

## 2013 SRA Workshops, Baltimore, Maryland

Workshops are offered Sunday and Thursday, either Full Day, a.m. Half Day, or p.m. Half Day

“S” after a number = Sunday

“T” after a number = Thursday

### **Sunday 8 December Full Day – 8:30 am-5:30 pm**

#### **Workshop 1S: Benchmark Dose Modeling – Basic Methodologies**

**Cost:** Pre-registration \$275/Onsite \$325

**Organizer:** J. Allen Davis, MSPH, U.S. Environmental Protection Agency

**Instructors:** J. Allen Davis, MSPH, U.S. Environmental Protection Agency; Jeff Gift, U.S. Environmental Protection Agency; Jay Zhao, Ph.D., U.S. Environmental Protection Agency

**Description:** The objective of this full-day workshop is to provide participants with interactive training on the use of the U.S. Environmental Protection Agency’s (EPA) Benchmark Dose Software (BMDS) and its application to risk assessment. Use of BMD methods addresses many of the limitations of the traditional No Observed Adverse Effect Level (NOAEL) approach. BMD modeling involves fitting mathematical models to dose-response data in order to identify points of departure for use in human health risk assessments. In this interactive training workshop, EPA instructors will present: the basic theory of BMD modeling (including selection of a benchmark response level, model fitting and comparison), a demonstration of EPA’s BMDS 2.4, and individual and group modeling exercises. Instructors will focus on the use of the new Excel-based BMDS Wizard templates that are provided with BMDS 2.4. The BMDS Wizard streamlines BMD analyses by allowing users to build BMDS inputs, run models, and import results in Excel. In addition to importing all results, it is capable of recommending best-fitting models using customizable decision criteria.

Participants are not required to have any previous BMD experience, but it is recommended that they familiarize themselves with basic concepts through the online tutorial and training materials provided on the EPA BMDS website (<http://epa.gov/ncea/bmlds/training/index.html>).

Participants need to bring their own laptops to the workshop with BMDS 2.4 installed. The latest version of the software program can be found at: <http://epa.gov/ncea/bmlds/>. In order to use the BMDS Wizard templates, Microsoft Excel must be installed on the user’s laptops.

#### **Workshop 2: Cumulative Risk Assessment: Addressing Combined Environmental Stressors**

**Cost:** Pre-registration \$350/Onsite \$400

**Organizer:** Linda K. Teuschler, M.S., U.S. Environmental Protection Agency

**Instructors:** Linda K. Teuschler, M.S., U.S. Environmental Protection Agency; Amanda Evans, MSPH, Association of Schools of Public Health Research Fellow; Richard C. Hertzberg, PhD, Biomathematics Consulting; Margaret MacDonell, PhD, Argonne National Laboratory; Moiz Mumtaz, PhD, Agency for Toxic Substances and Disease Registry; Glenn E. Rice, ScD, U.S. Environmental Protection Agency; Jane Ellen Simmons, PhD. U.S. Environmental Protection Agency; J. Michael Wright, PhD. U.S. Environmental Protection Agency

**Description:** Cumulative risk assessment (CRA) addresses the impacts of multiple chemical and nonchemical stressors on real world individuals and communities, resulting in complex

exposures for individuals and populations with a variety of vulnerabilities, in applications that range from environmental justice and community sustainability to individual health promotion and protection. Nonchemical stressors include biological and physical agents (e.g., microbes and noise) as well as socioeconomic stressors and psychosocial conditions (e.g., associated with natural disasters). Public concerns that can initiate CRAs include (1) elevated environmental measurements or biomonitoring data; (2) multiple sources of pollutants or stressors; and (3) changes in disease rates or patterns (e.g., leukemia cluster) or ecological effects (e.g., loss of wildlife diversity). This workshop focuses on human health and begins with an overview of three CRA elements: analysis, characterization, and quantification (as feasible) of the combined risks from multiple stressors. Teaching methods include lectures and hands-on exercises. Presentations highlight basic concepts, methods, and resources for conducting a population-based CRA. A central theme is integrating exposure and dose-response information with population characteristics during planning and scoping based on initiating factors. Vulnerability factors are addressed, e.g., diet/nutritional status, behaviors, genetic traits, socioeconomic status, sensitivities, and psychosocial stress. Methods for estimating human health risks are discussed and applied, including epidemiologic approaches and assessing the joint toxicity of chemical mixtures. In the exercises, participants develop chemical, biological and physical stressor groups using exposure and toxicity factors, link them with population vulnerability factors and conduct a risk characterization. Participants are asked to bring a calculator.

