing the Process. U.S. National Research Council. National Academy Press, Washington, D.C.

U.S. EPA. 1989. Risk Assessment Guidance for Superfund. United States Environmental Protection Agency, Washington, DC. EPA/540/01.

U.S. EPA. 1992. Dermal Exposure Assessment: Principles and Applications, Interim Report. Exposure Assessment Group Office of Health and Environmental Assessment United States Environmental Protection Agency Washington, D.C. 20460.

U.S. EPA. 1997. Exposure Factors Handbook. Volumes I, II, and III. Office of Research and Development. United States Environmental Protection Agency. EPA/600/P-95/002Fa. August, 1997.

U.S. EPA. 1999. Risk Assessment Guidance for Superfund: Volume 3 - (Part A, Process for Conducting Probabilistic Risk Assessment). United States Environmental Protection Agency. Office of Solid Waste and Emergency Response, Washington, D.C.

U.S. EPA. 2001a. Risk Assessment Guidance for Superfund. Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment). Interim Review Draft – for Public Comment. Office of Emergency and Remedial Response, United States Environmental Protection Agency. EPA/540/99/005. Online: www.epa.gov/superfund/programs/risk/ragse/index.htm. Accessed: October, 2003.

U.S. EPA. 2001b. Risk Assessment Guidance for Superfund. Volume 3 Part A – Process for Conducting Probabilistic Risk Assessment. Office of Emergency and Remedial Response, United States Environmental Protection Agency. December, 2001. EPA 540-R-02-002. www.epa.gov/superfund/RAGS3A/index.htm.

U.S. EPA. 2002. Child-Specific Exposure Factors Handbook. National Center for Environmental Assessment, Washington, DC. EPA-600-P-00-002B. September, 2002.

U.S. EPA. 2004. Exposure Scenarios. National Center for Environmental Assessment, Washington, DC. EPA/600/R-03/036.