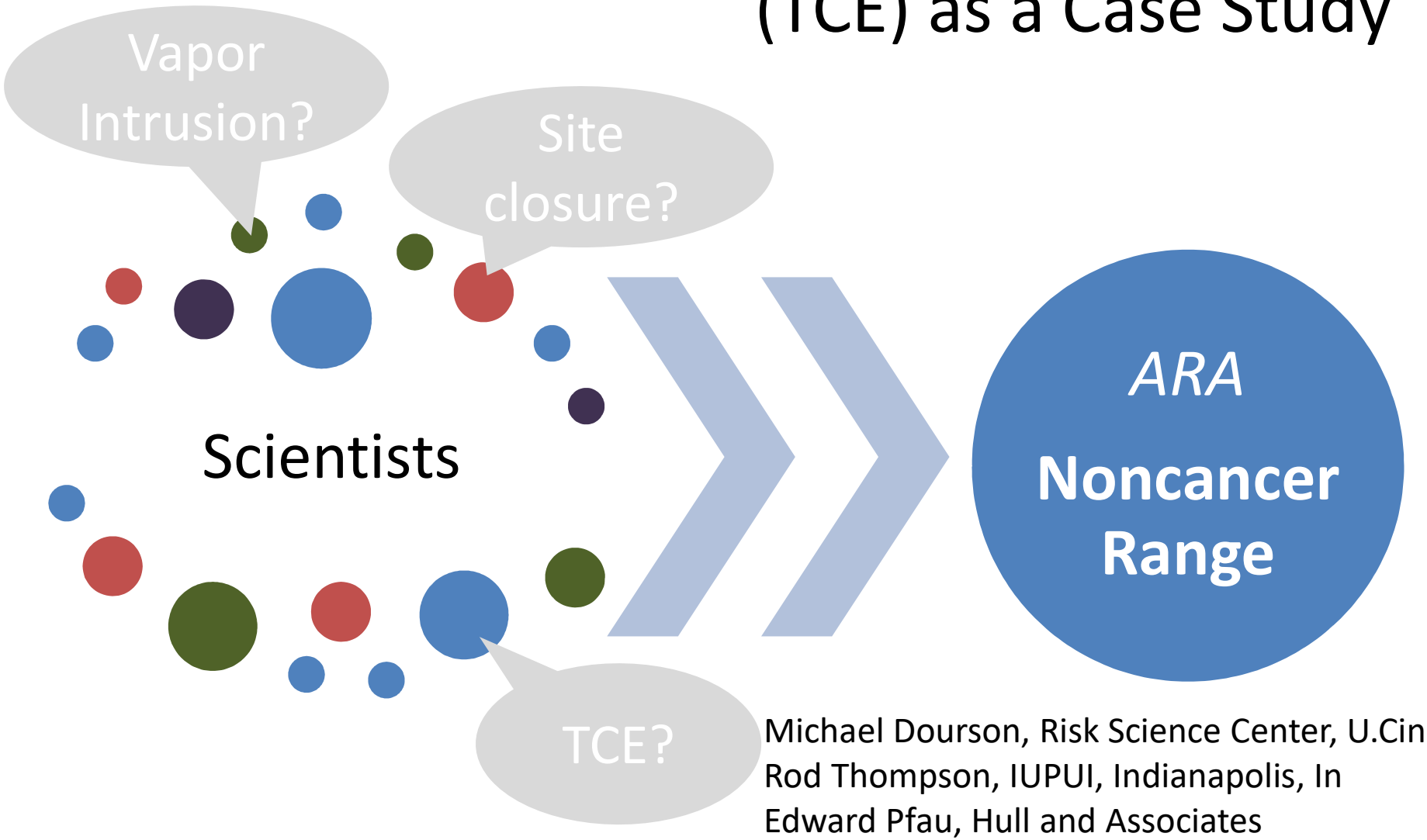
Managing the Non-Cancer Risks at Hazardous Waste Sites: Trichloroethylene (TCE) as a Case Study



