PROBABILISTIC RISK ASSESSMENT: CURRENT DEVELOPMENTS AND APPLICATIONS FOR ENVIRONMENTAL ASSESSMENT AND MANAGEMENT

Society for Risk Analysis and Interstate Technology Regulatory Council Workshop

Lecturer and Organizer Bios

Edmund A. Crouch

Dr. Crouch is a Senior Scientist with Cambridge Environmental Inc. He has published widely in the areas of environmental quality, risk assessment, and presentation and analysis of uncertainties. He has co-authored a major text in risk assessment, *Risk/Benefit Analysis*. Dr. Crouch serves as an expert advisor to various local and national agencies concerned with public health and the environment, and has served on two National Academy of Science Committees. He has written computer programs for the sophisticated analysis of results from carcinogenesis bioassays; has developed algorithms (on the levels of both theory and computer implementation) for the objective quantification of waste site contamination; and has designed Monte Carlo simulations for purposes of fully characterizing uncertainties and variabilities inherent in health risk assessment. Dr. Crouch is widely regarded as an insightful peer-reviewer; he has detected and corrected numerous, critical, otherwise hidden flaws in the technical underpinnings of proposed regulations for environmental protection and related areas. Dr. Crouch holds a B.A. in Natural Sciences (Theoretical Physics) (1972) and a Ph.D. in High Energy Physics (1975), both from Cambridge University, United Kingdom.

Jeffrey A. Crum

Mr. Jeffrey Crum is a senior toxicologist with Hamp, Mathews and Associates in Michigan. Mr. Crum specializes in developing approaches to assess and mitigate human health risk associated with subsurface vapor intrusion to indoor air. Mr. Crum received his M.S. in toxicology from Michigan State University in 1992, and has published his research on the reproductive and developmental toxicity of heptachlor to mink. From 1990 to 2004, he worked as a toxicology specialist for the Michigan Department of Environmental Quality's (DEQ) Remediation and Redevelopment Division.

Mr. Crum brings over 15 years experience as a regulatory toxicologist to environmental consulting. While at DEQ, Mr. Crum was primarily involved with the development of health risk assessment methodologies used to derive generic cleanup criteria for Part 201 and Part 213 of Act 451, the Natural Resources and Environmental Protection Act. He was the state-wide expert in two specialized quantitative health risk assessment methodologies used to calculate cleanup criteria - groundwater and soil volatilization to indoor air inhalation criteria, and groundwater contact criteria. Mr. Crum has substantial experience in reviewing human health and ecological risk assessments for compliance with state and federal regulations.

Most recently, Mr. Crum has developed expertise in assessing the ecological risks associated with environmental lead from shooting ranges, trichloroethylene health risk assessment, and assessment of methane gas hazards to buildings.

Stephen M. DiZio

Dr. DiZio is the Chief of the Human and Ecological Risk Division of the California Department of Toxic Substances Control (DTSC). He earned a BS from Lafayette College in 1972 and a Ph.D. from the University of Delaware in 1977. He began his career as a Toxicology Study Director for Wyeth Laboratories conducting safety evaluation for new drugs. He worked for the California Department of Health Services from 1987 through 1992, before accepting a position with ENVIRON Corporation as a Manager in Health Sciences. In late 1993 he returned to the DTSC where his present responsibilities include supervision of a division consisting of twenty nine Toxicologists ten Industrial Hygienists, one Hazardous Substances Scientist (retired annuitant), one contract analyst, and an Office Technician.

These people are responsible for risk assessment review for Site Mitigation, Hazardous waste Management, and Enforcement in California, as well as training needed to comply with the DTSC worker health and safety plan. He is a full member of the Society of Toxicology (SOT) and was the appointed Chair of the Animals in Research Committee for the years 1999-2000 and 2000-2001. He is presently the Secretary-Treasurer of the SOT Risk Assessment Specialty Section, He is also a past-president of the Genetic and Environmental Toxicology Association of Northern California.

