

Human Health Risk Assessment (HHRA) & Ecological Risk Assessment (ERA)

In the City of Greater Sudbury and its surrounding area

Study Document/Reports Independent Expert Review Panel (IERP)

REQUEST FOR PROPOSAL

PURPOSE

The Technical Committee overseeing the Sudbury Soils Study is requesting detailed proposals and cost breakdowns from the pre-qualified organizations expressing interest in coordinating an Independent Expert Review Panel (IERP) to provide expert review of Study documents/reports related to a Human Health Risk Assessment (HHRA) and Ecological Risk Assessment (ERA).

1.0 SUDBURY SOILS STUDY – BACKGROUND INFORMATION

The Sudbury Soils Study was initiated in 2001 for the purpose of carrying out a Human Health and Ecological Risk Assessment associated with elevated levels of metals present in Sudbury soils. The Study has been focusing on risks associated with six Chemicals of Concern (COC), nickel, copper, cobalt, arsenic, lead and selenium, originating from Inco Limited and/or Falconbridge Limited atmospheric emissions.

A Technical Committee was formed to oversee the Study, including membership from the Ontario Ministry of the Environment, Sudbury and District Health Unit, City of Greater Sudbury, Health Canada's First Nations and Inuit Health Branch, Inco Limited and Falconbridge Limited. The Technical Committee is supported by a Public Advisory Committee consisting of a Chair, residents of the City of Greater Sudbury and members from the Wahnapiatae and Whitefish First Nation communities. The position of Independent Process Observer was also created early in the process. The Process Observer attends all meetings related to the Sudbury Soils Study. The Process Observer is independent of any committee, represents the interests of both the general public and the environment and regularly reports to the public on the progress of the study.

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 are C. Wren & Associates Inc., Cantox Environmental Inc., RWDI, SGS Lakefield and Goss Gilroy Inc.

The Study is not only locally important to the Sudbury community, but it is also important to the national and international mining community, as it is a leading-edge, human health, and ecological risk assessment.

In September of 2001, the Ontario Ministry of the Environment issued a report entitled Metals in Soil and Vegetation in the Sudbury Area (Survey 2000 and Additional Historical Data). The report documented elevated soil metal levels in the Sudbury area, particularly nickel, copper, cobalt and arsenic (called Chemicals of Concern – COC), originating primarily from three major smelters that have operated in the Sudbury region (Copper Cliff, Falconbridge and Coniston). Levels of these four elements were found to exceed Table A Criteria as listed in an Ontario Ministry of the Environment 1997 document, “Guideline for Use at Contaminated Sites in Ontario”. MOE Table A effects-based guidelines for nickel, copper, cobalt and arsenic are based on the potential for injury to sensitive plants. “*Soil concentrations above the Table A guidelines do not imply that plant injury will occur, but rather that it **may** occur if the most sensitive plant species are present and the soil characteristics are such that the contaminant is bioavailable*”. The MOE recommended that “*the soil information obtained from the 2001 sampling program, in conjunction with the data from this report and the extensive existing Sudbury environmental data base, form the essential building blocks upon which an ecological and human health risk assessment for impacted communities in the City of Greater Sudbury will be developed.*” The report’s primary recommendations were that additional sampling be undertaken in “urban” and “remote” areas, and that Human Health and Ecological Risk Assessment studies be carried out.

In 2001, an intensive soil sampling program was initiated by the Ministry of the Environment, Inco and Falconbridge. Upon detailed review of these data, both Pb and Se were added to the list of CoC’s, based on their elevated levels in the soil in a broad geographical area and their connection to the smelting operations. These data, along with MOE’s historical soils data, form the core data set upon which the risk assessments have been developed.

Inco Limited and Falconbridge Limited volunteered to sponsor an HHRA and ERA and have been carrying out the risk assessment studies throughout 2003 and 2004 under the direction of the Technical Committee.

A vision statement for the project was developed as follows:

*A transparent process
that provides a thorough scientifically sound assessment
of the environmental and health risks to the Sudbury community,
and effectively communicates the results
so that future decisions are informed and valued.*

The Committee established objectives for the HHRA / ERA, which focused on characterizing, and where appropriate, quantifying the risks to the environment, biota and humans from CoC’s in the soil.

All interim scientific reports produced by the SARA Group are forwarded to one of two Scientific Advisors whose role is to undertake critical reviews of the documents. The aim of these reviews is to arrive at the final reports without missing any significant data gaps or scientific interpretation.

For further details regarding the Sudbury Soils Study, please refer to the Study's website at www.sudburysoilsstudy.com.

