TERA Board of Directors & Corporate Officers 2013

Year indicates ending year of current term.

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TERA MISSION

Toxicology Excellence for Risk Assessment (TERA) is a non-profit and tax-exempt organization organized for scientific and educational purposes. Our mission is to support the protection of public health by developing, reviewing and communicating risk assessment values and analyses; improving risk methods through research; and, educating risk assessors, managers, and the public on risk assessment issues.

TERA's Core Principles and Values

TERA is an independent non-profit and as such we embrace our core principles and values in all our activities. These core principles guide day-to-day TERA operations - from our consideration of new projects and sponsors, to our scientific evaluations and communication of results.

Honesty and Integrity

We operate at the highest level of ethical and scientific standards, fully communicating issues and uncertainties

Independence

We approach our work with an open mind and objectivity, without regard to sponsor or stakeholder interests

Transparency

We share our work broadly to maximize benefit to public health

Collaboration

We use collaboration as a fundamental and preferred approach to technical problem resolution

TERA was founded on the belief that an independent non-profit organization can provide a unique function to protect human health by conducting scientific research and development on risk issues in a transparent and collaborative fashion and communicating the results widely.
2013 FINANCIAL SUMMARY

Income: $2,360,263
Expenses: $2,321,694
Net Gain for 2013: $38,569

2013 TERA Project Time by Sponsor

13% Collaborations
Projects/Sponsors
- Beyond Science and Decisions
- International Toxicity Estimates for Risk
- Kidschemicalsafety.org
- Lessons Learned, Challenges, & Opportunities: The US Endocrine Disruptor
  Screening Program
- Occupational Alliance for Risk Sciences

37% For Profit
Project Sponsors
- American Cleaning Institute
- Amgen
- American Chemistry Council
- Elly Lilly
- Genentech

63% Government/Non-Profit
Project Sponsors
- Consumer Product Safety Commission
- Health Canada
- NIOSH
- National Library of Medicine
- Texas Commission on Environmental Quality

2% Training
Project Sponsors
- Dose Response Boot Camp
- Food & Drug Administration Training Course
- Occupational Exposure Training Course
So much to share...

**First Place Presentation Awarded**
Ms. Alison Willis was awarded first place in graduate student presentations for her presentation, “Species sensitivity to photo-induced toxicity in sheepshead minnow (Cyprinodon variegates) and zebrafish (Danio rerio), and interspecific variability in LC50s for three phototoxic PAHs (fluoranthene, pyrene, anthracene) in zebrafish (Danio rerio)” at this year’s Ohio Valley Chapter Society for Environmental Toxicology and Chemistry meeting.

**Presentation on Genotox Impurities**
Dr. Reena Sandhu presented a talk entitled “An Introduction to Genotox Impurities” at the Canadian Association of Professional Regulatory Affairs (CAPRA) symposium on Regulatory Toxicology and Safety held at the Prince Westin Hotel in Toronto, Ontario, Canada. For more information on the conference, please visit the CAPRA website at [http://www.capra.ca/](http://www.capra.ca/)

**TERA President joins Toxicology Education Foundation**
Dr. Michael Dourson joined the Board of Trustees for the Toxicology Education Foundation (TEF). TEF’s mission is to encourage, support, and promote charitable and educational activities that increase the public understanding of toxicology.

**Keeping up with Evolving Risk Methods – the ARA Dose Response Framework**
Need help keeping up with the pace of risk science?

The ARA Dose Response Framework is a library of risk methods, with tools to help you find the method you are looking for, and case studies to illustrate real work applications.

Search by key term, or browse by problem formulation, the Framework offers an overview of how the method works, when it’s applicable, and a discussion of limitations.

The ARA Dose Response Framework 2.0 is available in beta at [www.chemicalriskassessment.org](http://www.chemicalriskassessment.org).

**ARA’s Work on Contaminated Site Issues**
The Alliance for Risk Assessment (ARA) has taken on 2 important projects dealing with chemical specific contaminated sites. For one sponsor, the ARA is forming a workgroup to develop practical application guidance for the use of USEPA Reference Concentration and Inhalation Unit Risk (IUR) values for trichloroethylene for the purpose of site cleanup and closure. For PFOA-PFOS, the ARA developed an interim position to be built through a collaborative effort to review the available information regarding human health hazard identification/characterization and dose-response assessments (oral cancer and non-cancer) for PFOA and PFOS.
TERA has continued to expand international connections, supported primarily by our training efforts, with three substantial international trips:

**Australia & New Zealand**
Dr. Mike Dourson and Ms. Patricia Nance set sail for a 19 day trip to Australia & New Zealand. They first attended the SRA World Congress on Risk in Sydney, where they presented posters on uncertainty in OELs, Dose-Response Workshop Framework, and ITER/RISKie/ARA. The following week they were joined by Ms. Bette Meek, University of Ottawa, and Ms. Ann Parker, TERA, to teach the Dose-Response Assessment Boot Camp for over 40 attendees from Australia and New Zealand. The final week of the trip, Dr. Dourson and Ms. Nance met with ESR (Institute of Environmental Science and Research Ltd) in Christchurch and then moved north to Wellington to meet with key staff from various New Zealand government agencies, including the Ministry of Health, Ministry of the Environment, Environmental Protection Authority, and Department of Labor.

**Nigeria & Ghana**
Dr. Bernard Gadagbui ventured to Africa to teach a 5 day course on risk assessment, primarily training officials from the National Agency for Food and Drug Administration and Control (NAFDAC) and academia. Dr. Gadagbui also met with Ghana EPA, Food and Drugs Board, Ghana Standards Authority, and University of Ghana regarding TERA’s risk assessment training.

**Turkey**
Dr. Lynne Haber completed the world tour in Turkey. Dr. Haber taught a 1-day overview of risk assessment and recent developments in conjunction with the Turkish Society of Toxicology meeting. She gave a lecture at the Turkish SOT meeting, and gave a lecture at Yeditepe University in Istanbul. Dr. Haber also met with a representative of the Dokay Group.

**TERA Selected as a Global Host Institution**
The Society of Toxicology (SOT) selected TERA to host Dr. Sri Noegrohati of Gadjah Mada University, Indonesia, under its 2013 Global Senior Scholar Exchange program. The program aims to increase the global impact of toxicology by working to strengthen toxicology programs and capacity at universities in developing countries. TERA assisted Dr. Noegrohati in developing training modules for undergraduate and graduate students that integrate knowledge of toxicology testing and risk assessment.
It has been 30 years since the publication of “Regulatory History and Experimental Support of Uncertainty (Safety) Factors.” The purpose of the paper was to present a brief regulatory history of uncertainty factors and to discuss supporting experimental observations, showing a mix of uncertainty and safety considerations. And it did just that, as it is considered one the “classic citations” in the area of risk assessment. A simple search on Google shows that “Dourson and Stara (1983)” appears over 14,000 times in various publications.

This paper looked at the data behind the standard safety/uncertainty factors and helped set the tone for the systematic use of more data, rather than defaults, in the estimation of the Acceptable Daily Intake (ADI). In the intervening years, many have published additional improvements in this area of science, culminating in a report by the International Programme on Chemical Safety (IPCS) on Chemical Specific Adjustment Factors (CSAFs) in 2005. As described by one risk assessment scientist:

“I happened to be reading something today about risk assessment and I glanced at the reference list. I came to the realization that this year is the 30th anniversary of the Dourson and Stara (1983) paper on uncertainty factors... This paper, in my view, is a seminal work, which redefined a basic concept. I'm glad I ran across it today... and we all are, fortunate [for] the interest and the clarity of thought to question what really was the basis for the status quo. As I matured as a toxicologist and a risk assessor I became fond of a saying: facts are stubborn things, but there is uncertainty in generating and using them. Dourson and Stara (1983) had the audacity to make that more apparent... and did us all the favor of making us more honest in our evaluations.

Dourson and Stara (1983) is currently running behind Lowry (1951) as the most-cited scientific paper in history, but there still is yet time...”

-Rich Costlow (R_CostlowConsultingllc@comcast.net)
We are pleased to announce our expanded suite of ecological and environmental science services, complementing our strong historical reputation in health risk assessment and industrial hygiene.

Our staff now includes scientists with broad experience in ecotoxicology, environmental fate, and ecological risk and hazard assessment of chemical ingredients, products and by-products.

For more information on our Ecotoxicology or Ecological Risk Assessment Program go to http://www.tera.org/EcoTERA or contact Alison Willis at Willis@TERA.org.

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Alliance for Risk Assessment Dose-Response Framework

The ARA’s Dose Response Framework is now on the National Library of Medicine’s Enviro-Health Links. The framework provides a “roadmap” to guide the risk practitioner from problem formulation through dose-response evaluation techniques.

Methods are systematically organized into three categories; qualitative decision, quantitative screening decision, and in-depth assessment. Within each category, the risk assessor is guided to methods that address key issues, such as Mode of Action assessment, vulnerable population assessment, endogenous/background exposure, and data integration.

