



ITRC PROJECT PROPOSAL

Risk Assessment Guidance and Training: State-of-the-Art Principles and Practice

Please use brief statements or bullet items to input the requested information

PROPOSAL DATE: March 23, 2011

Proposal Contact:

Proposed State ITRC Team Leaders:

Team Lead 1
To be determined

Team Lead 2
To be determined

Federal Contact:

Reeder L. Sams II, PhD
ORD/NCEA/ USEPA (B-243-01)
Research Triangle Park, NC 27711
Telephone: 919-541-0661 FAX: 919-541-2784
Email: Sams.Reeder@epa.gov

Call for Proposals Topical Area

RISK Risk assessment: *General or specific approaches of risk assessment and management for specific contaminants, media (soil, groundwater, etc.), and receptor categories (e.g. children, ecological receptors). Proposals are sought that seek to align state and federal risk assessment approaches.*

Problem Statement (why is this project necessary and relevant to ITRC's purpose & mission¹?)

Risk assessment is an ever-evolving process that significantly impacts human health, economics, ecological health, and social decision-making. A critical need and problem that faces risk assessment professionals throughout the US is having sufficient, up-to-date information and training on state-of-the-art principles and practices focusing on human health. Additionally, during times of scarce resources and the continuously evolving knowledge in risk assessment, staffs of state environmental agencies need comprehensive guidance on how to understand and conduct risk assessments, which, in turn, enables effective and efficient implementation of their duties to safeguard environmental and public health.

One of the primary avenues by which the Interstate Technology Regulatory Council (ITRC) accomplishes its mission is to develop technical regulatory guidance documents and training courses for sound, innovative solutions to environmental challenges. This is in line with the annual summary of state priority issues that ITRC has prepared for the past three years listing "risk" as a top priority and training in the area of risk as essential for continued environmental and public health protection. Because continued learning is so important, this proposal focuses on the development of a comprehensive risk assessment guidance and training course focused on the needs of ITRC's stakeholders.

¹ **ITRC Purpose:** To advance innovative environmental decision making
ITRC Mission: Develop information resources and help break down barriers to the acceptance and use of technically sound innovative solutions to environmental challenges through an active network of diverse professionals.

In the past, IRTC has developed useful, and focused guidance documents and training courses for risk assessment and risk management (Determination and Application of Risk-Based Values- guidance documents and corresponding training can be found at <http://www.itrcweb.org/Training#topic-24>); but there is a need for continuing efforts to provide comprehensive guidance and training that draws upon the newest approaches. **The scope of a comprehensive risk assessment guidance and training course would include modules in the four primary areas of hazard identification, dose-response assessment, exposure assessment, and risk characterization with a greater focus on the last two areas that have provide the most utility for state agencies.** An additional area of focus for guidance and training as resources allow, could include risk communication. Risk communication is often a critical component leading to public acceptance of the risk assessment calculation and risk management approaches taken by the government, either at the federal, state, or local level.

The key factor in this training will be the collaboration between the IRTC's members and federal agencies to develop a comprehensive risk assessment guidance document and training course specific for state and local governments, industry partners, and consultants because it demonstrates the optimal use of available resources. This collaboration would capitalize on EPA's risk assessment expertise and existing training materials to enable a path forward, aligning state and federal risk assessment approaches.

EPA is a global leader in conducting state-of-the-science health risk assessments and its assessments are often the first to apply new Agency risk assessment guidelines, scientific methods and data. The current state-of-the art risk assessments rely on peer-reviewed epidemiological and laboratory animal studies to identify hazards associated with exposure to environmental contaminants and to perform quantitative dose-response analysis. The risk assessment professionals who are the representatives from state risk assessment organizations and who will be part of the collaborative effort will bring first-hand experience such as the issue-based scenarios that they deal with on a daily basis. Incorporating issue-based scenarios will capitalize on the years of experience from risk assessors at the state and federal level and will be a huge boost to the training of new and junior staff without drawing down resources from participating organizations. The resulting ITRC products will enable senior staff to use the resources they have more effectively and to assign the most knowledgeable risk assessors to the actual job of risk assessment rather than teaching.

Outreach and communication to states, industry partners, consultants and the public about state-of-the-art risk assessment practices as used and implemented today by the states and the federal government is critical. A comprehensive risk assessment guidance document and training course is the optimum vehicle to inform and educate these stakeholders. This proposal is timely and relevant to ITRC's purpose of advancing innovative environmental decision making; and, it relevant to ITRC's mission of continuing to develop new information resources and to break down barriers to the acceptance and use of technically sound innovative solutions to environmental challenges.

Proposed Scope to Address Problem (what is the approach for this project?) Please note that technology research and demonstration project proposals are not valid for this RFP.

The EPA's National Center for Environmental Assessment (NCEA) will sponsor the ITRC team to develop materials and provide training to State risk assessors. This risk assessment training program should contain the current, state-of-the-art risk assessment practices as supported by

many ECOS resolutions (e.g. resolution number 01-8 Aug. 28, 2001 and revised Aug. 30, 2010 and resolution number 04-6, Oct. 4, 2004 and revised Aug. 29, 2010).

