2007 Annual Report

Toxicology Excellence for Risk Assessment (*TERA*)

Cincinnati, Ohio

March 30, 2008

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TERA: Providing Public Service Through Excellence in Risk Assessment

In 1995, Dr. Michael Dourson brought his vision of toxicology excellence for risk assessment to life. He organized *TERA* as a non-profit and independent corporation for improving the science of risk assessment through a focus on partnerships among *all* members of the risk assessment community. *TERA* supports the protection of public health by developing and communicating risk assessment information, sponsoring peer reviews and consultations, improving risk methods through research, and educating interested parties on risk assessment issues. *TERA* focuses on high quality science and building bridges and collaboration among diverse stakeholder groups. *TERA*, a nonprofit corporation, is committed to serving the needs of the risk assessment community. For example *TERA* developed the *ITER* database to assist risk assessors in identifying available risk values (see www.tera.org/iter). *TERA* donates a percentage of staff time to serve the risk assessment community, professional societies, and the public. In addition, our State HELP program and Alliance for Risk Assessment initiative assist states and local governments. Today, our mission to support the protection of public health and our vision to provide toxicology excellence for risk assessment remain unchanged. See highlights below and visit www.tera.org to see more of what *TERA* has accomplished.

Dose-Response Assessment Boot Camp

"This was the best course I have ever taken."

TERA launched the Dose-Response Assessment Boot Camp in October 2007. The very successful course was attended by scientists from U.S. state agencies, private corporations, and U.S., Canadian, Australian, and New Zealand federal agencies. The course instructors, from both *TERA* and the U.S. EPA, had a wide range of expertise. The next two Boot Camps are scheduled for March 31 to April 4, in Cincinnati and September 15 to 19 in Washington D.C. The Dose-Response Boot Camp is an intensive, in-depth, hands-on training course in hazard characterization and dose-response assessment techniques for developing human health risk assessments. Upon completing the course, participants are able to derive and evaluate risk values and supporting documentation for non-cancer and cancer risk assessments. Five Certification Management (CM) points are available from the American Board of Industrial Hygienists (ABIH).

Risk Information Exchange (RiskIE)
A Resource of the Alliance for Risk Assessment (ARA)

The Alliance for Risk Assessment (ARA) introduced the Risk Information Exchange (RiskIE), a free Internet database that contains notifications about in-progress and recently completed human health risk assessment projects. RiskIE includes chemical-specific risk value and methods development projects, as well as training modules, white papers, and other risk documents. Currently, RiskIE contains 3200 projects from 24 organizations in 8 countries! By identifying groups working on a chemical or issue of interest, stakeholders (e.g., states, provinces, tribes, industry, public interest groups, or federal agencies) are able

to provide input on assessments that are underway and/or develop collaborations with document authors. The networking created by this system helps decrease duplication of effort and encourages data sharing - resulting in higher quality assessment documents. Currently found in beta version at http://www.allianceforrisk.org/RiskIE.htm, RiskIE will soon join the National Library of Medicine's TOXNET system (http://toxnet.nlm.nih.gov/) where it will serve as a companion to the International Toxicity Estimates for Risk *(ITER)* database of peer reviewed chronic human health risk data (see also www.tera.org/iter). The ARA provides an open and transparent multi-stakeholder approach for addressing the technical support needs of state and local risk assessors, environmental organizations, and the regulated community. RiskIE and *ITER* are risk resources that help meet the ARA's goals of transparency, efficiency, and improved communication in risk assessment. Visit www.allianceforrisk.org for more information.