Methods interlink with case studies to illustrate real-world application, and summaries that outline the minimum data requirements, and evaluate the method’s ability to address human variability, sensitive populations, and background exposures or responses. The framework is available on the ARA website at www.allianceforriskassessment.org or contact Dr. Michael Dourson, Dourson@tera.org.

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TERA is Expanding Ecologically

We are pleased to announce our expanded suite of ecological and environmental science services, complementing our strong historical reputation in health risk assessment and industrial hygiene. Our staff now includes scientists with broad experience in ecotoxicology, environmental fate, and ecological risk and hazard assessment of chemical ingredients, products and by-products.

For more information on our Ecotoxicology or Ecological Risk Assessment Program go to http://www.tera.org/EcoTERA or contact Alison Willis at Willis@TERA.org.
The International Toxicity Estimates for Risk (ITER) is a free database of over 700 peer reviewed chronic human health risk values from organizations around the world. ITER is growing in content and usage, and is proud to announce two major content enhancements to benefit the international risk community:

- In 2013, over 90 Concise International Chemical Assessment Documents (CICADs) from the World Health organization (WHO) have been added to ITER
- With the help of Summit Toxicology, ITER will soon include Biomonitoring Equivalents (BEs) for over 40 chemicals. BEs present an entirely new type of content for ITER users.
- International Programme on Chemical Safety (IPCS) and Texas Commission on Environmental Quality (TCEQ) values have been added to ITER! The ITER entries for IPCS chemicals are based on the IPCS CICAD documents. The TCEQ values are based on TCEQ's Development Support Documents (DSD). More values from both organizations will be loaded as they become available.

Check out ITER at www.tera.org/iter

OARS is an initiative to facilitate sharing of information with workers and occupational health and safety professionals. OARS provides a forum for information exchange about exposure guidance for chemical stressors, methods for improving occupational risk assessments, and training opportunities. The OARS serves as the home of exposure guide values, and related guideline documents, for chemical stressors. These guide values and supporting documentation related to worker and community exposure levels for chemical and physical agents and stressors are published by the OARS.

OARS has added its first newly developed WEEL on trans-1-Chloro-3,3,3-trifluoropropylene (HCFO-1233zd(E)). The second OARS-WEEL, Octamethylcyclotetrasiloxane (D4), is currently open for external review comments. All current AIHA and TERA WEEL values are available in a tabular format at http://www.tera.org/OARS/.

For more information on OARS or WEELs contact Ann Parker (parker@tera.org).
Multi-stakeholder Workshop on Lessons Learned, Challenges, and Opportunities: The U.S. Endocrine Disruptor Screening Program
TERA organized and conducted this public workshop in April 2013, which brought together over 240 scientists from federal regulatory agencies, NGOs, industry, contract laboratory scientists, and academic researchers to review and discuss the challenges and lessons learned from the initial experiences with Tier 1 screening assays under the US Environmental Protection Agency’s Endocrine Disruptor Screening Program (EDSP). It provided a framework for retrospective analysis of the data generated and to collect the insight of multiple stakeholders involved in the testing. A number of key learnings and recommendations related to future endocrine testing and evaluation emanated from the collective sessions and the workshop report is available now online on the ALTEX website at http://www.altex.ch/Online-first_95.html and in PubMed PMID:24114257.

Workshop on Mode of Action for Nuclear Receptor Mediated Liver Cancer
Four manuscripts from the September 2010 Nuclear Receptor Workshop organized by TERA have been published in Critical Reviews in Toxicology (January 2014). The workshop explored the development of dose-response approaches to nuclear receptor-mediated liver cancer, within a Mode of Action (MOA) Human Relevance Framework (HRF). Workshop case study teams, comprised of a diverse and multi-disciplinary panel of experts, prepared papers on the AHR, CAR, and PPAR alpha receptors, and TERA and the workshop co-chairs authored an additional overview paper describing the workshop and overarching issues. Each case evaluated the key events leading to liver tumors, and discussed whether the biology of the nuclear receptor necessitates a minimum threshold of ligand to affect activation, gene expression, and subsequent biological and toxicological responses. The report is available at http://www.tera.org/peer/nuclear_receptor/.