### **Workshop 3S: Probabilistic Risk Analysis with Hardly Any Data**

**Cost:** Pre-registration \$275/Onsite \$325

**Organizers & Instructors:** Scott Ferson, Ph.D., Applied Biomathematics; Kevin Shoemaker, Ph.D., Stony Brook University

**Description:** This full-day tutorial introduces and compares methods for developing a probabilistic risk analysis when little or no empirical data are available to inform the risk model. The talks are organized around the basic problems that risk analysts face: not knowing the input distributions, not knowing their correlations, not being sure about the model itself, or even which variables should be considered. Possible strategies include traditional approximative methods and recent robust and bounding methods. Numerical examples are given that illustrate the use of various methods including traditional moment propagation, PERT, maximum entropy, uniformity principle, probability bounds analysis, confidence boxes, Bayesian model averaging, and sensitivity analysis. All of the approaches can be used to develop a fully probabilistic estimate useful for screening decisions and other planning. The advantages and drawbacks of the various approaches are examined. Essentially, the drawbacks are that bounding approaches may say too little about risks, and the rough and ready approximate methods may say too much. The discussion addresses how defensible decisions can be made even when little information is available, and when one should break down and collect some data and, in that case, what data to look for. The presentation style will be casual and interactive. Participants will receive a handout and CD of the illustrations used during the tutorial.

#### **Workshop 4: Introduction to Monte Carlo Simulation for Exposure Assessments with Freeware Excel Tools**

**Cost:** Pre-registration \$350/Onsite \$400

**Organizers & Instructors:** Tom Armstrong, CIH, PhD, TWA8HR Occupational Hygiene Consulting, LLC; Mike Jayjock, PhD, CIH, Jayjock Associates, LLC

**Description:** This workshop provides background and working experience with Monte Carlo Simulation (MCS) methods with a focus on exposure modeling assessments for consumer, general population and environmental applications. MCS methods generally 1) define calculation input probability distributions for a calculation algorithm, 2) generate random values of the inputs from selected probability distributions, 3) perform the modeling calculations using those random inputs and 4) aggregate and statistically evaluate the results. MCS methods have use in exposure assessment practice for estimating exposures, past, present or future from mathematical models. The results, as probability distributions, have utility in risk assessment by comparison to metrics of acceptable exposure.

The workshop will review basic MCS methods, and provide a synopsis of available software, both commercial and freeware options. Instructors will provide examples of the use of MCS methods in estimating exposures to toxic agents. Following the presentation of examples, participants will have increasingly detailed exercises designed for them to learn the use of the software, selection of input distributions, completion of the calculations, and interpretation of the calculation results. Prior to the course start, participants will be asked to provide examples for consideration for several selected to work through as in-class case studies. An understanding of the quantitative sensitivity analysis, as well as the difference of and need for additional uncertainty analyses will be developed. The critical relationship between variability and epistemic uncertainty as it relates to the inputs, results and final analysis will be covered in detail.

Participants will be expected to bring their own notebook PC with MS Excel and ability to enable macros, in order to keep notes on the handouts, and to run the software for the participant case studies.

#### **Workshop 5: Eliciting Judgments to Inform Decisionmaking**

**Cost:** Pre-registration \$300/Onsite \$350

**Organizers:** Aylin Sertkaya, Ph.D., Eastern Research Group, Inc.; Cristina McLaughlin, US Food and Drug Administration

**Instructors:** Aylin Sertkaya, Ph.D., Eastern Research Group, Inc.; Cristina McLaughlin, US Food and Drug Administration; Frank Hearl, M.S., PE, National Institute for Occupational Safety and Health (NIOSH); Michael Davis, Ph.D., Independent Consultant

