BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:)
) R09-9
PROPOSED AMENDMENTS TO) (Rulemaking-Land)
TIERED APPROACH TO CORRECTIVE)
ACTION OBJECTIVES)
(35 Ill. Adm. Code 742))
)

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NOTICE

Dorothy Gunn, Clerk
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James R. Thompson Center
100 W. Randolph, Suite 11-500
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(Via First Class Mail)

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Chicago, Illinois 60601
(Via First Class Mail)

Participants on the Service List
(Via First Class Mail)

PLEASE TAKE NOTICE that I have today filed with the Office of the Clerk of the Illinois Pollution Control Board the Illinois Environmental Protection Agency's ("Illinois EPA") Motion for Leave from the Filing and Service Requirements, Supplemental Studies and Reports List, Errata Sheet Number 3, and the Pre-filed Testimony of Heather Nifong, Thomas C. Hornshaw, and Tracey Hurley a copy of each of which is herewith served upon you.

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

By: Kimberly A Geving
Kimberly A. Geving
Assistant Counsel
Division of Legal Counsel

DATE: February 20, 2009

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BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

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)
PROPOSED AMENDMENTS TO) R09-9
TIERED APPROACH TO CORRECTIVE) (Rulemaking-Land)
ACTION OBJECTIVES)
(35 Ill. Adm. Code 742))
)

MOTION FOR LEAVE FROM FILING AND SERVICE REQUIREMENTS

NOW COMES the Illinois Environmental Protection Agency ("Illinois EPA") and, pursuant to 35 Ill. Adm. Code 101.500, moves the Illinois Pollution Control Board ("Board") to waive the filing requirement pursuant to 35 Ill. Adm. Code 101.306(a) and waive the service requirement pursuant to 35 Ill. Adm. Code 101.304(b) for one of the Illinois EPA's Incorporations by Reference.

In support of its motion, the Illinois EPA asserts that it believes the document was included in its initial filing of the proposed amendments in this matter. Additionally, the Illinois EPA was required to pay another copyright fee to ASTM International for this extra copy, which is today filed with the Board. Furthermore, each additional copy would require a separate copyright fee, resulting in great expense to the Illinois EPA.

WHEREFORE, the Illinois EPA seeks relief from the filing and service requirements for the following title: (1) ASTM D 1946-90, Standard Practice for Analysis of Reformed Gas by Gas Chromatography, Reapproved 2006.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

By: Kimberly A Geving
Kimberly A. Geving
Assistant Counsel
Division of Legal Counsel

DATED: February 20, 2009

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Supplemental Studies and Reports List

Agency for Toxic Substances and Disease Registry. (November 2007). Minimal Risk Levels (MRLs).

Agency for Toxic Substances and Disease Registry. (December 2006). Minimal Risk Levels (MRLs).

California EPA. Office of Environmental Health Hazard Assessment. Toxicity Criteria Database. http://www.oehha.ca.gov/risk/ChemicalDB/index.asp

Heath, Ralph C. (1983). Basic Ground-Water Hydrology. United States Geological Survey Water-Supply Paper 2220. http://pubs.er.usgs.gov/djvu/WSP/wsp_2220.pdf

Howard, Philip H., W.F. Jarvis, W.M. Meylan, and E.M. Michalenko. (1991). Handbook of Environmental Degradation Rates. Lewis Publishers, In. Chelsea, Michigan. Available at the Illinois EPA Library, Call Number: 363.7384 HOWA2

National Institute for Occupational Safety and Health (NIOSH). (2005). NIOSH Pocket Guide to Chemical Hazards. http://www.cdc.gov/niosh/npg/default.html

Syracuse Research Corporation (SRC). CHEMFATE Database. SRC. Syracuse, NY. http://www.srcinc.com/what-we-do/databaseforms.aspx?id=381

Syracuse Research Corporation (SRC). PHYSPROP Database. SRC. Syracuse, NY. http://www.srcinc.com/what-we-do/databaseforms.aspx?id=386

United States Geological Survey. Water Basics Glossary of Terms. http://capp.water.usgs.gov/GIP/h2o_gloss/ Last modified January 13, 2009.

