



TERA

**Toxicology Excellence
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*a nonprofit corporation
dedicated to the best use
of toxicity data for risk values*

Independent Expert Review Panel for the Sudbury Soils Study

Dr. Michael Dourson

Ms. Jacqueline Patterson

Dr. Charley Pittinger, Visiting Scientist

Ms. Joan Strawson

Toxicology Excellence for Risk Assessment (*TERA*)

**Presentation to Sudbury Soils Technical Committee and Public
Advisory Committee**

April 13-14, 2005



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Overview of Presentation

- Who is *TERA*?
- *TERA* Experience
- Administrative Ground Rules
- Independent Peer Review
- World Trade Center Example



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Toxicology Excellence for Risk Assessment (TERA)

Statement of Purpose & Mission Founded in 1995

Toxicology Excellence for Risk Assessment (*TERA*) is a non-profit, 501(c)(3) corporation organized for scientific and educational purposes.

The mission of *TERA* is to protect public health by developing and communicating risk assessment values, to improve risk assessment methods through research, and to educate the public on risk assessment issues.



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Who Is TERA?

- *TERA* is home to 13 scientists and 3 administrative staff.
- Our scientific staff includes 6 PhDs and 5 others with Masters degrees. Four of our scientists are board certified toxicologists.
- We have a combined experience of more than 125 years in the fields of risk assessment, environmental science, and regulatory toxicology.
- *TERA* has its origins in EPA's risk assessment programs and continues to produce cutting edge risk assessments following EPA and others' methods.



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Key Staff for Sudbury IERP

- Michael L. Dourson, Ph.D., DABT, is the founder and Director of *TERA*. With 15 years at EPA, he was instrumental in developing EPA's non-cancer risk assessment methodology and was Chair of the RfD/RfC Work Group.
- Charles Pittinger, Ph.D., *TERA* Visiting Scientist, currently employed by BB&L, ecological risk assessment expert.



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Key Staff for Sudbury IERP, cont.

- Joan Strawson (formerly Dollarhide) M.S., MTSC, JD, with *TERA* since 1996, she was at EPA for 5 years as the Director of the Superfund Health Risk Technical Support Center, developing provisional risk values for site assessments.
- Jacqueline Patterson, M.En., with *TERA* since 1995, she worked 12 years for EPA and was the key person responsible for the development and management of the IRIS database.



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Experience Related to Sudbury Soils Study

- *TERA* has extensive experience in the area of metals risk assessment. We have conducted reviews and work on projects involving contaminants such as arsenic, nickel, copper, lead, and selenium for a variety of organizations.
- Participated in a peer review of the soil investigation and human health risk assessment conducted for the Rodney Street Community Pt. Colborne, Ontario, by the Ontario Ministry of the Environment.
- *TERA* scientists have organized peer reviews as well as served as expert peer reviewers on several other metals of concern in Sudbury



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TERA Experience with Peer Review

- *TERA's* largest program – peer review in high demand and source of half of total work effort in past several years
- Wide variety of organizations, many of whom return for additional reviews
- Reviews cover a wide variety of complex and innovative scientific issues
- Experience with public involvement and participation in reviews
- Awarded five-year cooperative agreement from US EPA to develop peer consultation/review concepts.



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Administrative Ground Rules

- The *TERA* group should not communicate with Inco or Falconbridge directly on any technical or scientific issues. Any direct communication with companies is restricted to contract/financial issues.
- All other communications should occur thru a designated contact person (Brian McMahon) and all Emails should be copied to WG members (City, Health Unit, MOE , Inco, and Falconbridge)
- Companies, TC, SARA Group, PAC, and members of the Sudbury community should not communicate with IERP members, except as allowed during the IERP meeting.



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Independence **is essential for a credible review**

- Inco and Falconbridge are paying costs of IERP process
- Technical Committee directs work
- **TERA independently** selects panel, runs meeting, and prepares report
- **TERA** has no contact with companies beyond invoicing



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What is Peer Review?

- For risk assessment products, it involves an in-depth assessment of the assumptions, calculations, alternate interpretations, methodology, and conclusions. Peer review panels may seek to reach consensus or common agreement regarding the adequacy of the product reviewed.



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TERA's Independent Peer Review Process

- Scientific screen of the documents to insure they are ready for review, and to identify critical scientific issues and questions for development of the charge and needed expertise for panel
- Develop the scientific charge to the panel
- Identify appropriate expert candidates and select panel members. Identify conflicts of interest and biases
- Schedule meeting and logistical arrangements
- Prepare meeting report of discussions, conclusions, and recommendations
- Distribute the results to the public



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Examples of Conflicts of Interest

- Author of the document to be reviewed
- Personal financial interest in or relationship with sponsor companies
 - Employee or consultant
 - Retired pensioner
 - Investments
- *“Applies not only to the personal financial interests of the individual but also to the interests of others with whom the individual has substantial common financial interest if these interests are relevant to the functions to be performed.” [NAS]*
 - May include spouse or minor children, and individual’s employer, business partners, or others with substantial common financial interest



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The Charge to Reviewers

- The charge is a critical element of each peer review that serves as an outline for the meeting discussion.
- Purpose of the charge is to identify all of the key scientific issues under review and direct the panel to thoroughly consider each one without leading the panel to any specific conclusion.
- Developed by *TERA* with input from the authors and Technical Committee.



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Example Meeting Structure

1. Introductory Remarks, Ground Rules and Conflict of Interest discussion
2. Short presentation by authors
3. Panel asks clarifying questions of authors
4. Short period for technical comments from public
5. Chair facilitates in-depth discussion of each charge question by panel. Authors available for questions.



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World Trade Center Residential Assessment

- Meeting held in NYC, October 2002
- Document prepared by federal, state and city agencies
- *TERA* selected panel and organized meeting
- Public invited to nominate experts, attend meeting to observe, submit oral and written comments
- Final report summarized discussions, and conclusions. Included copies of public comments.



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WTC Residential Assessment, Charge (Abbreviated)

Exposure Issues:

- Comment on whether the exposure scenarios used will protect the public health of all potentially exposed populations.
- Are children adequately protected by the risk-based criteria as developed?
- Were the assumptions and exposure input parameters correct?

Exposure Specific Issues:

- Comment on the appropriateness of developing risk-based criteria based on wipe sampling data for areas near the WTC site.
- Is estimating dose using a mass/area approach appropriate?
- Were the appropriate exposure scenarios and exposure input parameters applied? Are children adequately protected?
- Would the use of existing health standards or occupational exposure limits have been a more appropriate method for analysis of residences near the WTC site?



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What Will Final Report Look Like?

We anticipate the report will include the following:

- Plain language Executive Summary
- Summary of panel discussions and conclusions
- Reference to comments identified in the Draft IERP Report and a discussion of the adequacy of the changes made to the documents by the authors in response to the IERP comments.
- Appendices
 - Charge to panel and meeting agenda
 - Short bios of panel members
 - Written public comments
 - Author presentation slides



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Release of Final IERP Report

Suggested actions:

- News Release summarizing IERP conclusions
- Chair attends Public Open House to present and explain IERP conclusions
- Others?



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