Development of Novel Methods

In collaboration with NCTR and ENVIRON, we have developed a new approach for informing mode of action (MOA) analysis for cancer risk assessment (Moore et al., Reg. Toxicol. Pharm. 51(2):151-61). The essence of the approach focuses on using transgenic *in vivo* shuttle vector models to directly evaluate mutations in the tumor target tissue in the same rodent strain. This sort of approach is specifically noted in EPA's Draft Framework for Determining a Mutagenic Mode of Action for Carcinogenicity, and would allow one to directly evaluate the Hill criteria of temporality and dose-response. Such an analysis is particularly useful for mutagenic chemicals with multiple plausible MOAs. In another project related to new technologies, we are collaborating with Gradient in work for the USEPA on characterizing the pathophysiological progression (including biomarkers) for several endpoints of interest. In particular, we have outlined the processes leading to fibrosis (using phosgene as a case study), including relevant repair processes. In work for NIOSH, we evaluated the appropriateness of the current default IDLH methodology by such methods as modeling acute lethality data for case-study chemicals, conducting regression analysis of animal lethal concentrations and human lethal effect thresholds, and analyzing the distributions of the animal:human ratio of effect levels. We have also developed a framework for evaluating the magnitude of adult-to-child toxicokinetic differences in inhalation dosimetry of gases.

Application of State-of-the-Art Methods for Human Health Assessment

TERA has a number of projects in which we are developing and applying cutting-edge approaches in the development of human health risk assessment documents. We have conducted an extensive mode of action (MOA) analysis of tumors induced by acrylamide in rats (thyroid, tunica vaginalis mesothelioma, and mammary gland), including detailed evaluation in light of EPA's modified Hill criteria, and guidance for evaluating human relevance, as well as EPA's draft guidance for evaluating mutagenicity as a MOA. Three papers are in preparation or have been submitted from this work (Dourson et al.; Haber et al.; Maier et al.). We have also evaluated acute exposure to two sensory irritants (chloropicrin and MITC), using several modeling approaches (including benchmark

concentration, categorical regression, and the ten Berge (2007) approach to modeling responses when both exposure duration and exposure concentration are varied). For NIOSH, we have applied a new system of skin notation assignments to more than 70 chemicals.

Involving Expert Peers in Risk Assessment

TERA works to design an approach that is most effective for the type of work product, stage of development, and purpose for engaging experts. Peer input, peer consultation, and peer review are three approaches we use, all of which follow the principles that are the cornerstone of our program – selection of appropriate expertise, scientific robustness, and transparency. A fourth principle, independence, is essential for all peer reviews and an important consideration for peer input and consultation efforts. These principles were described in a recent *TERA* publication (Meek et. al., 2007. Risk Analysis 27(6):1609). Recent Peer Reviews or Peer Consultation meetings organized by *TERA* addressed topics including, statistical relationships to describe toxicity of petroleum substances, carcinogenicity of 1,3-butadiene, adult-to-child toxicokinetic differences, community-wide ecological and human health risk for Sudbury, Ontario, a methodology for developing Effect Screening Levels, QSAR for genotoxicity and carcinogenicity, and a harmonized trichloroethylene PBPK Model.

TERA Visiting Scientist

As part of efforts to build collaborations with the broader toxicology and risk assessment community, *TERA* has a program for visiting scientists, in which scientists (often senior) from other organizations are engaged with *TERA* for a fixed period of time or on a defined project. In 2007, *TERA* was pleased to host Dr. Kannan Krishnan of the University of Montreal. Dr. Krishnan spent two weeks of his sabbatical at *TERA* as a Visiting Scientist, collaborating on a framework for comparing dosimetry in children and adults exposed via inhalation to volatile organic chemicals. While at *TERA,* he also presented two seminars, and interacted with staff on several topics.

Program Updates

Global Risk Assessment Resources: International Toxicity Estimates for Risk *(ITER)* and Risk Information Exchange (RiskIE) Databases