Peer Consultation Workshop on the Relationship between PAC Profile and Toxicity of Petroleum Substances
In 2007 TERA organized and conducted an expert peer consultation to review a report by Petroleum HPV Testing Group that hypothesized that toxicity observed in repeated-dose dermal toxicity studies is related to polycyclic aromatic compound (PAC) content. A statistical method using the PAC profile to predict dose–response for untested high-boiling petroleum substances was evaluated. A series of papers describing the PAC method, underlying data, statistical validation, predictive modeling results, and possible applications of the results has been published. TERA scientists authored a paper on the peer consultation process, including an evaluation of the PAC authors’ responsiveness to the peer panel’s recommendations. Assessing the mammalian toxicity of high-boiling point petroleum substances, Reg. Tox and Pharm (Volume 67, Issue 2, Supplement - pp. S1-S94 (1 November 2013).
Public Service

TERA staff continued to dedicate significant effort providing support to local communities and governments, as well as supporting scientific development through pro bono activities and our TERA Corporate Development funds. Highlights of TERA staff’s public service during 2013 are provided below.

Professional Societies. TERA staff are members of many professional societies, including the Society for Toxicology (SOT), the Society of Risk Analysis (SRA), and the American Industrial Hygienist Association (AIHA). Many hold office or leadership positions within these professional societies. During 2013, TERA scientists held numerous positions, including vice president of the African Society for Toxicological Sciences (ASTS), vice-president elect of the SOT Ethical Legal and Social Issues Specialty Section, co-chair of the subcommittee that organizes continuing education workshops, SRA annual meeting, president of SOT’s Special Interest Group - ASTS (African Society of Toxicological Sciences), and councilor of the regional chapter of SOT. Other areas of professional involvement included membership in the AIHA Workplace Environmental Exposure Levels Committee, and membership of the education committee and web committees of SOT, and World Congress committee of SRA.

Publications. TERA staff routinely volunteer their time to review scientific papers for peer-reviewed journals. TERA staff have also authored and co-authored a number of journal articles and book chapters in 2013. A brief list of our recent publications follows this page, with a full list of publications at http://www.tera.org/Publications/Publications.html.

Community Service & Other Activities. TERA prides itself on being involved with our local communities. We have given guest lectures at the University of Cincinnati on toxicology and risk assessment, and one staff member serves as an Adjunct Associate Professor in the University of Cincinnati’s Department of Environmental Health, providing lectures to graduate students and serving as a member of the Advisory Committee for the Biological Monitoring Core. One staff member serves on the Cincinnati Environmental Advisory Committee, and another is on the board of a local land trust. TERA is also a member of the Cincinnati Alliance for Chemical Safety (ACS), for which a staff member is the communications chair, and another staff member gave a lecture at an ACS monthly meeting. Staff members have volunteered their time to review papers for journals and to serve on peer review panels for the ITER database, for EPA, and for private and other nonprofit organizations. Staff members have also participated in international meetings as indicated earlier in this report. TERA is also involved with local activities, such as Earth Day. TERA staffed a booth at Cincinnati’s Earth Day Celebration that focused on educating the public on toxicology and risk assessment and how it relates to their daily lives. Children’s activities were also provided through Kids + Chemical Safety (www.KidsChemicalSafety.org) where we seek to address the needs of parents and families by providing balanced and scientifically accurate chemical health information.
TERA staff have authored and co-authored a number of journal articles and book chapters in 2013. A full list of TERA’s publications can be found on our website at http://www.tera.org/Publications/Publications.html. TERA scientists serve as peer reviewers for many journals.

### JOURNAL ARTICLES


### BOOK CHAPTERS


### POSTERS AND PRESENTATIONS

**2013 SRA**

Toxidromes - A decision-making tool for early response to chemical mass exposure incidents: Kirk; Hakkinen; Ignacio; Kroner; Maier; Patterson
Practice makes perfect: Lessons and outcomes based on mode of action/human relevance framework application to case studies: Willis; Maier; Reichard; Haber; Patterson

A Decision Tool for Assessing Polymers and Polymeric Substances with Potential Hazards to Human Health: Gadagbui; Maier; Nance; JayJock; Franklin

Development of Chemical-Specific Adjustment Factors for Long-Lived Chemicals: PFOS as a Model Chemical: Haber; Dourson; Mohapatra:

Workplace Environmental Exposure Level (WEEL) Methodology with Octamethylcyclotetrasiloxane (D4) as a Case Study: Parker; Nance; Maier

Workshop on lessons learned, challenges, and opportunities: The U.S. Endocrine Disruptor Screening Program: Patterson; Becker; Borghoff; Casey; Dourson; Fowle; Hartung; Holsapple; Jones; Juberg:

Kids + chemical safety: a tool for educating the public about chemicals: Nance; Kroner; Dourson

Rethinking Risk Data: ITER 2.0: Kroner; Wullenweber; Willis:

Presentations

Best Practices for Independent Peer Reviews: Patterson; Nance; Dourson: High quality peer review is very valuable to ensure that the science used to support regulatory and public health decisions is sound. Peer reviewers evaluate the adequacy of the scientific data to support the conclusions. They consider whether key data were identified and interpreted correctly, appropriate methodologies were used, analyses of data are appropriate, uncertainties have been clearly identified along with the attending implications of those uncertainties; and information and conclusions are clearly communicated. Increasing attention has been given to selection of peer reviewers and determining whether particular individuals may have conflicts of interest. Ensuring the independence of the experts is an essential principle for high quality peer review. Other key principles and practices are also important: using a robust scientific approach to focus the experts on the key scientific issues and questions; selection of experts with appropriate discipline knowledge and contextual experience; and transparency in the process and communication of results to be most beneficial to informing public health decisions. Additional practices and activities have been suggested, such as instituting an independent evaluation of whether document authors addressed the recommendations of the peer reviewers in finalizing their documents. As peer review becomes more widely used by government agencies and others, the perspectives and thoughts of the experts themselves must also be considered.

Lessons for Information Exchange in Occupational Risk Science: The OARS Initiative Opportunities and Challenges. Maier; Nance; Ross: The demand is growing for occupational exposure guidance to support risk assessment for workplace exposures. The demand is fed by the expectation that risk analysis will more fully address the global portfolio of chemicals in commerce. A range of traditional and new dose-response techniques are being applied to fill the void. However, risk science and risk policy differences result in OEL guides that differ among organizations and that can result in a confusing landscape of OELs and related health benchmarks. One concept to address this transitional phase in occupational risk assessment is to develop programs that foster harmonization of methods. Harmonization is viewed as an approach to foster shared understanding and ultimately increased utility of the range of OELs and OEL methods available. Currently, numerous sources of information are available, but no unified source of occupational risk methods documentation has been compiled. In addition, decision guides to sort through the confusing landscape of guidance have been demonstrated as adding value for risk assessment practitioners. Such tools have been compiled in the context of a collaborative - the Occupational Alliance for Risk Assessment. The
impacts regarding information exchange techniques and education and outreach strategies employed are described based on lesson learned through a 2-year implementation program.

2013 SOT


A Decision Tool for Assessing Polymers and Polymeric Substances with Potential Hazards to Human Health: B K Gadagbui, A Maier, P Nance, M Jayjock, C Franklin

Mode of Action and Human Relevance of Rodent Tumors: James Klaunig and Lynne Haber, co-chairs, March 11, 2013

cll Mutant Frequencies and Types of Mutations in the Lung of Big Blue Mice Exposed to Ethylene Oxide for up to 12 Weeks by Inhalation: M G Manjanatha, S D Shelton, Y Chen, B L Parsons, B Gollapudi, N Moore, L T Haber, M M Moore

Gain and Loss of K-ras Mutations in Mouse Lungs Following Inhalation Exposure to Ethylene Oxide: B L Parsons, M G Manjanatha, M B Myers, K L McKim, Y Wang, B Gollapudi, N P Moore, L T Haber, M M Moore

Characterizing the Impacts of Uncertainty and Scientific Judgment in Exposure Limit Development: A Maier, R Sussman, B Naumann, R Roy

Mode of Action Evaluation for Lung Tumors in Mice Exposed to Ethylene Oxide Via Inhalation: L T Haber, B L Parsons, N P Moore, B Gollapudi, M G Manjanatha, M J LeBaron, M M Moore

Winner of “top 10 abstracts in risk assessment” from the Risk Assessment Specialty Section

Advancing Human Health Risk Assessment: Charting a Course Through Committee Recommendations: M Dourson, R Becker, L T Haber, L H Potter, T Bredfeldt, P Fenner-Crisp

Integrating Hazard Characterization Approaches for Evaluating the Potential of Consumer Products to Cause Asthma: J Patterson, A Maier, M J Vincent, B K Gadagbui

Chemical Hazards Emergency Medical Management (CHEMM): Chemical Specific Acute Patient Care Guidelines for Pre-hospital and Emergency Department/Hospital Management: P J Hakkinen, D Siegel, A Maier, F Chang, A Wullenweber, J Strawson, A Willis, P Nance, O Kroner, R Sandhu

Approaches for Deriving an OEL for Peracetic Acid and Occupational Risk Management Considerations: N Pechacek, A Maier, L T Haber

Derivation of an Occupational Exposure Limit for Inorganic Borates Using a Weight of Evidence Approach: M J Vincent, A Maier, E Hack, P Nance, W Ball

SETAC 2013

Interactions of single compounds and mixtures of PAHs in the presence of UV in larval zebrafish and implications for other environmental contaminates: A Willis, J Oris