Philip Goodrum

Dr. Philip Goodrum received his Ph.D. in environmental engineering from SUNY College of Environmental Science and Forestry in 1999, where he developed a probabilistic exposure model to investigate childhood lead poisoning. He is a senior scientist with Syracuse Research Corporation, with extensive experience in providing support to state and federal agencies on uncertainty analysis. He assisted EPA's Superfund program in developing RAGS Volume 3, Guidance for Conducting PRA. He currently serves as a program manager to conduct and evaluate PRAs for EPA's Office of Pesticide Programs, Ecological Fate and Effects Division. He is a co-PI for the Probabilistic Risk Assessment Center of Central New York, where he develops software, databases, and case studies to provide greater access to probabilistic approaches. Dr. Goodrum has been teaching short courses on modeling and probabilistic risk methods since 1995, and teaches a class on environmental modeling at SUNY ESF. He maintains interests in Bayesian statistics and the use of uncertainty analysis is risk management. In his free time, Dr. Goodrum enjoys rediscovering childhood through the eyes of his two-year old son, and climbing the high peaks in the White Mountains of New Hampshire.

Scott Ferson

Dr. Scott Ferson is a senior scientist at Applied Biomathematics (www.ramas.com), a research firm on Long Island in New York specializing in methods for ecological and environmental risk analysis. His research focuses on developing reliable mathematical and statistical tools for ecological and human health risk assessments and on methods for uncertainty analysis when empirical information is very sparse. Ferson holds a Ph.D. in ecology and evolution from the State University of New York at Stony Brook. He is an author of *Risk Assessment for Conservation Biology* (Chapman and Hall) and editor of the collected volumes *Quantitative Methods for Conservation Biology* (Springer Verlag) and *Ecological Modeling in Risk Assessment: Chemical Effects on Populations, Ecosystems, and Landscapes* (Lewis Press). He is also author of the new book *RAMAS Risk Calc Software 4.0: Risk Assessment with Uncertain Numbers* (Lewis Publishers). He has written over 70 other scholarly publications, including several software packages, in environmental risk analysis and uncertainty propagation. His research has addressed quality assurance for Monte Carlo assessments, exact methods for detecting clusters in small data sets, backcalculation methods for use in remediation planning, and distribution-free methods of risk analysis appropriate for use in information-poor situations. He has served on expert panels for the U.S. Environmental Protection Agency, National Academy of Sciences, and the National Institutes of Health.

Annie Jarabek

Annie Jarabek is currently a US EPA Visiting Scientist in the Department of Computational Biology at the CIIT Centers for Health Research. Via this assignment, she is working on a joint project to develop value-of-information (VOI) analyses as a means to inform uncertainty factors applied for intrahuman and interspecies extrapolation. The approach will focus on formalizing confidence in mechanistically-based model descriptions of dosimetry and tissue reactions for inhaled irritant gases.

Ms. Jarabek is the principal author of the EPA's methods to derive inhalation reference concentrations (RfCs) that incorporate dosimetry modeling of inhaled particles and gases to improve characterization of dose. Her most recent EPA research involved developing mode-of-action dosimetry models for the inhalation, oral, and dermal routes. As a Senior Toxicologist and Special

Assistant to the Associate Director for Health in the National Center for Environmental Assessment of the EPA's Office of Research and Development, Annie represented the Agency on a number of public-private partnership steering committees that developed case studies for the application of mode of action information per the 1996 proposed cancer assessment guidelines. These case studies included ingested perchlorate and inhaled formaldehyde, acetaldehyde, and vinyl acetate. She continues to consult on committees evaluating how to harmonize approaches of noncancer and cancer and on the use of biomarkers such as DNA adducts in risk assessment. Annie also contributed to the practice of using dosimetry modeling for route-to-route extrapolation and participated in technical reviews and negotiations to use pharmacokinetic data to inform alternative testing strategies. Annie was involved with implementation of the benchmark dose approach for dose-response modeling. She developed a Bayesian application that provides for statistical combination of dose-response estimates and allows for calculation of risk above reference levels. That work was recently extended to combine health and ecotoxicological risks. She also contributed to other Bayesian applications that evaluated historical tumor data and motor activity analyses across multi-generation studies.

Annie has received one silver and four bronze medals for her work in the Agency. She has provided invited presentations on dosimetry methods, mode of action, and statistical considerations for dose-response assessment to the National Academy of Sciences (NAS), the Science Advisory Board (SAB) of EPA, the Toxicology Forum, and the EPA=s Risk Assessment Forum. She also serves on a committee to the National Occupational Research Agenda in risk assessment.