STATEMENT OF MISSION

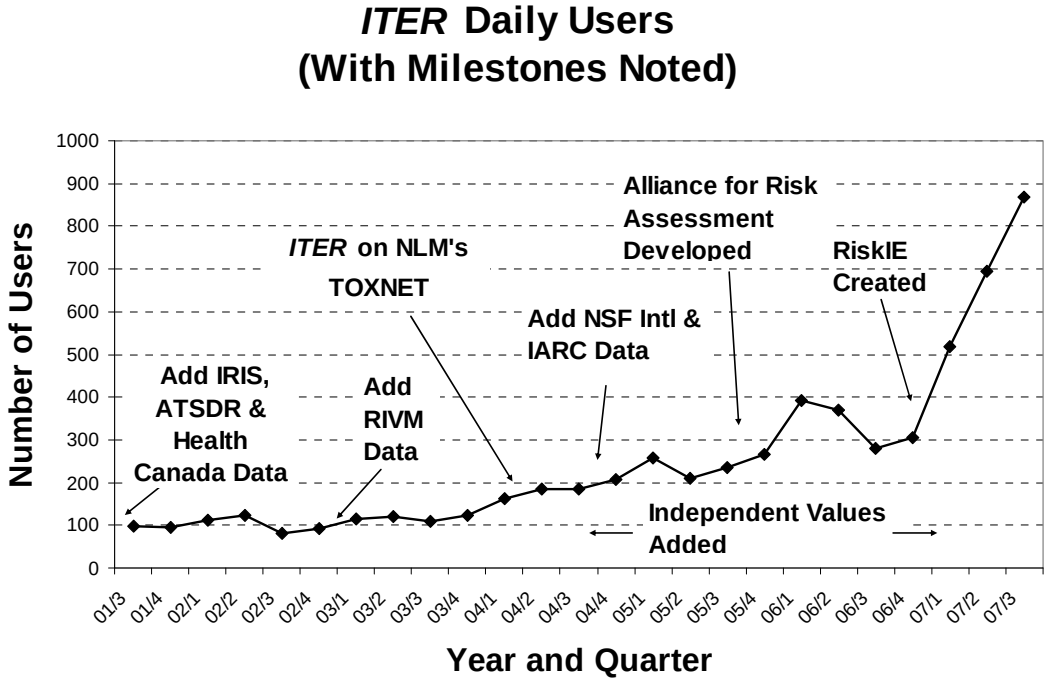
To compile, distribute, and maintain a comprehensive database of peer reviewed risk assessment values and a database of in progress human health risk assessment work, both of which provide risk assessors tools to access current risk information, encourage data

sharing and collaboration among organizations, and ultimately help protect public health through the use of the best toxicity information.

- We have provided the International Toxicity Estimates for Risk *(ITER)* database to the risk assessment community since 1996, having developed and expanded *ITER* during this time to add more organizations and to offer a more searchable version of *ITER* to users via the National Library of Medicine's (NLM) TOXNET compilation of databases.
- We created the Risk Information Exchange (RiskIE) in 2007 to provide risk assessors with notifications about a variety of human health risk assessment projects that are underway. As of the end of 2007, RiskIE is tracking over 3200 in progress or recently completed risk assessment projects conducted by 22 different organizations representing 8 different countries. We anticipate that RiskIE will join *ITER* on TOXNET during 2008.

HIGHLIGHTS OF 2007

Our *ITER* web statistics for 2007 (based on usage of original *ITER*) show that we had an average of 692 users per day – once again, a new annual record. This is more than double the number of average daily users from 2006. As shown in the *ITER* daily users graph, we are continuing to see an upward trend in the number of users per day in comparison to prior years (see graph below). This data reflects users of the original *ITER* database. The data from *ITER* on TOXNET shows that there is an average of 1990 queries per month to *ITER* on the TOXNET system.



PROGRAMMATIC HIGHLIGHTS

General

- Continued to coordinate with NLM, DoD, EPA, *CTC*, States, and other parties to further the concept of the Alliance for Risk Assessment (ARA) as related to *ITER* and RiskIE.
- Presented posters on *ITER* and RiskIE at the Toxicology and Risk Assessment Conference (TRAC). Submitted an invited manuscript to the journal, *Toxicology and Applied Pharmacology,* on *ITER* and RiskIE for publication (in 2008) with other TRAC proceedings regarding risk data resources.
- Conducted an analysis of RiskIE to identify how many chemicals were being evaluated by 4 or more organizations, and presented the results in a poster at the 2007 Society for Risk Analysis (SRA) Annual Meeting.