**Description:** Decision makers must frequently rely on data or information that is incomplete or inadequate in one way or another. Judgment, often from experts and occasionally from non-experts, then plays a critical role in the interpretation and characterization of those data as well as in the completion of information gaps. But how experts or other stakeholders are selected and their judgments elicited matters – they can also strongly influence the opinions obtained and the analysis on which they rely. Several approaches to eliciting judgments have evolved. The workshop will cover topics ranging from recruitment, elicitation protocol design, different

elicitation techniques (e.g., individual elicitations, Delphi method, nominal group technique, etc.) to aggregation methods for combining opinions of multiple individuals. The role of judgment elicitation and its limitations, problems, and risks in policy analysis will also be addressed. The workshop will include presentation of two case studies that will include a discussion of the selection process; elicitation protocol development, elicitation technique utilized, and the various issues that arose before, during, and after the elicitation process and the manner in which they were resolved. The class will conclude with a hands-on exercise where participants will learn about calibration of experts using a mobile application.

### **Sunday Half Day Morning – 8 am-Noon**

#### **Workshop 6: Ensuring Occupational Safety Risk Assessment Quality**

**Cost:** Pre-registration \$250/Onsite \$300

**Organizer & Instructor:** Abel Pinto, Ph.D., Safe@Plant

**Description:** Industries are plagued by risky situations resulting in workplace accidents and injuries with significant economic costs. Occupational Safety Risk Assessment (OSRA) on workplace sites is the first and key step to reduce safety hazards (and, consequently, the number and severity of work accidents) in order to achieve inherent safety, particularly to support decision-making in safety programs.

The paramount importance of OSRA process creates the necessity to identify criteria for evaluating the results of such analysis, in terms of completeness and depth of assessment. This advanced coverage workshop will analyze and discuss, in depth, the causes of OSRA criticisms namely: inaccuracy (mainly in the probabilities); incompleteness; difficulty of checking final results; inadequate criteria for evaluating the results; and complexity and laboriousness of the methods. This workshop will present criteria to evaluate the OSRA process, in terms of completeness and adequacy of results, through a systematic analysis of the overall process and will give guidance to determine analysis objectives and define the boundaries, estimate the need of resources, select reliability data, select the hazards identification and risks evaluation methods and document the results (in a traceable way).

Attendants will be invited to debate problems that arise during the OSRA process using their own experiences. Attendants should bring their laptops.

### **Sunday Half Day Afternoon – 1 pm-5 pm**

#### **Workshop 9: Risk Ranking using FDA-iRISK: A Comparative Risk Assessment Tool**

**Cost:** Pre-registration \$200/Onsite \$250

**Organizer:** Yuhuan Chen, Ph.D., FDA Center for Food Safety and Applied Nutrition (FDA CFSAN)

**Instructors:** Yuhuan Chen, Ph.D., FDA Center for Food Safety and Applied Nutrition (FDA CFSAN); Greg Paoli, MSc, Risk Sciences International; Régis Pouillot, DVM, Ph.D., FDA Center for Food Safety and Applied Nutrition (FDA CFSAN); Sherri Dennis, Ph.D., FDA Center for Food Safety and Applied Nutrition (FDA CFSAN)

**Description:** Stakeholders in the system of food safety, in particular government agencies, need evidence-based, transparent and rigorous approaches to estimate and compare the risk of foodborne illness from microbial and chemical hazards as well as the public health impact of

interventions. FDA-iRISK, a new Web-based, comparative risk assessment tool, has become available for public use since October 2012. The peer-reviewed tool has many built-in functions and features that allow users to conduct fully probabilistic risk assessments relatively rapidly and efficiently. It enables users (including but are not limited to risk assessors) to build, view and share scenarios that reflect their real-world or theoretical food-safety issues. Users may then compare risks and assess the impact of interventions, for example, or vary the data they enter to explore how changes in various practices in the food chain would affect public-health outcomes. Risk managers and other stakeholders can use the estimates of public health impact to inform food safety policy and management decisions.

The purpose of this workshop is to enable attendees to better understand what FDA-iRISK is and how it works, as well as providing attendees a hands-on opportunity to develop risk scenarios using the tool (available for free at <http://irisk.foodrisk.org/>). To illustrate the capacity of FDA-iRISK, collaborators will present case studies to demonstrate its potential application as a web-based database and a quantitative risk assessment tool to store evidence in a consistent, structured and systematic fashion, and then assess and compare the health impact of microbial and chemical hazards in foods.