Annie is active in both Society of Toxicology (SOT) and the Society for Risk Analysis (SRA). Annie stepped down in 1998 from a three-year term as an elected councilor to the SRA and continues to serve the SRA on the annual meeting program and workshop committees. She was recently elected to serve on the Awards Committee of the SOT. Annie has received four different awards for outstanding presentation from the Risk Assessment Specialty Section of the SOT since 1992 and received an award for best manuscript demonstrating a risk assessment application in 2001. Annie was elected in 2002 to serve a four-year term as an officer of the Risk Assessment Specialty Section of the SOT and is currently presiding as its President for 2004-2005.

John W. Kern

Dr. Kern established KERN Statistical Services, Inc. in 2000, providing geostatistical and general statistical services for ecologists, risk assessors/managers, wildlife biologists and engineers. He completed his Ph.D. in statistics at the University of Wyoming in 1995 with a dissertation in geostatistics and received an M.S. in Applied Mathematics at Montana State University in 1986 specializing in numerical analysis. Dr. Kern actively supports state and federal agencies at several of the largest and most complex contaminated sediment sites in the country, including the Tittabawassee, Pine and Kalamazoo Rivers in Michigan, the Fox River in Wisconsin, the Hudson River in New York, and the Coeur d'Alene River in ID. Dr. Kern has worked in all phases of the superfund process at contaminated sediment sites including preliminary screening studies, risk assessment, design and analysis of remedial investigation and feasibility studies, design and implementation of long term monitoring studies, and oversight of dredging design and implementation.

In addition, Dr. Kern has over 10 years experience consulting on a variety of geostatistical, sampling-design and analysis projects associated with environmental and ecological field studies, regulatory compliance monitoring, wildlife impact assessment and monitoring. Dr. Kern regularly presents customized short-courses and workshops at regional and national meetings of the Society of Environmental Toxicology and Chemistry and The Wildlife Society, as well as for state and federal agencies including the National Oceanic and Atmospheric Administration, Office of Surface Mining and Reclamation, United States Fish and Wildlife Service and United States Environmental Protection Agency.

Igor Linkov

Dr. Linkov is a Senior Scientist at Cambridge Environmental Inc in Cambridge, MA and an Adjunct Professor of Engineering and Public Policy at Carnegie Mellon University in Pittsburgh, PA. . He has performed state-of-the-art ecological and human health risk assessments and environmental investigations for contaminated sites in the U.S.A and worldwide. Dr. Linkov's skills include environmental risk assessment, study of contaminated sites, probabilistic modeling, project management, risk communication, litigation support, policy analysis, risk assessment for emerging threats, toxicology, and biostatistics. He is also developing software for environmental modeling, decision support and risk assessment. His current research interests include decision analysis, probabilistic modeling, and risk assessment as well as the development of risk-based approaches to environmental decision-making. Prior to joining Cambridge Environmental, Dr. Linkov was a Senior Risk Assessor and Team Leader at ICF Consulting, where he conducted environmental risk assessments in support of government and commercial clients. He also worked for Arthur D. Little and Menzie-Cura & Associates. At Harvard University, Dr. Linkov researched carcinogenic potencies of chemicals for risk-based regulatory policies and applied Bayesian updating methodology to environmental modeling. Dr. Linkov is the past chair of the Ecological Risk Assessment Specialty Group of the Society for Risk Analysis and is president-elect of its New England Chapter. He serves as a scientific advisor to the Toxic Use Reduction Institute, a position that requires nomination by the Governor of Massachusetts. Dr. Linkov has a BS and MSc in Physics and Mathematics (Polytechnic Institute, Russia) and a Ph.D. in Environmental, Occupational and Radiation Health (University of Pittsburgh). He completed his postdoctoral training in Biostatistics, Toxicology and Risk Assessment at Harvard University.

