

Approaches to Managing TCE Risks

NEWMOA Vapor Intrusion Workshop

Tuesday, April 14, 2015
Lowell, Massachusetts

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Why Do Chemical Standards Vary?

Different values not uncommon:

- Federal vs State
- State vs State
- Agencies within a State
- Programs within an Agency
- Within a single Program
(e.g., over time)



Why Do Chemical Standards Vary?

- Statutory Language:
Different Laws = Different Results
- Different Goals:
Protect Workers \neq Protect Children
- Timing:
Today's Standards \neq Yesterday's Values
- Cost-Benefit Analysis
Costs & Benefits \neq Absolute Truths
- Scientific Interpretation



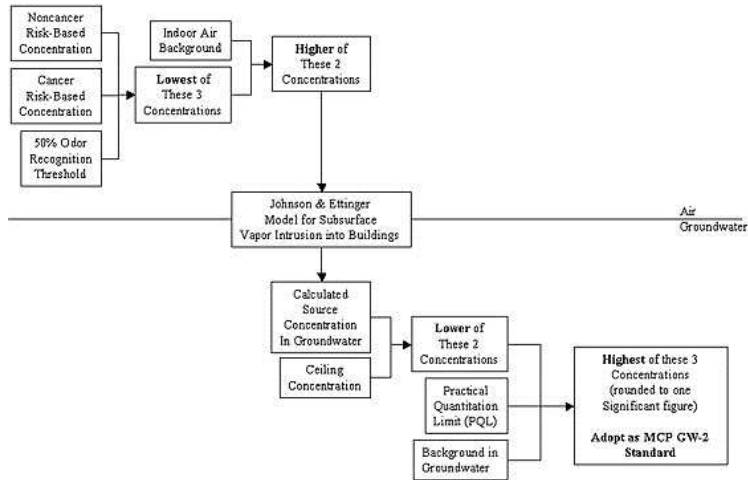
EXAMPLE:

VI-Related TCE Values in the Massachusetts Cleanup Program

- 5 notification criteria
- 6 promulgated cleanup standards
- 4 indoor air risk- based short-term levels
- 10 indoor air screening criteria
- 2 soil gas screening values



Derivation of MCP GW-2 Standards



Derivation of MCP GW-2 Standards

$$[OHM]_{air-nc} = RfC \times HI \times \frac{AP \times C_2}{EF \times EP} \times C_1$$

$$[OHM]_{air-ca} = \frac{ELCR}{UR_{air}} \times \frac{AP \times C_2}{EF \times EP}$$

$$[OHM]_{target-gw} = \frac{[OHM]_{target-air} \times d}{\alpha \times HLC_0 \times C}$$

$$\alpha = ??$$

<http://www.mass.gov/eea/agencies/massdep/cleanup/regulations/documentation-for-gw2-standards.html>



α

- L_F - Depth below grade to bottom of enclosed space floor
- L_{WT} - Depth below grade to water table
- T_S - Average soil/groundwater temperature
- h_A - Thickness of Soil Stratum A
- h_B, h_C - Thickness of Soil Strata B and C
- ρ_b^A - Soil dry bulk density
- n^A - Soil total porosity
- θ_w^A - Soil water-filled porosity
- L_{crack} - Enclosed space floor thickness
- ΔP - Soil-bldg. pressure differential
- L_B - Enclosed space floor length
- W_B - Enclosed space floor width
- H_B - Enclosed space floor height
- w - Floor-wall seam crack width
- ER - Indoor air exchange rate



Why Do Chemical Standards Vary?

Because there are good
Legal, Scientific, Economic
and Policy reasons.

Consistency is good, but a *foolish consistency*...



Risk Management for TCE in Indoor Air

How are site response decisions actually made?



Remember from this morning...