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Abstract

- The 2011 EPA reference concentration (RfC) TCE presents risk managers evaluating vapor intrusion with two challenges:
  - Discerning TCE concentrations that are attributable to subsurface contamination, and
  - Selecting remedial objectives that result in acceptable indoor TCE levels.
- RfCs exhibit several precautionary adjustments, but do not show a range as for cancer (i.e., 10^{-4} to 10^{-6}). Thus, risk managers do not often consider an RfC range when deciding.
- A method for determining the safety range for noncancer hazard is presented:
  - Comparable to the cancer risk range
  - Consistent with the uncertainty inherent in EPA's RfC calculation.
  - TCE Safety range was judged to be 3 to 30 ($\mu g/m^3$).

State's Relocation or Immediate Response Action Levels

Problem Formulation: So which "safe" levels are correct?

State	Urgent/Immediate Action Residential	Urgent/Immediate Action Commercial	Imminent Action Residential	Imminent Action Commercial
Alaska	2	8.4		
California	6	(24)		
Connecticut	5	8		
Indiana	20			
Massachusetts	6	24	20	60
New Hampshire	2	8.8		
New Jersey	4	18		
New York	20			
Ohio	6.3	26	20	60
Region 09	6	24		
Region 10	2	8		
Region 7	2	8		

State's Very Rapid Response Action Levels

All of these are in the safe range for the appropriate group!

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Massachusetts	6	24	20	60
New Hampshire	2	8.8		
New Jersey	4	18		
New York	20			
Ohio	6.3	26	20	60
Region 09	6	24		
Region 10	2	8		
Region 7	2	8		

Problem Response: Alliance for Risk Assessment (*ARA*)

- *ARA* Steering Committee accepts proposal Summer 2012
  - United States Army Corps of Engineers, Oregon Department of Environmental Quality, Indiana Department of Environmental Management, U.S. Environmental Protection Agency (EPA), University of Cincinnati, College of Medicine, Texas Commission on Environmental Quality, Agency for Toxic Substance & Disease Registry, Neptune & Company, Inc.
- TCE Workgroup formed in the Fall of 2012
  - Open invitation, broad interest and participation
  - Trichloroethylene (TCE) Risk Assessment Guidance for Contaminated Sites (April 2013)
  - Webcast: Practical Guidance for Contaminated Sites: TCE Risk Assessment Case Study (November 4, 2013); over 300 scientists from multiple international organizations, including government, industry, academia and NGOs, on 6 conference calls and one webinar.
  - Alliance for Risk Assessment (*ARA*) review Summer of 2015
  - Publication in the Spring of 2016

Purpose: Guidance for Noncancer Range at Contaminated Sites

- Develop a range in noncancer risks, similar to the range used for cancer risks in management of waste sites, using readily available information from U.S. EPA and elsewhere.
- Create range to enable evaluation of uncertainty in the noncancer benchmark.
- Demonstrate confidence in this range so that the range can be considered in the determination of management choices.

NAS (2014) & IRIS Process

- **Finding:** EPA could improve documentation and presentation of dose-response information.

- **Recommendation:** EPA should clearly present two dose-response estimates: **a central estimate (such as a maximum likelihood estimate or a posterior mean) and a lower-bound estimate for a POD from which a toxicity value is derived.** The lower bound becomes an upper bound for a cancer slope factor but remains a lower bound for a reference value.

NAS (2014) & IRIS Process

- **Finding**: IRIS-specific guidelines for consistent, coherent, and transparent assessment and communication of uncertainty remain incompletely developed. The inconsistent treatment of uncertainties remains a source of confusion and causes difficulty in characterizing and communicating uncertainty.

- **Recommendation**: Uncertainty analysis should be conducted systematically and coherently in IRIS assessments. To that end, EPA should develop IRIS-specific guidelines to frame uncertainty analysis and uncertainty communication. Moreover, uncertainty analysis should become an integral component of the IRIS process.