Workshop participants are asked to bring a laptop or a tablet for the hands-on exercise. Internet connection required to access FDA-iRISK will be provided at the workshop (no other software is needed).

### **Workshop 10: Stakeholder's Involvement through Scientific Reasoning: Communicating Risk without Risk Communication**

**Cost:** Pre-registration \$275/Onsite \$325

**Organizers & Instructors:** José Palma-Oliveira, Ph.D., University of Lisbon; Igor Linkov, Ph.D., US Army Engineer R&D Center

**Description:** The way risk communication is usually conceptualized and implemented has stakeholder persuasion as a primary objective, either explicitly or implicitly. The focus is on the "proper" way of communicating risk information given the quality of the scientific evidence of risk even though multiple ways of framing the information based on the psychometric, cultural or even mental models approaches, traditional approach to risk communication has failed in many cases resulting in significant stakeholder unease and stress. Stakeholders can be profoundly distrustful in relation to the conclusions of science and technological "computations", however they are sensitive to scientific reasoning, particularly when integrated in formal hypothesis generation and testing, data collection and decision modeling. These issues will be discussed in the workshop.

This workshop will focus on alternative approaches of bringing stakeholders on board in projects where risk is a significant driver for decision. This was proven to be successful in sorting environmental conflicts. Tools of decision analysis and risk communications will be presented and discussed in the context of siting problems in Portugal and Tunisia where the communities strongly show their opposition (even with riots with military forces involved) and environmental management decisions in the US. These cases will show how they were able to overcome the opposition and radically diminish or eliminate the psychosocial stress.

Presentations and discussions will be done at basic level appealing to a broad audience with diverse background.

**Workshop 11: Fundamental Concepts of Risk Assessment, Risk Perception and Risk Communication**

**Cost:** Pre-registration \$300/Onsite \$350

**Organizer:** Branden B. Johnson

**Instructors:** Branden B. Johnson, Decision Research, Inc.; Darrell W. Donahue, Maine Maritime Academy

**Description:** Meetings and publications of the Society for Risk Analysis can be daunting to newcomers. More generally, risk analysis incorporates and spans many disciplines. It is often difficult for people, even those who work on some topic within risk analysis—be it toxicology, terrorist threat assessment or human behavior—to understand how their work fits into the risk analysis “big picture.” Likewise, disciplinary training does not prepare people to understand, much less converse with, fellow practitioners. This workshop, taught by two experts with extensive histories in practice, government and academia, is designed to fill that gap. We introduce fundamental risk analysis concepts and terminology, including elements of risk management, risk assessment, and risk perception and communication. Exercises (microbial risk focused) will be used to allow the participants to apply these basic concepts of risk analysis. Upon completion of this course, students will understand the fundamental concepts of risk analysis. The workshop is suitable for first time Society for Risk Analysis Annual Meeting attendees, as well as all individuals new to risk analysis and those who have been involved in only a limited aspect of risk analysis. They will be prepared to engage comfortably in the range of conversations that distinguish Society for Risk Analysis Annual Conferences.

**Workshop 12: Methods and Case Studies to Integrate Lifecycle Assessment (LCA) and Risk Analysis**

**Cost:** Pre-registration \$275/Onsite \$325

**Organizer:** Elisabeth Gilmore, Ph.D., School of Public Policy, University of Maryland

**Instructors:** Joule Bergerson, Ph.D., Institute for Sustainable Energy, Environment and Economy, University of Calgary; Elisabeth Gilmore, Ph.D., School of Public Policy, University of Maryland; Paulina Jaramillo, Ph.D., Engineering and Public Policy, Carnegie Mellon University; Ketra Schmitt, Ph.D., Centre for Engineering in Society, Concordia University; Eric Williams, Ph.D. Golisano Institute for Sustainability, Rochester Institute of Technology