- 2011 EPA released new “Reference Concentration” or RfC of $2 \mu\text{g}/\text{m}^3$
- $2 \mu\text{g}/\text{m}^3$ is safe for short- and long-term exposure
- RfC considers developmental effects (fetal cardiac malformations) that may occur after only a few days exposure during early pregnancy
- RfC based on animal studies with supporting human epidemiology



TCE Toxicology

Weight of Evidence on Cardiac Defects

- Rats: two positive studies, two negative studies
 - Positive studies, from one research group, somewhat unusual dose response
- Supported by two positive studies in rats on metabolites
- Supported by chick embryo studies with TCE and metabolites
- Supported by mechanism studies
- Supported by epidemiology studies



TCE Developmental EPI

- Bove et al. 1995, '96, 2002
 - Ecological study - public drinking water and birth outcomes
 - TCE associated with SGA, NTDs, cleft palate, cardiac defects
- ATSDR 2008 Study of TCE VI at Endicott NY
- NRC 2006 Review: *“the epidemiologic studies—although limited individually—as a whole showed relatively consistent elevations for cardiac malformations with similar relative effect sizes of 2- to 3-fold, some of which were statistically significant, associated with TCE exposure across multiple studies.”*
- Camp Lejeune (Ruckart et al., 2014)
 - TCE associated with SGA and NTDs



Forand et al. 2012 Endicott NY

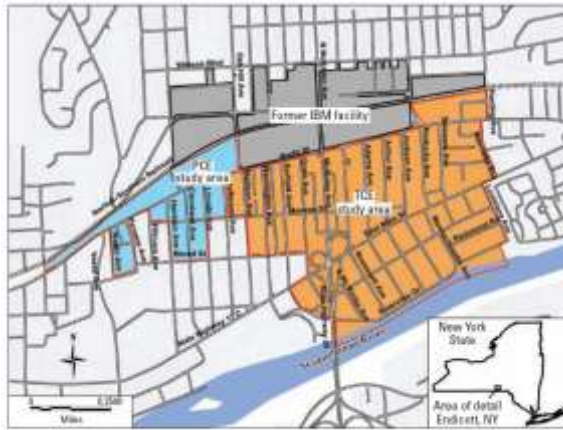


Figure 1. The TCE and PCE study areas and the location of the former IBM manufacturing facility, Village of Endicott, New York (USA).



- TCE Vapor Migration, no drinking water exposure
- N= approx 2500 in TCE study area
- TCE indoor measurements median = 16 ug/m3, up to 140 ug/m3

Forand et al. Endicott Results

Table 2. Adjusted RRs* (95% CIs) for adverse birth outcomes in the PCE, TCE, and combined study areas, Village of Endicott, New York (USA), 1978–2002.

Adverse birth outcome	PCE area		TCE area		Combined study area	
	n	RR (95% CI)	n	RR (95% CI)	n	RR (95% CI)
LBW	12	0.70 (0.39, 1.27)	76	1.36 (1.07, 1.73)**	88	1.20 (0.96, 1.50)
Very LBW	1	0.39 (0.06, 2.78)	14	1.61 (0.94, 2.78)	15	1.32 (0.79, 2.23)
Preterm birth	20	0.74 (0.47, 1.16)	93	1.02 (0.82, 1.27)	113	0.95 (0.79, 1.16)
Very preterm birth	1	0.22 (0.03, 1.58)	20	1.37 (0.87, 2.14)	21	1.09 (0.70, 1.69)
SGA	35	1.04 (0.74, 1.47)	117	1.23 (1.03, 1.48)**	152	1.19 (1.01, 1.39)**
Term LBW	4	0.60 (0.23, 1.60)	37	1.68 (1.20, 2.34)**	41	1.42 (1.04, 1.94)**

*Models were adjusted for mother's age, education, race, and number of previous live births; infant's sex; and adequate prenatal care (Kessner index). *p < 0.05; **p < 0.01.

Table 3. Adjusted RRs* (95% CIs) for birth defects in the in the PCE, TCE, and combined study areas, Village of Endicott, New York (USA), 1983–2000.

