



TERA

**Toxicology Excellence
for Risk Assessment**

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

Independent Expert Review Panel for the Flin Flon Soils Study

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Presentation to Community Advisory Committee

Flin Flon Soils Study

April 15, 2009



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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.

www.tera.org



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Staff of board certified toxicologists with extensive experience in risk assessment, regulatory toxicology, and peer review.

- Prepare high quality risk assessments and organize expert peer reviews
- Improve the underlying methods for risk assessment through research and publication
- Distribute peer reviewed risk values through the International Toxicity Estimates for Risk (*ITER*) database - www.tera.org/iter
- Train others on state-of-the-science risk methods.



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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 seek to reach consensus or common agreement regarding the adequacy of the product reviewed.



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Independence

is essential for a credible review
***Administrative ground rules to protect
independence of the process***

- TERA communication with HBMS limited to invoicing/contract.
- TAC and others communications with TERA occur through a designated contact person.
- TERA **independently** selects panel, runs meeting, and prepares report
- HBMS, TAC, CAC, Intrinsic, and members of the Flin Flon community should not communicate with IERP members.



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TERA's Independent Peer Review Process

1. 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.
2. Develop the scientific charge to the panel.
3. Identify appropriate expert candidates and select panel members. Identify conflicts of interest and biases.
4. Schedule meeting and logistical arrangements.
5. Prepare meeting report of discussions, conclusions, and recommendations.
6. Distribute the results to the public.



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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 the **key** scientific issues and guide the panel to thoroughly consider each one; leading to independent panel conclusions.
- Developed by *TERA* with input from the authors and TAC.



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Panel Selection Procedures

- Identification of scientific expertise necessary to address key issues in charge.
- Search for appropriate candidates, evaluate credentials
- Contact most promising for interest and availability. Query them on conflicts of interest and biases.
- Select a panel that is balanced with regard to necessary disciplines and has a diversity of perspectives.



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Conflict of Interest (COI)

An independent panel is essential for a credible scientific review

TERA follows National Academy of Sciences (NAS) procedures for panel selection and conflict of interest.

- *NAS defines a conflict of interest as “any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual’s objectivity or (2) could create an unfair competitive advantage for any person or organization. ...The term ‘conflict of interest’ means something more than individual bias. There must be an interest, ordinarily financial, that could be directly affected by the work of the committee.”*



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Bias

- *“Questions of lack of objectivity and bias ordinarily relate to views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group.” [NAS]*
- Biases are not necessarily disqualifying, but a balance of potentially biasing backgrounds or professional or organization perspectives is needed.
- Some potential sources of bias may be so substantial that they would prevent an individual from considering others perspectives or relevant evidence contrary to their strongly held position.



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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. Chair facilitates in-depth discussion of each charge question by panel. Authors available to answer panel questions.



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What Will the Final IERP Report Look Like?

We anticipate the report will include the following:

- Executive Summary
- Summary of panel discussions, conclusions, and recommendations
- Discussion of the adequacy of the changes made to the HHRA by the authors in response to the IERP comments.
- Appendices
 - Charge to panel and meeting agenda
 - Short bios of panel members
 - Author presentation slides