**Description:** This workshop aims to provide an introduction or refresher on lifecycle assessment (LCA) with hands-on activities and examples for how to integrate LCA into risk and decision analysis tools. LCA is a fundamental technique for evaluating the environmental effects associated with all stages of a process, product or technology from the extraction of raw materials to disposal, known as a “cradle-to-grave” perspective. As a result, LCAs can extend

the scope of characterizing risks for products and processes. In the first part of the workshop, we provide an overview of theory and tools for LCA. Second, we run a hands-on activity with the participants to conduct simple LCAs with process and economic input output methods and learn about the associated tools and databases. We look at coal with carbon capture and storage and personal computers. Third, we will compare the results from a series of recent case studies on shale gas to examine different approaches, data, and uncertainty. We conclude with a discussion of how LCA can be integrated into benefit-cost and risk analysis, including an example of carbon capture and storage. After this workshop, participants should be able to conceptualize and conduct a simple LCA using existing tools, evaluate and critique the results of LCAs, and apply LCAs for decision and economic analysis. Participants need to bring a laptop.

## **Thursday Workshops**

### **Thursday Full Day 8:30 am-5:30 pm**

#### **Workshop 1T: Benchmark Dose Modeling – Advanced Topics**

**Registration:** Pre-registration \$275/Onsite \$325

**Organizer:** J. Allen Davis, MSPH, U.S. Environmental Protection Agency

**Instructors:** J. Allen Davis, MSPH, U.S. Environmental Protection Agency; Jeff Gift, U.S. Environmental Protection Agency; Jay Zhao, Ph.D., U.S. Environmental Protection Agency

**Description:** The objectives of this full-day workshop are to provide participants with training on how to use the U.S. Environmental Protection Agency's (EPA) Benchmark Dose Modeling Software (BMDS) and related software programs to facilitate advanced BMD analyses. Advanced dose-response models can be used when incorporating the following specialized data types into human health risk assessments:

- Data on multiple independent tumors in a single bioassay (the MS\_Combo model)
- Cancer data where survival rates differ due to exposure (the Multistage Weibull Time-to-Tumor [MSW] model)
- Repeated response data common to many neurotoxicity test guidelines (the Toxicodiffusion model)
- Concentration  $\times$  time data (the ten Berge model)
- Categorical data on multiple endpoints from multiple bioassays and multiple species (the Categorical Regression [CatReg] model)

Specifically, EPA instructors will present: the theory behind each of the above advanced models, a demonstration of the various software packages used to run these models, and individual class modeling exercises.

Participants are expected to have a firm understanding of basic benchmark dose methods, either through work-related experience, or completion of at least the introductory portion of online training courses (<http://epa.gov/ncea/bmds/training/index.html>).

Participants need to bring their own laptops to the workshop with BMDS 2.4, the Multistage Weibull executable, and the R statistical package (version 2.15.0 or greater) installed (with

necessary administrative rights). The latest version of the software programs can be found at: <http://epa.gov/ncea/bmds/>, [epa.gov/ncea/catreg](http://epa.gov/ncea/catreg), and <http://www.r-project.org/>. Specific installation instructions for the software programs can be found on the websites or in documentation that can be downloaded from the websites.

### **Workshop 3T: Probabilistic Risk Analysis with Hardly Any Data**

**Cost:** Pre-registration \$275/Onsite \$325

**Organizers & Instructors:** Scott Ferson, Ph.D., Applied Biomathematics; Kevin Shoemaker, Ph.D., Stony Brook University

**Description:** This full-day tutorial introduces and compares methods for developing a probabilistic risk analysis when little or no empirical data are available to inform the risk model. The talks are organized around the basic problems that risk analysts face: not knowing the input distributions, not knowing their correlations, not being sure about the model itself, or even which variables should be considered. Possible strategies include traditional approximative methods and recent robust and bounding methods. Numerical examples are given that illustrate the use of various methods including traditional moment propagation, PERT, maximum entropy, uniformity principle, probability bounds analysis, confidence boxes, Bayesian model averaging, and sensitivity analysis. All of the approaches can be used to develop a fully probabilistic estimate useful for screening decisions and other planning. The advantages and drawbacks of the various approaches are examined. Essentially, the drawbacks are that bounding approaches may say too little about risks, and the rough and ready approximate methods may say too much. The discussion addresses how defensible decisions can be made even when little information is available, and when one should break down and collect some data and, in that case, what data to look for. The presentation style will be casual and interactive. Participants will receive a handout and CD of the illustrations used during the tutorial.