Birth defect group ^a	PCE area		TCE area		Combined study area	
	n	RR (95% CI)	n	RR (95% CI)	n	RR (95% CI)
All reportable birth defects	17	1.24 (0.75, 2.05)	44	1.07 (0.79, 1.47)	61	1.11 (0.85, 1.45)
Surveillance birth defects	10	1.44 (0.72, 2.88)	25	1.43 (0.96, 2.14)	35	1.43 (1.01, 2.03)**
All cardiac defects	5	1.42 (0.46, 4.39)	15	2.15 (1.27, 3.62)**	20	1.97 (1.22, 3.16)**
Major cardiac defects	2	2.91 (0.73, 11.65)	6	2.40 (1.00, 5.77)*	8	2.53 (1.21, 5.31)**
Conotruncal defects	1	4.91 (0.69, 34.90)	3	4.91 (1.58, 15.24)**	4	4.92 (1.84, 13.11)**

*Models were adjusted for the mother's age, education, race, and number of previous live births; infant's sex; and adequate prenatal care (Kessner index). ^aThere were no births in the study areas with NTDs, orofacial clefts, or cloacal atresia; therefore, these outcomes are not shown. *p < 0.05; **p < 0.01.

- Higher smoking in study area but not well controlled – LBW, SGA affected in a subanalysis
- Recent meta-analysis: maternal smoking assoc with cardiac defects (Lee and Lupu, 2013)

TCE Developmental Immunotoxicity

- TCE well established as immunotoxicant
 - Impairs some immune functions
 - Stimulates autoimmunity, mice and humans
 - Developing immune system appears sensitive to low level exposure
- TCE RfC equally dependent upon developmental immunotoxicity



At what point above $2 \mu\text{g}/\text{m}^3$ is TCE exposure a concern pregnant women?

- USEPA has not yet developed guidance for evaluating short-term TCE exposure with new RfC
- MassDEP raised the issue with its Health Effects Advisory Committee
- Short-term levels of concern identified for
 - Women who may be in their first 8 weeks of pregnancy;
 - General population;
 - Residential settings; and
 - Workplace settings



Federal Approach: USEPA HQ

- Richardson memo (Aug 2014)
 - Regional Superfund Managers

Existing guidance provides that responders should consider *early or interim* action(s) where appropriate to eliminate, reduce, or control the hazards posed by a site. In doing so, IRIS generally provides the best available toxicological information in support of *early or interim* action for buildings where investigations of indoor air contamination identify site-related concentrations of TCE.



Region 9 Approach, July 2014

- Rapid intervention to avoid developmental risk
 - Vulnerable period – 3 wks of heart development in first trimester
 - Acute intervention concentrations for residential and industrial/commercial
 - Accelerated vs Urgent Action
 - <http://www.epa.gov/region9/superfund/prg/files/r9-tce-interim-action-levels-response-recs-memo-2014.pdf>



USEPA Region 9 Numerical Recommendations

EPA Region 9 Interim TCE Indoor Air Response Action Levels - Residential and Commercial TCE Inhalation Exposure from Vapor Intrusion		
Exposure Scenario	Accelerated Response Action Level (HQ=1)	Urgent Response Action Level (HQ=3) ¹
Residential *	2 µg/m ³	6 µg/m ³
Commercial/Industrial ** (8-hour workday)	8 µg/m ³	24 µg/m ³
Commercial/Industrial ** (10-hour workday)	7 µg/m ³	21 µg/m ³

Accelerated Action: rapid mitigation, sampling confirmation
Urgent Action: immediate cessation of exposure, relocation of workers



USEPA Region 1 Approach

- Site-specific, case-by-case
- Multiple lines of evidence
 - Soil gas, indoor air
- At least one site so far which required more immediate action



USEPA HQ Response to Recent Challenge

Halogenated Solvents Industry Association Challenge to RfC

- Inappropriate dependence upon Johnson 2003 cardiac defect study
- Invoked Information Quality Act (IQA)
 - IRIS not being objective, key study not reproducible