To date, the EPA is developing approximately 11 days of course material for comprehensive risk assessment and risk communication course specific for EPA Regions and Program Offices as the primary audience. The majority of these courses are complete, while some are in development (ARA 501-505) and will be completed within the calendar year. These materials would be made available to the ITRC team and represent a starting point for the development of guidance documents and courses specific for states, industry partners, consultants, and the general public. Courses that have been developed by the EPA include presentation materials, instructor notes, and a detailed reading packets. A brief outline of these course materials is as follows:

EPA Region and Program Office Risk Assessment Courses

Basics of Risk Assessment (BRA)

BRA101: Introduction: Risk Assessment and EPA's Office of Research and Development

BRA102: Laws and Regulatory Foundations for Risk Assessment

BRA103: Development and Overview of Current Regulatory and Advisory Values

Basics of Human Health Risk Assessment (HBA)

HBA201: Overview of Human Health Risk Assessment

HBA202: Overview of Human Health Toxicity Values

HBA203R: Overview of the Development of IRIS Toxicity Assessments

Science Behind Human Health Hazard Assessment (HSR)

HSR301: Animal Toxicology: Study Designs and Selected Organ Toxicity

HSR302: Epidemiology and Human Studies

HSR303: Incorporation of Mode of Action into Risk Assessment

HSR304: Uncertainty and Variability

HSR305: Quantitative Methods and Models: Dosimetry Adjustments and PBPK Concepts (3hr)

HSR306: Quantitative Methods and Models: Benchmark Dose Approach

HSR309: Case study—Development of a human health risk assessment

Exposure Assessment (EXA)

EXA401: General Concepts in Exposure Assessment

EXA402: Approaches for Quantifying Exposure

EXA403: Developing Exposure Scenarios

EXA404: Monitoring and Modeling Strategies

EXA405: Fate and Transport

EXA406: Obtaining and Using Exposure Factor Data

EXA407: Calculating Doses and Assessing Uncertainty and Variability

EXA409 Case study—Lead Contamination and Local Exposure

Exposure Assessment (EXA) continued

EXA408: Interpreting Biomonitoring Data and the Use of Simple Pharmacokinetic Models to Characterize Dose

EXA410: Case study—The Columbus Municipal Solid Waste Incinerator

Advanced Risk Assessment Approaches (ARA)

ARA501: Chemical Mixtures

ARA502: Aggregate and Cumulative Risk

ARA503: Exposure Models

ARA504: Risk Characterization

ARA505: Risk Communication

Targeted Users (who will use products generated by this project?)

State risk assessors, local government and academic members who use risk based values and conduct risk assessments.

Summary of Deliverables (primary project product(s))

This proposal includes the following deliverables:

- Technical regulatory guidance document (and an overview document as deemed necessary by the team). The team will consider developing a web-based document due to the large amount of material needed to understand and perform risk assessment
- At least one internet based training module
- An in-person classroom-based course depending on the need for a longer training session

Impact (how will this project result in more effective environmental decision making?)

Training on current state-of-the-art risk assessment practices as used and implemented by the States will result in more informative state and local decision makers. Also, this interaction will help to incorporate new state-of-the-science methods as they become available, and maintain high quality risk assessments for use in cleanups or other state regulatory needs. Overall this will improve the performance, quality, and transparency of the States' risk assessment programs.

Project Schedule

- 1) January 2012: ITRC Team initiation and membership development
- 2.) January 2012 – December 2012: Membership development, work scope development, outline of guidance document, division of work among team members, and development of overview document, if necessary.
- 3) January 2013 – December 2013: Development and completion of document(s)
- 4) January 2014 – December 2014: Development and completion of internet based training course(s), development of implementation plan, resource-dependent consideration of developing a classroom based course
- 5) Calendar year 2015, 2016: Conduct training, implement solutions, gain state concurrence, and possibly develop classroom training

Proposed Personnel

ITRC Team Leads

To be determined

Potential Team Membership

- States with established environmental programs with expertise in risk assessment
- Federal agencies with expertise in risk assessment both human health and ecological risk assessment (e.g., Center for Disease Control and Prevention, Department of Defense,

Environmental Protection Agency, Department of Health and Human Services, etc.).
EPA can provide team members from the several regional and program offices

Potential Team Membership/Needs

- Skill mix of Team Members required in the following areas: general risk assessment, toxicology, site assessment exposure assessment, statistics, training, education, risk communication

Proposed In-Kind/Direct Project Funding

EPA funding at the full resource amount for 3 years (2012-2015)

Related Work:

Training Course: Determination and Application of Risk-Based values (http://www.clu-in.org/conf/itrc/risk_040810/)

Corresponding Guidance Documents

(<http://www.itrcweb.org/Guidance/DocumentList?teamID=44>)

RISK 1: Examination of Risk-Based Screening Values and Approaches of Selected States (December 2005)

RISK 2: Use of Risk Assessment in Management of Contaminated Sites States (August 2008)

Training Course: Remediation of Risk Management Documents (<http://clu.in.org/live/archive/>)

Corresponding Guidance Documents

RRM-1: Project Risk Management for Site Remediation (March 2011)