### **Thursday Half Day Morning – 8 am-Noon**

#### **Workshop 13: Advanced Workshop on Nanoscale Materials – What Can We Learn from Big Data Sets?**

**Cost:** Pre-registration \$300/Onsite \$350

**Organizers & Instructors:** Jo Anne Shatkin, Vireo Advisors; Christine O. Hendren, Ph.D., Duke University, Center for the Environmental Implications of NanoTechnology (CEINT)

**Description:** The field of emerging nanoscale risk assessment is by nature one in which data, methods and policies are developing in parallel to address unique aspects of nanotechnology and nanomaterials that may require novel approaches to risk analysis. Therefore, to enable intelligent prioritization of research investments, assessment of risks, and ultimately decision-making for manufactured nanomaterials, iterative feedback is needed between researchers, risk assessors, decision makers, and those affected by decisions. This workshop will provide an immersive experience where participants can experience and contribute to this feedback process at the leading edge of the field of nano risk assessment.

This workshop is part of an investigation into the use of alternative testing strategies (ATS) in risk analysis for nanoscale materials. We will convene a diverse group of international experts



to discuss how existing and novel *in vitro* assays may be applied in a “multiple models” approach to inform the risk assessment of novel nanoscale materials in assessing hazard, potency and exposure potential. This effort builds on a number of recent expert meetings regarding the development and use of high throughput screening (HTS) by examining the availability and applicability of existing and novel ATS methods for a multiple models approach to toxicity, environmental and exposure analysis of emerging nanoscale materials (ENM) in the risk analysis paradigm.

Through a collaboration with the OECD Working Party on Nanomaterials, SRA is evaluating the potential for a multiple models approach involving alternative testing strategies (ATS) for nanomaterial risk assessment. Examples of these strategies will be discussed, and findings from a preliminary analysis of data sets using ATS will inform a lively discussion how these methods may be used to inform risk assessment for nanomaterials in a multiple models approach. Speakers from U.S. and Canadian governmental agencies will frame this issues. Workshop participants will learn about the current and emerging testing strategies for nanomaterials, and how they can be used to inform a weight of evidence approach, incorporating them in risk assessment.

The main objectives of the workshop are to provide an interactive learning experience where participants work to collectively: 1) understand continuing critical gaps in understanding of the health and environmental risks posed by the use of ENM, and propose methods for filling the gaps, and 2) organize these gaps in terms of the decisions the information would ultimately support.

### **Thursday Half Day Afternoon – 1 pm-5 pm**

#### **Workshop 14: Identifying and Testing Assumptions: Key to More Accurate, More Efficient Risk Assessments for Clients**

**Cost:** Pre-registration \$250/Onsite \$300

**Organizer & Instructor:** Jay Grusin, Ph.D., The Analytic Edge (LLC), [analytictradecraft.com](http://analytictradecraft.com)

**Description:** Assumptions underpin the inferences we make about the future from what is known and so (consciously or not) they drive every risk assessment from beginning to end. They need to be identified and tested as part of the analytic process that takes place *before* the bottom line assessment is integrated into the lead sentences, but it is often not done or done poorly. Unstated and unexamined, assumptions are unexploded mines waiting to sink our best assessments of the probability, scope, and intensity of risk and potential mitigation strategies. Drawing on decades of experience as an analyst and instructor, retired senior CIA officer Dr. Jay Grusin introduces participants to a straight forward process intelligence analysts use up front to identify and test the assumptions that drive their work.

Using this approach forecasts can be more accurate, persuasive, and transparent. Users can more easily focus on the highest priority threats and vulnerabilities, make informed decisions, and evaluate mitigation strategies. Such clarity also builds the trust required to forge relationships with clients.

Because the workshop teaches an overall approach to the analytic process it can be applied immediately across multiple dimensions of risk analysis, areas or expertise, using qualitative or

quantitative data. The process can be used individually or to drive collaboration. It can also provide quality assurance for inputs into quantitative assessments, including modeling.

The workshop is intensely hands-on. Participants will practice with examples with the goal of understanding how to apply the approach to their own work.