U.S. EPA. (July 1997). Health Effects Assessment Summary Tables. FY 1997 Update. EPA Publication No. EPA 540/R-97-036. Available at http://nepis.epa.gov

U.S. EPA. Integrated Risk Information System. http://cfpub.epa.gov/ncea/iris/index.cfm

U.S. EPA. Provisional Peer Reviewed Toxicity Values. Superfund Health Risk Technical Support Center. National Center for Environmental Assessment, Office of Research and Development. Cincinnati, OH 45268, (513) 569-7300.

U.S. EPA. (January 2004). Superfund Chemical Data Matrix. http://www.epa.gov/superfund/sites/npl/hrsres/tools/scdm.htm

U.S. EPA. (July 2004). Water9, Version 2.0. http://www.epa.gov/ttn/chief/software/water/

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BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	)	
	)	
PROPOSED AMENDMENTS TO TIERED APPROACH TO CORRECTIVE ACTION OBJECTIVES (35 Ill. Adm. Code 742)	))))	R09-9 (Rulemaking-Land)

ERRATA SHEET NUMBER 3

NOW COMES the Illinois Environmental Protection Agency ("Illinois EPA") through one of its attorneys, Kimberly Geving, and submits this ERRATA SHEET NUMBER 3 to the Illinois Pollution Control Board ("Board") and the participants listed on the Service List. Tracey Hurley, Tom Hornshaw, and Heather Nifong will provide oral testimony in support of these changes at the hearing on March 17, 2009.

Section	
742.200	"Capillary Fringe" means the zone above the water table in which water is held by surface tension. Water in the capillary fringe is under a pressure less than atmospheric. "Carcinogen" means *a contaminant that is classified as a category A1 or A2 carcinogen by the American Conference of Governmental Industrial Hygienists; a category 1 or 2A/2B carcinogen by the World Health Organization's International Agency for Research on Cancer; a "human carcinogen" or "anticipated human carcinogen" by the United States Department of Health and Human Service National Toxicological Program; or a category A or B1/B2 carcinogen* or as "carcinogenic to humans" or "likely to be carcinogenic to humans" *by the United States Environmental Protection Agency in the integrated risk information system or a final rule issued in a federal Register notice by the USEPA.* [415 ILCS 5/58.2]

	"Residential Property" *means any real property that is used for habitation by individuals, or* where children have the opportunity for exposure to contaminants through soil ingestion or inhalation (indoor or outdoor) at educational facilities, health care facilities, child care facilities or ~~outdoor~~ recreational areas. [415 ILCS 5/58.2]
	"Saturated Zone" means a subsurface zone in which all the interstices or voids are filled with water under pressure greater than that of the atmosphere.
	"Unconfined Aquifer" means an aquifer whose upper surface is a water table free to fluctuate under atmospheric pressure.
	"Water Table" means the top water surface of an unconfined aquifer at atmospheric pressure.
742.210	Add a new Incorporation by Reference: United States Environmental Protection Agency (2005). "Guidelines for Carcinogen Risk Assessment (2005)". U.S. Environmental Protection Agency, Washington, DC, EPA Publication No. EPA/630/P-03/001F, 2005. (Available online at http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=116283).
742.225(b)(5)	Delete this new subsection in its entirety.
742.225(d)	If a person chooses to composite soil samples or average soil sample results to demonstrate compliance relative to the outdoor and indoor inhalation exposure routes ~~route~~ or ingestion routes, the following requirements apply:
742.510(b)	Groundwater remediation objectives for the groundwater component of the groundwater ingestion exposure route are listed in Appendix B, Table E. However, Appendix B, Table E must be corrected for cumulative effect of mixtures of similar-acting noncarcinogenic chemicals as set forth in Sections ~~Section~~ 742.505(b)(3) and (b)(4).