USEPA HQ Response to Recent Challenge

NCEA March 19, 2015 letter strongly defended use of cardiac endpoint in RfC

- HSIA concerns raised during IRIS SAB deliberations
- RfC relies upon 21 developmental studies, numerous support cardiac endpoint
- RfC based upon several different candidate endpoints all in same range
- Addresses details of the Johnson et al. 2003 study (e.g., concurrent controls)



Connecticut Approach, Feb 2015

- Current TAC is 5 ug/m³ – background
- Recognize that development risks in this range
 - 2 µg/m³ – full time exposure, residential
 - 8 µg/m³ – workplace exposure
- If I/C site exceeds limits it is prioritized for immediate follow-up
- Guidance and Toxicology Support Doc on DEEP website:

http://www.ct.gov/deep/cwp/view.asp?a=2715&q=560916&deepNav_GID=1626



Connecticut Approach (cont) Update the CT TCE MCL

- Federal MCL of 5 ug/L from 1980s
- Several reasons to consider updating
 - New toxicology
 - New detection limits
 - Developmental risk
 - MCL enforcement based upon yearly average of quarterly results
 - A quarter could have **up to 20 ug/L** and still pass
 - This is **4.6 fold above RfD**
 - Lowering MCL to 1 ug/L would address this risk



Massachusetts Required Response to “Imminent Hazards”

- Must be reported to DEP within 2 hours
- Triggers *Immediate Response Action (IRA)* to eliminate or reduce exposures
- MassDEP approves (oral/written) IRA’s
- Includes notice to Chief Municipal Officer and Board of Health
- Includes notice to affected individuals



Imminent Hazard Values for Pregnant Women (and Those Who May Become Pregnant)

<i>Residential Exposure Scenario^a</i>	Indoor Air Concentration	Concern Level	Actions
Fetal developmental effects (Subchronic Exposure Noncancer Risk, HQ=1)	> 6 µg/m³	Imminent Hazard 2-hr Notification	Immediate Response Action Goal to reduce levels to at least less than 6 µg/m ³ ASAP (within several days if possible)
<i>Typical Workplace Exposure Scenario^b</i>	Indoor Air Concentration	Concern Level	Actions
Fetal developmental effects (Subchronic Exposure Noncancer Risk, HQ=1)	> 24 µg/m³	Imminent Hazard 2-hr Notification	Immediate Response Action Goal to reduce levels to at least less than 24 µg/m ³ ASAP (within several days to a week if possible)



Imminent Hazard Values for All Receptors

<i>Residential Exposure Scenario</i>	Indoor Air Concentration	Concern Level	Actions
Immune system effects (Subchronic Exposure Noncancer Risk, HQ=10)	> 20 µg/m³	Imminent Hazard 2-hr Notification	Immediate Response Action initiated on an expedited time table
<i>Typical Workplace Exposure Scenario</i>	Indoor Air Concentration	Concern Level	Actions
Immune system effects (Subchronic Exposure Noncancer Risk, HQ=10)	> 80 µg/m³	Imminent Hazard 2-hr Notification	Immediate Response Action initiated on an expedited time table



Massachusetts Levels of “*More Urgent Concern*”

The probability of an adverse outcome generally increases with both the level and duration of exposure to oil and/or hazardous material. Therefore, higher concentrations of TCE in indoor air result in the need for heightened levels of effort to quickly reduce exposures to TCE.

MassDEP has also identified ***More Urgent Concern Levels*** for situations where pregnant women and those who may become pregnant are exposed to TCE concentrations well above the Imminent Hazard criteria.

Where TCE levels exceed the ***More Urgent Concern Levels*** of 20 µg/m³ in a home or 60 µg/m³ in a workplace, MassDEP should be consulted about available short-term options for reducing or eliminating exposures to pregnant women (or women who may be pregnant) while response actions are developed and implemented.



Massachusetts Response to TCE Imminent Hazards

- Actions put on accelerated schedule, including:
- **Immediate implementation:**
 - Ensure appropriate Fact Sheets are provided to Affected Individuals;
 - Vent the basement or lowest level of the building by opening windows;
 - Seal cracks/utility annular spaces in bottom floor of building and subsurface walls; and
 - Enclose and passively vent sumps.