ITER Development:

- Continued to expand *ITER* by adding a new column entitled, "IPRV" (Independently Peer Reviewed Values), and changing the existing *ITER* column to "*ITER* PR". The former column contains data that was peer reviewed outside *TERA*'s *ITER* Peer Review process and the latter contains data that was peer reviewed by *TERA*.
- Continued to update and expand *ITER* data with additional data from existing organizations (ATSDR, EPA, NSF International, RIVM, and IARC).
- Conducted numerous updates to *ITER* web pages.

RiskIE Development:

- Developed beta version of RiskIE on the ARA website and made continual improvements in format of RiskIE to balance ease of use and ease of data entry.
- Began discussions with NLM regarding the transition of RiskIE to TOXNET.
- As of the end of 2007, RiskIE was enhanced to include over 3,200 projects from 22 different organizations, representing 8 different countries. The data is now available as a searchable, sortable, and extractable database.

Peer Consultation and Review Program

TERA's Peer Consultation and Peer Review Program provides expert independent peer consultation and peer review of risk assessment related documentation through panel meetings or other venues. *TERA* has provided this service to the risk assessment community since 1996, having organized and conducted over 50 panel reviews and numerous letter reviews. Meetings are conducted in a transparent fashion and are open to the public. *TERA* manages all aspects of the peer consultation or review including the selection of the panel, identification of conflict of interest and bias, development of issues to focus panel discussions, meeting facilitation, and preparation of a meeting report. Results of reviews and consultations are distributed widely and available at http://www.tera.org/peer.

TERA finished the sixth and final year of a cooperative agreement with the U.S. EPA to develop procedures for peer consultations. Under this agreement, we developed procedures and best practices for peer consultations, building upon our experience with

expert peer review processes and applied these concepts to a number of types of risk assessment projects, including expert reviews of chemical risk assessment submissions under the Voluntary Children's Chemical Evaluation Program (VCCEP).

TERA conducted a number of peer reviews and consultations in 2007. Full reports from each review or consultation are available on our website at http://www.tera.org/peer/CurrentMeetings.html.

- *TERA* provides ongoing peer consultation and review support to government agencies. For example, for the Texas Commission on Environmental Quality (TCEQ) *TERA* organizes external expert peer reviews of supporting documents for the state's Effects Screening Levels (ESL) ESLs are chemical-specific air concentrations set to protect human health and welfare. ESLs are used in the evaluation of air permit applications as well as evaluation of air monitoring data and in the development of Protective Concentration Levels for remediation sites. For Health Canada, *TERA* has organized letter peer reviews and consultations on chemical assessment documents and screening level risk assessments being prepared under the Challenge initiative of the Canadian Chemicals Management Plan.
- *TERA* assisted the multi-stakeholder group in Sudbury Ontario with their community and area-wide human health and ecological risk assessments by organizing and conducting independent expert review panels. The risk assessments cover a 40,000 km^2 plus area encompassing the City of Greater Sudbury and includes over 300 inland lakes, wetlands, and many different types of ecological communities. The human health and ecological impacts from over a century of mining and smelting activities are being assessed to assist in determining the need for soil remediation and in future restoration projects.
- *TERA* organized and conducted a peer consultation of a predictive toxicity method developed by a consortium of petroleum companies. The industry group developed a methodology to predict the toxicity of untested petroleum substances based on the relationship between polycyclic aromatic compound profile of petroleum substances and select mammalian toxicity responses. The group proposes to use the results to fulfill data commitments in EPA's High Production Volume Chemical Challenge Program.

We continue to share our work with others through our website (www.tera.org/peer) and presentations and publications.

- We published a paper entitled *Engaging Expert Peers in the Development of Risk Assessments* in *Risk Analysis* (Meek et. al., 2007). This paper describes ways to involved scientific peers in the development of risk assessments by utilizing peer input, peer consultation and peer review. The concepts are those that *TERA* has developed from its peer review program and with the peer consultation cooperative agreement. For the manuscript, which we worked on with Health Canada, we used examples from Health Canada's experience with these tools to illustrate the principles of peer involvement. The concepts developed in this paper were presented in posters at the 2007 Society of Toxicology meeting as well as the 2007 Toxicology and Risk Assessment Conference.

