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# **Independent Expert Peer Review**

**Presentation to the Joint Committee for Review of  
Administrative Rules**

**August 21, 2006  
Madison, Wisconsin**

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# **Toxicology Excellence for Risk Assessment (*TERA*)**

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 inform the protection of public health by developing and communicating risk assessment values, improving risk assessment methods through research, and to educate on risk assessment issues.

- Independent non-profit – funding from individual mission-related projects sponsored by government and industry
- Objective approach and focus on science



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# What is Peer Review?

- Peer review involves review of a draft product for quality by specialists who were not involved in its preparation.
- An in-depth evaluation of the science, including an assessment of the assumptions, calculations, alternate interpretations, methodologies, and conclusions.
- Peer reviewers are scientists who have training and experience equal to the authors.
- Peer reviewers should be independent – of the authors and any sponsoring organization.
- Peer review serves to ensure that the quality of technical information meets the standards of the scientific community.
- Peer Review is not the same as Public Comment



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## **For a Peer Review to be Credible, it Must be Independent**

- Authors/sponsors should not participate in selection of peer reviewers
- Candidates should be carefully screened for conflict of interest and biases
- Panels should include reviewers with diverse perspectives and backgrounds
- List of questions (charge) for reviewers should cover key issues and be objective
- Reviewers must be provided with necessary documentation
- Process should be public and transparent
- Sponsors and authors should have limited interaction with the reviewers

**Keep the Focus on the Science**



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# Conflict of Interest (COI) and Bias

## National Academy of Sciences (NAS) procedures for panel selection

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.*”

NAS on **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.*”

- 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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## Panel Selection Procedures

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



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## Peer Review – Time and Cost

- How long does a panel peer review take?
  - 4-6 months, typically
  - May be longer if highly complex issues and controversies
- How much does a panel peer review cost?
  - Depends on extent of documentation and complexity of issues and materials
  - \$40,000 to \$70,000+ for a 2-day meeting



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# Some Independent Peer Reviews Organized by **TERA**

- Texas CEQ – expert panel reviewed state methods for estimating risk values
- Resorcinol safe dose for PA clean up
- Methylmercury site specific safe dose for use in Texas Superfund site
- Voluntary Children’s Chemical Evaluation Program (VCCEP) used by EPA
- World Trade Center Residential Clean up Levels
- Captan carcinogenicity classification

See <http://www.tera.org/peer> for meeting reports



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# Alliance for Risk Assessment (ARA)

- Alliance serves as a shared resource (including peer review) to facilitate collaborative risk issue resolution among diverse stakeholder groups.
- Designed with input from risk assessment colleagues from over 20 States.
- Evolved from discussions with state risk assessors and others who need better approaches to resolve risk issues in a timely and constructive manner.
- Example: uncertainty in determining appropriate risk values to use for chemicals like TCE has spurred interest from our State and local risk assessment colleagues.



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## Key Peer Review Staff

- 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 EPA RfD/RfC Work Group.
- Jacqueline Patterson, M.En., is the Peer Review Program Manager and Project Officer for EPA Cooperative Agreement on Peer Consultation. With *TERA* since 1995, she worked 12 years for EPA and was responsible for the IRIS database in the Cincinnati EPA office.
- 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 Superfund assessments.



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# **TERA Projects**

- **Organize independent expert peer review and consultation of risk assessment documentation**
- Prepare high quality risk assessments on specific chemicals
- Improve the underlying methods for risk assessment through research and publication
- Compile and distribute peer reviewed risk values through the International Toxicity Estimates for Risk (*ITER*) database
- State HELP – assist states and local governments with risk issues.

**TERA often brings together parties with divergent opinions to discuss the science and find a common path forward.**



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# International Toxicity Estimates for Risk (*ITER*) Database

- Part of the National Library of Medicine.
- Free web-based data.
- Contains peer-reviewed risk values for more than 600 chemicals from 5 agencies, plus independent groups.
  - ATSDR, EPA IRIS, Health Canada, RIVM (the Netherlands), NSF Int.
- Used by hundreds of risk assessors daily.
- Provides a central source for peer-reviewed risk values to foster data sharing.

<http://www.tera.org/iter>

# **More Details on *TERA* organized Peer Reviews**

Meeting reports and details available at

**<http://www.tera.org/peer>**



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# Texas Commission on Environmental Quality (TCEQ)

- A panel of expert scientists conducted a Peer Review of a technical guidance document prepared by the (TCEQ), State of Texas.
- Technical guidance describes the process used by staff of the Toxicology Section to develop Effects Screening Levels, Inhalation Reference Values, and Unit Risk Factors.
- Panel made numerous recommendations for improvements.
- TCEQ revised methods
- Information at [http://www.tceq.state.tx.us/implementation/tox/esl/peer\\_rev/PRmain.html](http://www.tceq.state.tx.us/implementation/tox/esl/peer_rev/PRmain.html)



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## Resorcinol

- A reference dose (RfD) for resorcinol was prepared by AMEC Earth and Environmental, Inc for the sponsor, Beazer East, Inc., who. prior to 1988.. owned and operated a facility that manufactured resorcinol.
- RfD (safe dose) developed to inform risk-based clean up decisions under Pennsylvania Department of Environmental Protection (DEP) regulations.
- Authors revised assessment with peer review panel recommendations. Panel's recommendations accepted by the Science Advisory Board of PA DEP



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# Methylmercury

- Safe dose of methylmercury for use at a Superfund site in Texas.
- Developed by consulting firm for the responsible party (Alcoa).
- Used more recent data from fish eating population than what EPA had based their value on
- *TERA* organized peer review panel agreed with choice of study but recommended slightly different value range.



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# Voluntary Children's Chemical Evaluation Program

- To develop and demonstrate the *TERA* peer consultation process, *TERA* is conducting Peer Consultation meetings for the pilot Voluntary Children's Chemical Evaluation Program ([VCCEP](#)).
- VCCEP is a voluntary pilot program and part of the U.S. EPA's Chemical Right-to-Know Initiative. The goal of the VCCEP pilot is to enable the public to better understand the potential health risk to children associated with certain chemical exposures.
- EPA asked companies that manufacture and /or import 23 chemicals to volunteer to sponsor chemical evaluations in a pilot program. Sponsorship requires the companies to collect or develop health effects and exposure information on their chemicals and then to integrate that information in a risk assessment and a data needs assessment.
- *TERA* organizes "peer consultations" with panels of experts for each of the submitted assessments. Reviewer recommendations regarding data needs are summarized in a meeting report. EPA makes decisions regarding the need for more testing.



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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.
- Sponsor: U.S. EPA, NYC, ATSDR



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# Captan Tumor Mode of Action

- EPA's cancer assessment for Captan was based on EPA's 1986 Cancer Guidelines.
- EPA OPP indicated they were not planning a re-evaluation, but would consider an independently reviewed reassessment.
- The Captan Task Force sponsored an updated analysis, which supported a non-linear mode of action.
- *TERA* convened an independent peer review panel. The panel provided several recommendations, but agreed with the nonlinear mode of action.
- EPA OPP accepted the conclusions of the independent peer review.