ALLIANCE FOR RISK ASSESSMENT

Working Together to Protect Public Health

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Dear Colleagues

We had a successful webinar last week with over 400 folks registered from around the world. Obviously, quite a bit of interest exists in developing "**Practical Guidance for Contaminated Sites**" and our use of "**Trichloroethylene (TCE) Risk Assessment and Management**" as a case study was also of intense interest. We envision 5 follow on tasks, but will not be able to do any of these without funding. Please consider funding this further effort in whatever way is best for your organization. All contributions are tax deductible and can be made as either a contract, gift letter, or credit card donation at a secure website https://www.givedirect.org/give/givefrm.asp?CID=4930.

The attached one page synopsis gives the 5 follow on tasks, but in brief they are:

- Two-day workshop to determine the exposure duration, frequency, and action levels for risk of developmental effects of TCE;
- One-day workshop to peer review methods document for noncancer hazard range;
- Develop methods text for sampling options for developmental and other effects from short-term exposure;
- Develop closure options based on above items; and
- Conduct briefings of state and federal agencies, local communities and others that will include relevant risk communication issues.

This additional effort will make use of currently available science and regulatory science policy, and guidance based on this effort will be fully supportable. In addition, this continued effort will further educate folks on the unique aspects of TCE cancer/non-cancer risk that in the past were always available, but not commonly needed, nor applied. Perhaps more importantly, continued work is expected to be both practical, in that any inexperienced risk manager or investigator can directly apply it to investigation or management decisions, and withstand legal challenge.

On behalf of,

David Gillay
Barnes & Thornburg LLP

Rod Thompson
Alliance for Site Closures

Calvin Willhite
Retired, CalEPA

Sincerely,

Ed Pfau
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TERA

Alliance for Risk Assessment (*ARA*)

(http://www.allianceforrisk.org)

Proposal: Peer Reviewed TCE Practical Guidance for Cancer/Non-Cancer and Developmental Risk, Sampling, Exposure Assessment and Data Interpretation.

A. Guidance will target current science and science policy needs for noncancer hazard ranges at waste sites, similar to cancer hazard ranges, using trichloroethylene (TCE) as a case study; work will explore fetal heart malformations; *in utero*, chronic, subchronic and acute exposure assessment; and risk management issues. These needs, assessments, and issues were defined at the Nov 4, Alliance for Risk Assessment (*ARA*) webinar and in the "Guidance for Contaminated Sites: Trichloroethylene (TCE) Risk Assessment Case Study" available at: http://www.allianceforrisk.org/Projects/TCE.html

B. Guidance will be developed by a panel of leading experts in each topical area below. Guidance will be written for the risk manager or investigator with limited expertise in risk assessment, toxicology or vapor intrusion.

C. Guidance will be peer-reviewed by a broadly selected expert science body with solicitation of comments from the public, USEPA, ATSDR and other national/international health and environmental agencies.

Guidance Topical Areas and Cost:

1. Fetal Heart Malformations and other Developmental Risk: Acceptable exposure concentrations, exposure duration risks, application guidelines; how to incorporate weight of evidence, and margin of safety analysis into risk management decisions. Two-day workshop with developmental toxicity experts to explore these issues in general and the specific effects of TCE (expected cost $125,000). For examples of similar workshops see: http://www.tera.org/Peer/MeetingReports/index.html.
2. Cancer/Non-Cancer Risk Range: (a) Understanding cancer/noncancer risk range interactions and decisions, non-cancer order of magnitude uncertainty; (b) how to apply the cancer/non-cancer risk range, acceptable exposure concentrations; and (c) how to understand risks above the RfC. One-day peer review of existing methods document at the Alliance for Risk Assessment (*ARA*) "Beyond Science and Decisions: From Problem Formulation to Dose Response project (expected cost $60,000). See: http://www.allianceforrisk.org/ARA_Dose-Response.htm.
3. Exposure Assessment: Develop sampling options for chronic, subchronic and acute exposures; exposure time, frequency, and duration recommendations and data analysis guidelines (expected cost $40,000).
4. Risk Communication: Conduct 20 briefings of state and federal agencies, local communities and others as needed; Resident/Occupant handouts clarifying toxic effects, screening levels, closure levels, risk of exposure, and indoor air background concerns (expected cost $20,000 to 60,000 depending on whether briefings are face-to-face).

ARA Building a Risk Assessment Community

5. Risk Compliant Closure Options: Develop closure options based on understanding long-term risk of vapor intrusion, how to understand data results relative to risk, and how to reduce or eliminate risks (expected cost $40,000).