Research Program

STATEMENT OF MISSION

- Move the science of risk assessment forward globally by improving the application of current methods, developing and defining new methods, and obtaining the data to support such applications.
- Educate the scientific community and the general public about advances in risk assessment research.

OVERALL STATUS

The research program works closely with the *VERA* program in identifying and addressing key issues related to risk assessment methods. While many of the research projects have traditionally been on the border between methods development and application to risk assessment, we have been developing marketing approaches for attracting more work on fundamental risk assessment methods issues. Our marketing in 2007 focused on building on our knowledge of fundamental biology coupled with risk assessment expertise, while also leveraging our collaborations with thought leaders in quantitative methods, including dose-response analyses, Bayesian networks and PBPK modeling. Research projects were conducted for a variety of government sponsors, including EPA, NIOSH, and industry sponsors.

HIGHLIGHTS FOR 2007

- In a developing project for a private sponsor, *TERA* is developing a toxicology summary for diacetyl, a respiratory irritant found in popcorn flavoring. This summary is intended to be shared with the AIHA WEEL committee or other groups developing occupational exposure limits (OELs) as a resource for deriving an OEL for this chemical.
- For a private sponsor, *TERA* analyzed the mode of action for the tumors induced by acrylamide in rats – thyroid, tunica vaginalis of the testis, and mammary gland.
- We have continued to market the Cooperative Research and Development Agreement (CRADA) with FDA/NCTR.
- In a project for NIOSH, we have been developing and demonstrating a decision support system for validating and using biomarkers in risk assessment.
- *TERA* is working with another consulting company (Gradient) on providing support to EPA for developing an approach for categorizing biomarkers and other endpoints along a pathophysiological progression.

Verifiable Estimates for Risk Assessment (*VERA*) Program

STATEMENT OF MISSION

To provide high quality risk assessment service by developing unbiased and science-based risk assessments for all sponsors, including government agencies, industry groups, and environmental groups.

OVERALL STATUS

The *VERA* program continues to be a significant contributor to the overall scientific effort of *TERA*. *TERA* staff worked on 13 significant projects (i.e., projects of more than 20 hours) during 2007, as well as a variety of other small projects. The program has maintained a diverse portfolio of work. Including smaller projects, *TERA* projects in 2007 were sponsored by industry (7), EPA (7), State governments (1), NIOSH (2), and miscellaneous sponsors (1 – boot camp).

TERA is viewed as a source of high quality technical expertise as evidenced by ongoing projects, requests for new work by existing and former sponsors, recent referrals, and requests for training. Specific project highlights demonstrating these points are presented below.

HIGHLIGHTS OF 2007

- *TERA* staff continued to be active in support of EPA. For the Office of Water, as part of the review of the toxicity of chemicals that occurs every 6 years for prioritization for future analysis, *TERA* reviewed the basis of assessments by EPA and other agencies for noncancer and cancer endpoints, as well as considered the availability of new studies, to determine whether there are new data that could affect the assessments. This work will lead to a Federal Register notice in 2008. *TERA* also developed the initial drafts of the toxicology data summary for support of the EPA NOx Science Assessment Document and presented our analysis at an EPA-sponsored workshop.
- Risk assessment development projects for NIOSH continued to grow. *TERA* provided support in a major effort for development and implementation of a new emphasis program for assigning skin notations to accompany occupational exposure limits. Building on success on prior work, *TERA* also continued to provide support for the development of Immediately Dangerous to Life or Health (IDLH) values for NIOSH. An updated IDLH methodology report was accepted by NIOSH and a manuscript version is being prepared for publication. *TERA* was successful in obtaining projects that demonstrate technical leadership in risk assessment development through risk assessment training development:
- *TERA* played a major role in the development of EPA's online training materials for use of Benchmark Dose Software (BMDS) in risk assessment, and assisted in the development of training materials for the use of categorical regression software (CatReg).
- *TERA* held its first Dose-Response Assessment Boot Camp in October 2007 in Cincinnati, Ohio.
- *TERA* scientists also continued to build work of interest to industry sponsors, including evaluation of an irritant, development of Occupational Exposure Limits (OELs), and hazard screening approaches. *TERA* continued to look for opportunities to pursue collaborations outside of North America. Our staff actively participated in Regional SOT sections for Africa and China and is pursuing potential collaborative projects based on these networks.