Anita K. Meyer

Anita Meyer currently is a risk assessor at the US Army Corps of Engineers Hazardous, Toxic and Radioactive Waste Center of Expertise. She serves as a consultant in toxicology and risk assessment to Corps of Engineers Districts and Headquarters. Prior to working for the Corps of Engineers, Ms. Meyer was a researcher in the Department of Pharmacology and Eppley Cancer Institute at the University of Nebraska Medical Center. She received her undergraduate and master's degrees from the University of Nebraska.

During her tenure at the Corps of Engineers, Ms. Meyer has had the opportunity to work on many challenging Formerly Used Defense Sites, Superfund, and active Army and Air Force environmental investigation and remediation projects. She has written and helped finalize numerous guidance documents on conducting environmental investigations and on conducting human health and ecological risk assessment for the Corps of Engineers and the Army.

Professional affiliations include Society for Risk Analysis, Interstate Technology Regulatory Council, Army Biological Technical Assistance Group and the Tri-Service Ecological Risk Assessment Workgroup.

W. LEE POE, JR.

Mr. Poe earned a B. S. in Chemistry from Tulane University in 1949 and a M. S. in Chemical Engineering from the University of Alabama in 1951. He obtained a technical position with E. I. Du Pont de Nemours & Company, the Operating Contractor for AEC-ERDA-DOE at the Savannah River Plant (SRP). SRP name was changed to Savannah River Site (SRS) in 1989. Mr. Poe has more than 51 years of experience in providing technical and management support for large-scale nuclear projects including chemical reprocessing and finishing, waste management, and environmental protection.

Mr. Poe has a thorough understanding of probabilistic risk assessment. PRA is used in environmental impact analysis and safety impacts of the projects like those that Mr. Poe managed or participated in at various stages of his career. He was lead engineer for scoping and preparation of environmental analysis (EA) and environmental impact analysis (EISs) in compliance with National

Environmental Policy Act for several operations including site, waste operations, burial grounds, high level waste tankage, Naval Fuel Material Facility, etc. He also has extensive experience in reactor and non-reactor nuclear design and evaluation including safety documentation, reviews of safety, and risk assessments at SRS, Rocky Flats, the Hanford site, and Los Alamos National Laboratory. He understands the technical aspects of equipment and processes to ensure safe operation and the implementation of facility modifications to increase safety levels to operating personnel and the public. He has participated in public forums on risk management alternative comparisons and risk ranking.

Since his retirement, Mr. Poe remains an active stakeholder/citizen-participant for SRS and Interstate Technology Regulatory Commission (ITRC). He reviews and comments on safety and environmental documents, site remediation and cleanup activities, and attends various public meetings on these activities. Mr. Poe led the stakeholder review in reaching consensus on input to DOE's risk prioritization activities. This process evaluated the consequences of actions and no actions and estimated the probability of these activities taking place. This process included stakeholder education on PRA approaches and consensus development on those aspects considered by the public as necessary. The stakeholders then worked with DOE to ensure that the important issues were implemented. This review is the basis for Mr. Poe's presentation at the Society for Risk Analysis workshop.

Ted Simon

Dr. Ted Simon received his Ph.D. in neuroscience from Georgia State University in 1989 and spent ten years studying the brain. In 1993, he joined the Environmental Protection Agency's Region 4 office in Atlanta, Georgia. With the EPA, Dr. Simon served as one of the lead authors of RAGS, Volume 3, Guidance for Conducting Probabilistic Risk Assessment.

He has taught classes in statistics and probabilistic risk methods since 1995. In addition to statistics and Monte Carlo method, he maintains interests in PBPK modeling and geostatistics. In his free time, Dr. Simon enjoys photography, yoga and playing the violin.

Jeffery A. Steevens

Dr. Steevens is a research toxicologist and team leader of the Environmental Risk Assessment Team at the U.S. Army Engineer Research and Development Center in Vicksburg, MS. He obtained his bachelors degree in biochemistry from the University of Missouri at Columbia and his doctorate degree in toxicology from the University of Mississippi. Currently his research activities are in the area of aquatic and sediment toxicology as well as ecological risk assessment. Dr. Steevens is involved in studies focusing on the toxicity and bioaccumulation of contaminants from sediments. These studies include developing new approaches to evaluate bioaccumulation of non-polar organic chemicals. He supports the military by conducting studies focusing on the toxicology of explosive compounds including trinitrotoluene, RDX, and HMX. Dr. Steevens is also a technical advisor to the military by providing expertise for the risk assessment of contaminated military facilities. He is a member of several national organizations including the Society of Environmental Toxicology and Chemistry, American Chemical Society, and Society of Toxicology. Dr. Steevens represents the U.S. as a scientific delegate to the International Atomic Energy Agency and the London Convention.