Developing the Range

An RfC is an estimate (**with uncertainty spanning perhaps an order of magnitude**) of a daily oral (for RfD) or continuous inhalation (for RfC) exposure to the human population (**including sensitive subgroups**) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

- Arsenic RfD on IRIS.
  - There was not a clear consensus among Agency scientists on the oral **RfD of 0.3 ug/kg-day**. Applying the Agency's RfD methodology, strong scientific arguments can be made for various values within a factor of 2 or 3 of the currently recommended **RfD value, i.e., 0.1 to 0.8 ug/kg-day**. It should be noted, however, that the RfD methodology, by definition, yields a number with inherent uncertainty spanning perhaps an order of magnitude.

Developing the Range (con't)

- In the IRIS Summary for TCE, U.S. EPA identified three candidate RfC values from principal and supporting studies for the noncancer inhalation toxicity of TCE. These are:
  - Candidate RfC of 2 μg/m^3 based on decreased thymus weight in female mice (Keil *et al.*, 2009);
  - Candidate RfC of 2 μg/m^3 based on fetal heart malformations in rats (Johnson *et al.*, 2003); and
  - Candidate RfC of 3 μg/m^3, based on toxic nephropathy in female rats (NTP, 1988).
- Each of these candidate RfCs may be evaluated with respect to the imprecision and the uncertainty inherent in its derivation.

Imprecision Versus Uncertainty

- **Imprecision** of a RfC is on both sides of the RfC. This is because a 2nd expert group might estimate a RfC higher or lower than the 1st group, if given the same information.
- **Uncertainty** in a RfC, in contrast, lies mainly above the RfC. This is because RfCs are based on lower bounds on points of departure & uncertainty factors are known to be protective.
- For risk management decisions, uncertainty in the RfC is generally more important than imprecision. Managers are interested in making decisions that protect public health and uncertainties in a RfC are generally more informative.

Different Uncertainty Ranges for TCE RfCs

Table 7. Uncertainty ranges for different TCE RfCs in μg/m^3. Shaded areas indicate best **overall uncertainty range** for risk management.

Study	IRIS UF [a]	Steep [b] Slope	Confidence		Uncertainty Ranges		
			Critical [c] Effect	Point of [d] Departure	Floor	Intermediate	Ceiling
Johnson et al (2003)	10	Lower	Low	Low	2	10	20
NTP (1988)	10	Higher	Medium	Medium to Low	3	9	30
Keil et al. 2009	100	NA	Medium	Medium to Low	2	20	190

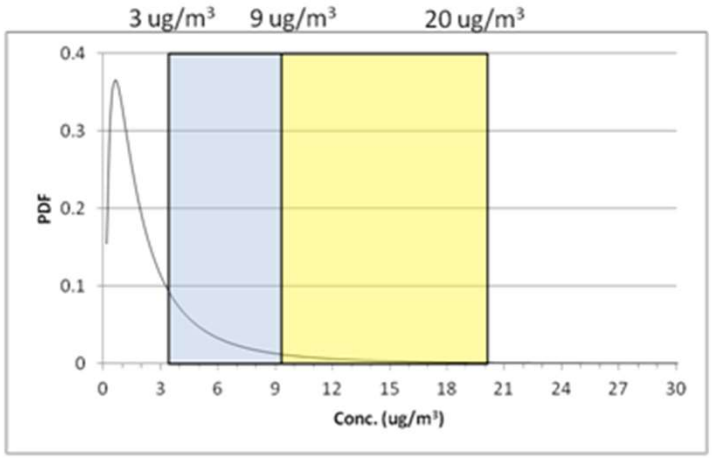

Figure 3a. Exposure distribution of indoor air concentrations primarily below the 3 µg/m^3 to 20 ug/m^3 hazard range. Relatively small proportion of exposures is higher than 3 µg/m^3. Nominal actions or no further action may be warranted for risk management.