Alliance for Risk Assessment

The Alliance for Risk Assessment (ARA) has continued to progress steadily in 2007. ARA provides a collaborative multiple-stakeholder approach for solving public health risk assessment issues and sharing resources to increase the output of technical risk assessment products. 2007 Milestones have included:

- **Formation of the ARA Steering Committee**. Comprised of nine well-qualified individuals of academic, industry, governmental, and environmental affiliations, the Steering Committee offers oversight and guidance in the project approval and selection process.
- **Launch of the Risk Information Exchange (RiskIE) beta**. Formerly known as the Hazard Assessment Notification System (HANS), RiskIE is a National Library of Medicine (NLM) funded web-based system for coordinating work on chemical risk value and methodology documents that are under development or revision. RiskIE beta is housed at http://allianceforrisk.org/RiskIE.htm. Ultimately, RiskIE will be interfaced with *ITER* and NLM's TOXNET.
- **Signed agreement with Texas Commission for Environmental Quality (TCEQ).** TCEQ has committed to conduct peer reviews of their Development Support Documents through the ARA.

TERA Public Service Activities

TERA staff continued to dedicate significant effort supporting scientific development through *pro bono* activities and our *TERA* Corporate Development funds. Highlights of the *pro bono* efforts of the staff through December 2007 are provided below.

- Served as peer reviewer of submitted manuscripts for the journal, *Regulatory Toxicology*.
- Multiple presentations occurred at national meetings: the Society for Risk Analysis Annual Meeting, Society of Toxicology Annual Meeting, and the Toxicology and Risk Assessment Conference.
- Served on several scientific committees, for example, the AIHA WEEL (Maier), NSF International (Dourson), Underwriters Lab (Haber).
- *TERA* staff members are officers in professional societies: the Society for Risk Analysis Ohio Chapter (Secretary - Gadagbui).
- Served on committees for professional societies, for example, SRA World Congress Finance Committee (Nance and Dourson), Conference Committee for SRA (Patterson), Awards Review Committee for SOT RASS (Haber), and formation of Toxicologists of African Origin - Special Interest Group (TAO-SIG) for SOT (Gadagbui).
- Provided Courses or Lectures to Universities or Professional Societies: risk assessment lectures for several graduate courses at the University of Cincinnati (Dourson and Maier), Miami University of Ohio (Patterson), and as continuing education courses at the Toxicology and Risk Assessment Conference and SRA annual meeting (Haber and Maier).
- Participated in local environmental group efforts: participated in local group events hosted by the Alliance for Chemical Awareness (Nance, Dourson and Haber), served as member of the board and as editor for *Wetland Matters* newsletter for Oxbow Inc. (Poehlmann), and newsletter and webpage editor for EchoBats Inc. (Nance).
- Provided comments on several documents: EPA's "Framework for Determining a Mutagenic Mode of Action for Carcinogenciity" (Haber), Health Canada's UF (Dourson and Nance).
- Provided comments on several health issues: comments on methylmercury and fish to the Virginia DEQ (Dourson and Nance).

TERA 2007 Publications

Dourson, M.L. and Parker, A. 2007. Past and Future Use of Default Assumptions and Uncertainty Factors: Default Assumptions, Misunderstandings, and New Concepts. Hum Ecol Risk Assess. 13(1):82-88.

Hasegawa R, Hirata-Koizumi M, Dourson M, Parker A, Hirose A, Nakai S, Kamata E, Ema M. 2007. Pediatric susceptibility to 18 industrial chemicals: A comparative analysis of newborn with young animals. Regul Toxicol Pharmacol. 47(3):296-307.

Meek, M.E., J. Patterson, J. Strawson and R. Liteplo. 2007. Engaging Expert Peers in the Development of Risk Assessments. Risk Anal. 27(6):1609-1621.