Ewen C. D. Todd

Ewen C. D. Todd is Director of the National Food Safety and Toxicology Center (NFSTC) at Michigan State University. He is also Adjunct Professor in the Department of Food Science and Human Nutrition. At the NFSTC, Dr. Todd coordinates research in microbiology, toxicology, epidemiology, risk assessment and social science in the area of food safety, distance education programs, and outreach in the community. He is a graduate of Glasgow University with a B.S. degree in Bacteriology and a Ph.D. degree in bacterial systematics. Dr. Todd was formerly in the Bureau of

Microbial Hazards, Health Products and Food Branch, Health Canada, Ottawa, where he was a research scientist for 33 years working on methods development for pathogens in foods, foodborne disease investigation and reporting, costs and surveillance of disease, illnesses caused by seafood toxins, and risk assessment of foodborne pathogens such as *E. coli* O157 in hamburgers, *Salmonella* Enteritidis in eggs, *E. coli* O157:H7 in lettuce, *L. monocytogenes* in cabbage, and *Vibrio vulnificus* in oysters. He also helped develop risk management strategies for the NFSTC including producing videos and pamphlets on food safety education. He serves on the FAO/WHO expert consultation for producing a risk assessment for *L. monocytogenes* in ready-to-eat foods. He is also currently working on *Listeria* modeling projects with colleagues at MSU. He also is associated with MSU faculty involved with international projects in helping developing countries respond to SPS agreements. Dr. Todd has published more than 100 research papers, book chapters and booklets. He also has made over 250 presentations and posters at national and international meetings with over 170 invitations to speak. He has received the Government of Canada Distinctive Service Award for extraordinary teamwork and support to the Science and Technology Community; Recipient of the Excellence in Science Award for 1998 by Health Canada; Deputy Minister's Award of Team Excellence for the work done in promoting the Fight BAC! Campaign in Canada; the Professional Institute of the Public Service of Canada Gold Medal for Pure and Applied Science; and he is Fellow of the International Association for Food Protection.

William E Wright

Mr. Wright is a Principal Ecologist with MWH in Bellevue, WA. He has more than a quarter century of experience in environmental assessment and pollution control. His academic training is in the areas of molecular biology, bioenergetics, and biogeochemistry, and he has gained his experience as a consultant, regulator, researcher, and teacher. Mr. Wright has been providing stochastic risk analysis services for a decade and a half. His most recent major assignment has been project and technical management of several multimillion-dollar regional and mine-specific investigations and studies for the phosphate mining industry in southeastern Idaho.

Using stochastic approaches to risk analysis and decision analysis, Mr. Wright has saved clients as much as $15,000,000 in a single project by avoiding unnecessary investigation and cleanup costs. His application of these tools to the management plan for a suburban redevelopment of oil production and refining properties identified a $20,000,000 underestimate in cost, and spurred the effective use of these tools to identify alternative approaches to control project cost and schedule.

Mr. Wright started his decision and risk analysis career by conducting human and ecological health risk assessments. He quickly realized that conducting these assessments using conservatively biased point estimates to address uncertainty in the manner that the regulatory agencies dictated was seriously flawed because the conservatism compounds geometrically and results often end up exceeding the range of likely values. By using proven methods of probabilistic analysis, one is able to quantify the likelihoods and uncertainties of various risk estimates, thus providing risk managers with less biased results on which to base their decisions.

Mr. Wright's contributions to the field of risk assessment have been acknowledged by the United States Environmental Protection Agency's citation of one of his papers, on the application of maximum-entropy inference, in the Agency's guidance on probabilistic risk assessment. He has developed risk assessment guidance or training manuals for various agencies, including the United States Department of Energy, the British Columbia Ministry of the Environment, and the Canadian Council of Ministers of the Environment.