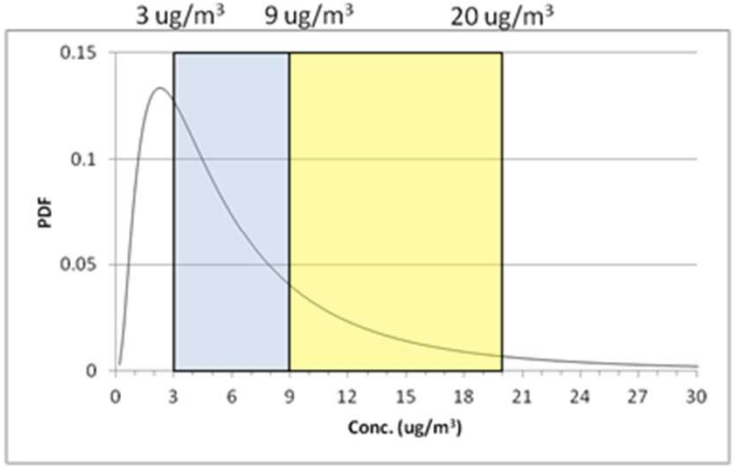

Figure 3b. Exposure distribution of indoor air concentrations falling within the 3 µg/m^3 to 20 µg/m^3 hazard range. Relatively small proportion of exposures is higher than 9 µg/m^3. Limited action may be warranted for risk management.

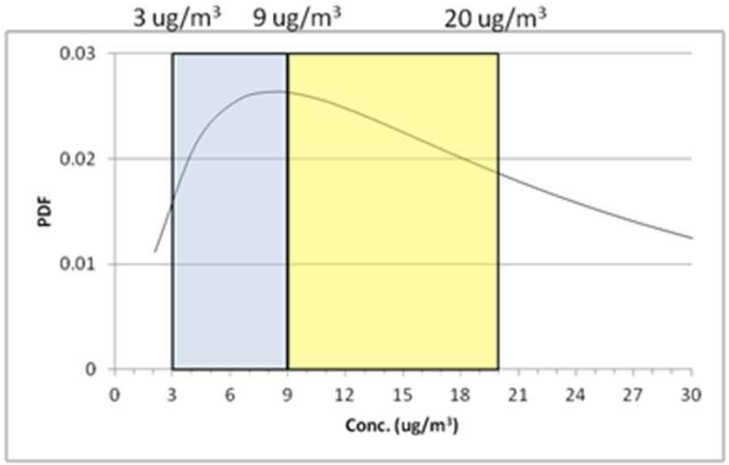

Figure 3c. Exposure distribution of indoor air concentrations freqeuently above the 3 µg/m^3 to 20 µg/m3 hazard range. Actions to reduce exposures may be warranted for risk management.

TCE Action Level Decision Matrix

Exposure Scenario	Normal Response	Accelerated Response	Prompt Action
	ug/m³	ug/m³	ug/m³
Residential	>3.2 but < 9.4	> 9.4 but < 21	> 21
Commercial (8 hr)	> 13 but < 39	> 39 but < 88	> 88
Action	Remedial objectives can be based anywhere in either range) based on chronic exposures. The objectives may be achieved within 6 months.	Remedial objectives can be based anywhere in either range based on intermediate-term exposures. The objectives may be achieved within 10 days to 3 months.	Remedial objectives can be based anywhere in either range based on short-term exposures. The objectives may be achieved within a matter of days.

Summary: Noncancer Range at Contaminated Sites

- A noncancer range was developed for the TCE RfCs. Range included floor, midpoint and ceiling.
- Range for EPA's TCE RfC was judged to be ***3 to 30 µg/m³***.
  - The results of the NTP study-based RfC were used to determine the floor and midpoint of this uncertainty range.
  - The highly controversial results from the Johnson et al. (2003) study-based RfC, while associated with low confidence, were considered for the ceiling level, but journal peer review recommended against this.
  - This 3 µg/m^3 to 30 µg/m^3 range was entirely within the wider individual uncertainty range from the Keil et al. (2009) study; therefore, this latter study was considered to be confirmatory.

Need for Further Effort

- Continue this dialogue regarding vapor intrusion risk assessment issues, including agencies and responsible parties.
- Study the proposed method for the noncancer risk range.
- Resolve discrepancies in TCE fetal heart findings from one lab compared with negative findings in all other labs.
- Determine appropriate TCE safe range & averaging time.

For more information go to:

http://www.allianceforrisk.org/Projects/TCE.html

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