Stern, B.R., M. Solioz, D. Krewski, P. Aggett, T.-C. Aw, S. Baker, K. Crump, M. Dourson, L. Haber, R. Hertzberg, C. Keen, B. Meek, L. Rudenko, R. Schoeny, W. Slob, T. Starr. 2007. Copper and Human Health: Biochemistry, Genetics, and Strategies for Modeling Dose-response Relationships. J. Toxicol. and Environ. Health, Part B. 10(3):157-222.

Stedeford T, Zhor J, Dourson ML, Banasik M, Hsu CH. 2007. The Application of Non-Default Uncertainty Factors in the U.S. EPA's Integrated Risk Information System (IRIS). Part I: UF(L), UF(S), and "Other Uncertainty Factors". J Environ Sci Health C Environ Carcinog Ecotoxicol Rev. 25(3):245-79.

Wexler, P., Hakkinen, P., Nance, P., Parker, A, Patterson, J. 2007. The Information Infrastructure of Toxicology. In: Principles and Methods of Toxicology. Ed. Hayes, A.W. 5th ed., CRC Press, Boca Raton, FL

Framework for Metals Risk Assessment. 2007. U.S. EPA Risk Assessment Forum. EPA 120/R-07/001. Several *TERA* staff were contributors.

Manuscripts in Preparation

Dourson, M., L.T. Haber, R. Hertzberg, B. Allen, A. Maier. Mode-of Action-based assessment for thyroid tumors in acrylamide-treated rats. Submitted.

Haber, L.T., A. Maier, O.L. Kroner, and M.J. Kohrman. Assessment of Human Relevance and Mode of Action for Tunica Vaginalis Mesotheliomas Resulting from Oral Exposure to Acrylamide. Submitted.

Maier, A., M. Dourson, L.T. Haber, R. Hertzberg, B. Allen. Mode-of Action-based Assessment for Mammary Tumors in Acrylamide-treated Rats. Submitted.

Haber, L.T., A. Maier and M. Dourson. The Mechanistic Basis of Alternative Shapes of Dose Response Curves. In preparation

Hack, C.E., Haber, L..T., Maier, A., Schulte, P., Fowler, B., Lotz, W.G. and Savage, R.E. 2008. A Method for biomarker validation and biomarker-based dose response: A case study with benzene and a Bayesian network. Submitted

Society for Risk Assessment 2007 *TERA* Posters and Presentations

Replacing Default Values for Uncertainty Factors with Specific Adjustment Factors: Reducing Uncertainty in Noncancer Risk Assessment. L.T. Haber B. Meek and A. Maier

Case studies for the Development of a Pathophysiological Progression Model. D.G. Dodge, L.T. Haber, J.E. Goodman, I. Pagan, G.L. Foureman and L.R. Rhomberg

Case Studies for the Development of a Pathophysiological Progression Model: Phosgene-induced Lung. L.T. Haber, E.J. Kopras, J.E. Goodman, D.G. Dodge, L.R. Rhomberg and I. Pagen

Deriving Skin Notations Based on the Improved Strategy Developed by the National Institute for Occupational Safety and Health. G.S. Dotson, B. Gadagbui, O. Kroner, P. Nance, T.J. Lentz and A. Maier

Development of a Pathophysiological Progression Continuum Model for Selected Toxicological Endpoints. I. Pagan, L.T. Haber, L.R. Rhomberg, J.E. Goodman, D.G. Dodge, and G.L. Foureman

Use of Animal Acute Toxicity Data to Derive Immediately Dangerous to Life or Health Concentrations: Extrapolating to Human Effect Thresholds. A. Parker, A. Maier, B. Gadagbui and G.S. Dotson

The Risk Information Exchange (RiskIE): A database to communicate in-progress risk assessment work. A Wullenweber, O. Kroner, A. Maier, P. Wexler, A. Rak and C. Tomljanovic