Massachusetts Response to TCE Imminent Hazards

- **Implemented as soon as possible, but which may require several days to two weeks to arrange:**
 - Adjust the HVAC system
 - Install carbon filtration on HVAC system; and
 - Bring portable air-purifying units (APUs) to the affected building



Massachusetts Response to TCE Imminent Hazards

- **Implementation as soon as possible, but which may require several weeks to two months to design, construct and test:**
 - Installation of a sub-slab depressurization system
 - Installation of air-to-air heat exchanger to over-pressurize the basement
 - Installation of a soil vapor extraction system



MassDEP Guidance Available Online

<http://www.mass.gov/eea/agencies/massdep/cleanup/regulations/site-cleanup-policies-guidance.html#4>

- A Fact Sheet, “*TCE Toxicity Information: Implications for Chronic and Shorter-Term Exposure*” targeted to the regulated community;
- Two sets of “*Frequently Asked Questions*”, for residential and workplace exposures, to address concerns raised by individuals who live and work in buildings affected by the TCE contamination;
- A template for public notices that are required at sites where actions are being taken to address Imminent Hazards;
- Documentation of MassDEP’s review of the USEPA’s toxicity values for TCE and the Department’s advisory committee recommendations for addressing short-term exposure; and
- (existing) technical guidance: “*Interim Final Vapor Intrusion Guidance*”



TCE Action Levels Across States

What is the immediate response level?

- Mass (Aug 2014): 6 $\mu\text{g}/\text{m}^3$ – Imminent Hazard
20 $\mu\text{g}/\text{m}^3$ – “more urgent concern”
- NH (Feb 2013): 8 $\mu\text{g}/\text{m}^3$ – Immediate action,
warnings, relocation
- CT (Feb 2015): 8 $\mu\text{g}/\text{m}^3$ – Prioritization of site,
immed action to \downarrow conc
(no employee warning level)
- USEPA Region 9: 8 $\mu\text{g}/\text{m}^3$ – Accelerated action;
24 $\mu\text{g}/\text{m}^3$ – Urgent action



Other States in Region

NYS: draft recommendation

- immediate action > 20 $\mu\text{g}/\text{m}^3$
- no distinction between resi and I/C
- In general, endeavor to bring indoor air to background or risk-based goal as quickly as possible regardless of chemical or endpoint

Maine: > 6 $\mu\text{g}/\text{m}^3$ – reduce exposure
> 20 $\mu\text{g}/\text{m}^3$ – immediately reduce exposure
for sensitive receptors (up to and including relocation)

VT: focus on cancer risk; site-specific
consideration of RfD/acute risk

Rhode Island: In general, endeavor to bring indoor air to background or risk-based goal as quickly as possible regardless of chemical or endpoint



OSHA PEL

- Remains at 100 ppm – 1980s
 - Based upon acute CNS effects, liver and kidney tox
 - Carcinogen status acknowledged
- PEL is 270,000 times > USEPA RfD
 - PEL doesn't apply to general public
 - Vulnerable receptors vs healthy workers, voluntary vs involuntary risk, continuous vs. workplace exposure
 - PEL doesn't apply same risk methodology and level of public health protection as RfD
- ACGIH TLV – lowered to 10 ppm - 2007
 - STEL = 25 ppm
 - TLV basis – CNS effects, renal toxicity
 - Developmental toxicity mentioned briefly
 - Cancer discussed but not part of PEL derivation



Summary

- TCE developmental effects make acute risk more urgent than cancer risk
- Impacts on VI, workplace safety, MCL
- Variety of Responses in Region
 - Numerical guidelines, intervention protocols
 - Case-by-case
 - Still Studying issues
- 6 -> 8 $\mu\text{g}/\text{m}^3$ short-term remediation target
- 20 -> 24 $\mu\text{g}/\text{m}^3$ warning/urgent action
- Monitor evolving science and reg determinations