The following is a brief summary of the Study documents/reports that will need to be reviewed by the IERP:

Volume I – General

This volume will deal with general components common to both the ERA and HHRA. It will focus on such topics as emission rates of the CoC's and air quality trends from the major emission sources. Patterns of CoC accumulation will be described in the terrestrial environment (soils and vegetation) and in the aquatic environment (water and sediment). As much as possible, baseline levels for each CoC will be estimated representing pre-industrial conditions.

Volume II - Human Health Risk Assessment

The HHRA will assess potential health risks and exposure pathways to CoC's via all relevant media (e.g., air, food, water, soil, etc.). It will identify routes of entry (e.g., dermal absorption, ingestion and inhalation) that could affect individuals living in the Sudbury community. Where relevant data exists, background exposure levels to CoC's will be provided in the report i.e., exposure that is not related to smelting operations.

Volume III - Ecological Risk Assessment

The Ecological Risk Assessment report will identify the various CoC exposure pathways within the Sudbury terrestrial and aquatic ecosystems. It will look at flora and fauna that have been identified as Valued Ecosystem Components (e.g., organisms of ecological significance or societal importance). Risks / effects at the organism, population and ecosystem levels will be evaluated, including effects to biodiversity and the overall ecosystem integrity.

A tentative outline of the "Table of Contents" for each of the three volumes above is provided in **Appendix A**.

Very rough estimates of the anticipated length of the three volume Sudbury Soils Study reports (Volumes I to III) are provided below. Please note that these estimates are very preliminary at this time and are provided to obtain a perspective of the amount of material to be reviewed. The actual length of the reports may vary from these estimates.

Estimated Volume Lengths:

Volume I	–	500 pages
Volume II HHRA	–	1500 to 2000 pages
Volume III ERA	–	1000 to 1500 pages

2.0 GENERAL SCOPE OF WORK

IERP COORDINATION ROLE

Candidate organizations must be able to demonstrate independence and freedom from biases relative to the Sudbury Soils Study and its sponsors, Inco Limited and Falconbridge Limited. Independence and freedom from bias must be identified, whether it is through direct involvement with the above stakeholders, or through other indirect means.

They must also be able to demonstrate solid experience in undertaking expert review processes, preferably in the context of:

- 1) Human health risk assessment of metals and arsenic in a mining community that consists of local residents and First Nations that garden, farm, hunt, fish, collect, and eat wild edibles;
- 2) Ecological risk assessment of metals and arsenic in terrestrial and freshwater aquatic ecosystems.

Once a candidate organization has been selected, their initial focus will be to establish the Independent Expert Review Panel. This will involve selecting a Chair, appointing appropriate Panel members, planning meetings, arranging travel and coordinating communications. Independence and freedom from bias must be demonstrated for any members selected to be on the panel, whether this be from direct or indirect means. Independence of the panel members must be maintained throughout the peer review process.

The actual Panel's review of the scientific merits of the final HHRA and ERA draft Study documents/reports is expected to begin by September 1, 2005.

At the request of the Technical Committee, a key member of the Panel (preferably the Chair), will need to be available to attend open houses or meetings in Sudbury to describe the review process and present the outcome of the Panel review.

3.0 DELIVERABLES OF THE INDEPENDENT EXPERT REVIEW PANEL

The Panel will review the scientific completeness and validity of three Study documents/reports making up the HHRA and ERA to ensure that appropriate and reliable science has been applied in the Study and its recommendations. The Chair will be responsible for the coordination and preparation of a “Draft IERP Report” of their findings, including comments, issues, weaknesses and deficiencies for submission to the TC.

The Technical Committee and its consulting team, the SARA Group, will be provided an opportunity to clarify issues raised by the “Draft IERP Report”. A teleconference / meeting will be held to provide SARA an opportunity to discuss the comments with the IERP to ensure they understand the comments and to seek agreement as to what changes would be needed. It is recommended that the Technical Committee’s Independent Process Observer be present at the teleconference / meeting to help ensure confidence in the independence of communications with the Panel.

After comments have been addressed by the TC and the SARA Group, the revised sections of the Study documents/reports will be re-submitted to the IERP and the IERP will provide a “Final IERP Report” of their findings that will be released to the Public.

4.0 SKILL SET REQUIREMENTS OF PANEL MEMBERS

The IERP is expected to consist of approximately 8 to 10 Panel members with skill sets collectively covering the following areas:

- **Ecological Risk Assessment** – in-depth expertise in advanced techniques used in ecological risk assessments.
- **Human Health Risk Assessment** – in-depth expertise in advanced techniques used in human health risk assessments.
- **Epidemiology** – expertise related to environmental exposures and health effects.
- **Human Toxicology** – expertise in interpretation of animal and human effects on reproduction, cancer development, neurotoxicity and other non-cancer endpoints, related to the CoC’s. Expertise related to health effects to children and seniors is required.
- **Exposure Pathways** – exposure modeling and bioavailability of various environmental media (particularly soils and gardens).
- **Airborne Particulates** – Dispersion and deposition modeling and environmental fate of the CoC’s.