Evidence-Based Dose Response Assessment for Thyroid Tumorigenesis from Acrylamide. M.L. Dourson, R. Hertzberg, B. Allen, L. Haber, A. Parker, O. Kroner, A. Maier and M. Kohrman

Evidence-based assessment of human relevance and mode of action for tunica vaginalis mesotheliomas resulting from oral exposure to acrylamide. L. Haber, A. Maier, O. Kroner, and M. Kohrman

Decision-making on toxicity testing – the Voluntary Children's Chemical Evaluating Program (VCCEP). J. Patterson and M. Dourson

Society of Toxicology 2008 *TERA* Posters and Presentations

Dose-Response Modeling for Occupational and Environmental Risk Assessment. D.G. Dolan and A. Maier – co chairs

- Introduction to Identifying Critical Effects for Quantitative Risk Assessment. Andrew Maier, Toxicology Excellence for Risk Assessment, Cincinnati, Ohio

Use of Data for Development of Uncertainty Factors in Non-Cancer Risk Assessment. J. Lipscomb and L.T. Haber - co chairs

- Overview and History of Default Values for Uncertainty Factors. Lynne T. Haber, Toxicology Excellence for Risk Assessment, Cincinnati, Ohio

A Framework to Evaluate Child-Adult Differences in Inhalation Dosimetry of Gases: Application to Selected Systemically-Acting Volatile Organic Compounds (Vocs). L.T. Haber, R. Gentry, T. Adamou, and K. Krishnan

Application of a Toxicological Surrogate Evaluation Framework: Alkyl Ammonio Acetates as a Case Study. A. Maier, R. Venkatapathy, and G. Simon

Extrapolating Human Effect Thresholds from Animal Toxicity Data for the Derivation of Immediately Dangerous to Life or Health Values. A. Parker, A. Maier, G. Dotson, and C.L. Geraci

Development of an Improved Strategy for the Derivation of Skin Notations. G. Dotson, A. Maier, B. Gadagbui, and C.L. Geraci

Case Studies For the Development of a Pathophysiological Progression Model . D.G. Dodge, L.T. Haber, E. Kopras, J.E. Goodman, I. Pagan, J.S. Gift, and L.R. Rhomberg

TERA Staff News and Contacts

TERA is pleased to announce that Dr. Bernard Gadagbui recently became a Diplomate of the American Board of Toxicology, joining four other senior *TERA* scientists with this distinction. Ms. Melissa Kohrman joined *TERA* as a Research Associate. Dr. Lisa Anderson completed a 3-week rotation in *TERA's* new Occupational Medicine Internship Program.

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TERA's Board of Trustees

TERA's Board of Trustees consists of up to 10 members who serve 3-year rotating terms. Listed below are *TERA's* Board members for 2007. The date in parenthesis indicates the year each member's term on *TERA's* Board of Trustees concludes.

Board of Trustees - 2007

Michael Dourson (perpetual)

Daniel Acosta (2007)

Michael Fremont (2008)

Sam Kacew (2008)

Randall Manning (2006)

Roger O. McClellan (2007) PAST CHAIR

Greg Romshe (2009)

Sue Ross (2008)

Chad B. Sandusky (2007) BOARD TREASURER

James D. Wilson (2007) CHAIR

Financial Statement

TERA's 2007 income was $2,213,714 and actual expenses totaled $2,022,390. This resulted in net income of $191,324.

As a neutral, non-profit corporation, TERA strives for work on both public and private projects in a roughly equal amount. In 2007 *TERA* conducted a larger percentage of work for government agencies and other non-profits (71%), while 23 % of work was for private sector sponsors. The table below shows the percentage of government and private work for each year since our inception. This balance of sponsors varies from year-to-year, reflecting the needs of sponsors and our goal of providing scientifically credible and neutral guidance.

Year/ Source	Government and other Nonprofit	Industry and Industry Related
1995	67%	33%
1996	37%	63%
1997	55%	45%
1998	63%	37%
1999	66%	34%
2000	59%	41%
2001	48%	52%
2002	72%	28%
2003	66%	34%
2004	82%	18%
2005	82%	18%
2006	79%	21%
2007	71%	29%