- **Statistics Applications** - Use of statistical methodology in the context of risk assessments.
- **Technical Writing** – Expertise in expressing technical concepts in plain language, necessary for assisting the panel in writing a Summary report that will be released to the public.

Based on their knowledge of qualified experts, the TC may offer names of potential peer reviewers, however, it is understood that the candidate organization selected to oversee the peer review process will have full charge of choosing the peer review Panel members.

5.0 TIMING AND FORM OF IERP REPORT

To initiate the document review component of the IERP process, the TC is targeting to have the three risk assessment volumes in the hands of the Chair of the IERP by **September 1, 2005**. The IERP review process is expected to be initiated at that time and proceed in the most efficient and practical manner, with completion of the Final IERP Report within 3 months.

Following its initial meeting and review, the IERP will be expected to issue a “Draft” IERP Report to summarize its findings. The IERP Chair will forward the Draft IERP report to the TC so as to provide an opportunity for the TC and SARA Group to address the Panel’s comments, or to provide information on issues requiring clarification. At the end of the review process, when the TC has issued a reply to the Chair addressing all IERP comments and concerns, the Chair will involve the necessary IERP members and issue a Final IERP Report. The Final IERP Report will include reference to comments identified in the Draft IERP Report, with a discussion as to whether the modifications made by SARA in the Study documents/reports satisfies the concerns of the Panel.

At the time of release of the Final IERP Report, the IERP Chair will be expected to issue a News Release announcing the public issuance of the Final IERP Report. It will be necessary for the TC to receive notification of the issuance date of the Final IERP Report and News Release at least two weeks in advance allowing the TC to prepare any necessary media communications.

A detailed schedule is to be provided in the Proposal that outlines the anticipated timelines and dates for completion of the IERP process, assuming a September 1, 2005 release date for the three Sudbury Soils Study risk assessment volumes.

Since it is difficult to guarantee that all three reports will be available on September 1, 2005 as planned, it would be of value for the IERP review process to have some flexibility built in to accommodate a one or two month delay, should unexpected circumstances occur. Identify the degree of flexibility that might be built into the process to accommodate a one or two month delay in the report delivery date of September 1,

2005. Indicate the potential impact that this might have on the review process, work schedule and financial forecast.

6.0 PROPOSAL FORMAT

The proposal is to be submitted in the following format:

Section A - Executive Summary (two pages maximum)

Summarize your experience and qualifications related to overseeing Expert Review Panels, with brief highlights on the approach that would be taken to coordinate the Sudbury Soils Study IERP. Provide a brief summary regarding potential biases or independence issues.

Section B - Approach to Coordination Role

- State your specific qualifications and related experience in undertaking Expert Review Panels, giving specific listings of related projects.
- State experience you have pertaining to the oversight of Expert Review Panels dealing with risk assessments (particularly HHRA's / ERA's)
- Provide comprehensive details on how you would execute the coordination role for the IERP (include reference to any guidance document for Peer Review Panels you might use to coordinate the peer review process)
- Provide comprehensive details on how you would manage the administration activities to facilitate the IERP schedule to provide the deliverables.
- Provide an IERP schedule or timeline of activities. Identify how long you anticipate it would take to complete the IERP review, once Study documents/reports are submitted to the Chair of the IERP (NOTE: It is anticipated that Study documents/reports for peer review are to be available on September 1, 2005).
- Identify the process you would carry out to select the Panel members with relation to the qualifications noted in 4.0. SKILL SET REQUIREMENTS OF PANEL MEMBERS.
- Provide estimate of person hours of Panel members in relation to schedule of activities.

Section C – Independence / Freedom from Biases

- Describe any bias or independence issue that might be perceived to influence your independence and fairness in the coordination role.

Section D – Resources

- Summarize what resources you have available or would use to facilitate your role in executing the coordination role for the IERP process.

Appendix B – Resume(s)

- Include resume(s) of the key individual(s) that would be assigned to the oversight role for the IERP.

7.0 CRITERIA FOR EVALUATING THE PROPOSALS

The Proposals will be evaluated on the following basis:

1. Experience and Qualifications (35 Points)
 - Coordinating peer review panels (with particular interest in experience related to similar HHRA / ERA projects)
 - Access to experts with appropriate in-depth experience and qualifications to participate as Panel members
2. Reputation and Independence (35 Points)
 - Positive reputation of organization
 - Independence of organization
 - Process to be used to ensure independence and freedom from biases
3. Resources (15 Points)
4. Financial (15 Points)
 - Reasonableness of the financial estimate for undertaking the IERP Process

APPENDIX A

Table of Contents

The following Tables of Contents are provided for estimating purposes only.