Appendix A, Table A	For the chemical 2-Chlorophenol (ionizable organic) change the footnote from [b] to [c]. Remove the chemical Methoxychlor from the table.
Appendix A, Table E	Under the Circulatory System column add (ingestion only) after the chemical Nitrobenzene. Under the Kidney column remove Nitrobenzene. Under the Liver column remove Nitrobenzene. Under the Respiratory System Column add Nitrobenzene (inhalation only) after the chemical Nickel.
Appendix A, Table F	Under the Kidney column add the chemical Nitrobenzene after the chemical 1,2-Dibromo-3-chloropropane (ingestion only). Under the Liver column add the chemical Nitrobenzene after the chemical Methylene Chloride.
Appendix A, Table I	For the chemical Arsenic change the Class I Groundwater Remediation Objective from 0.10 to 0.01.
Appendix A, Table L	For the chemical 2-Butanone(MEK) move the entire row to come after the chemical Butanol. For the chemical 2-Chlorophenol (ionizable organic) add a new footnote "c" after the chemical. In footnote [b] add the word "was" before "calculated". Add a new footnote [c] C_{sat} for pH of 6.8. If soil pH is other than 6.8, a site-specific C_{sat} should be calculated using equations S19 and J&E6a and the pH-specific Koc values in Appendix C Table I.
Appendix B, Table A	The entire row for the chemical 2-Chlorophenol should be moved and entered alphabetically under the Ionizable Organics. For the chemical Di-n-octyl phthalate change the Class I and Class II values from 5[d] to 5.2[d]. For the chemical Isopropylbenzene (Cumene) change the Class II value from 460[r] to 400[d].

For the chemical Methoxychlor change the Outdoor Inhalation value from 14[d] to ---[c], change the Class I value from 4.5[d] to 80[r], and change the Class II value from 4.5[d] to 400[r]. [Note: this is a change to an amendment we made in Errata Sheet 1]

For the chemical Nitrobenzene under the Ingestion column make the following change: 160[b] ~~39[b]~~ . Under the Outdoor Inhalation column change the value from 77[b,x] to 2.2[e]. Under the Class I column change the value from 0.02[r] to 0.078[r]. Under the Class II column change the value from 0.02[r] to 0.078[r]. Under the ADL column make the following change: * ~~0.26~~.

For the chemical 2,4,5-TP (Silvex) remove the footnote "i" in the Class I and Class II columns.

For the chemical Vanadium change the footnote "b" to an "r".

For the chemical 2,4-Dinitrophenol add a footnote "i" after the value in the Class I and Class II columns.

For the chemical MCPP (mecoprop) correct the spelling of "mecoprop" and add a footnote "i" after the value in the Class I and Class II columns.

For the chemical Arsenic make the following change in the Class I column: 0.01[m,r] ~~0.05[m,r]~~.

Appendix B, Table B

For the chemical Bis(2-ethylhexyl)phthalate change the Class II value from 200[d] to 68[d].

For the chemical Butyl benzyl phthalate change the Class I and Class II values from 1,000[d] to 340[d].

The entire row for the chemical 2-Chlorophenol should be moved and entered alphabetically under the Ionizable Organics.

For the chemical Di-n-octyl phthalate change the Class I and Class II values from 5[d] to 5.2[d].

For the chemical Isopropylbenzene (Cumene) change the Class II value from 460[d] to 400[d].

For the chemical Methoxychlor change both of the Outdoor Inhalation values (Industrial/Commercial and Construction Worker) from 14[d] to ---[c], change the Class I value from 4.5[d] to 80[r], and change the Class II value from 4.5[d] to 400[r]. [Note: this is a change to an amendment we did in Errata Sheet 1]

For the chemical 2-Methylphenol (o-Cresol) we made an error in Errata Sheet Number 1. We added a footnote "a" to the value in the Construction Worker Outdoor Inhalation column. This footnote should have been a "b".

For the chemical Nitrobenzene under the Industrial/Commercial Ingestion column make the following change: 4,100[b] ~~1,000[b]~~. Under the Industrial/Commercial Outdoor Inhalation column change the value from 120[b] to 4.3[e]. Under the Construction Worker Ingestion column make the following change: 1,200[b] ~~1,000[b]~~. Under the Construction Worker Outdoor Inhalation column change the value from 7.9[b] to 3.6[b]. Under the Class I column change the value from 0.02[r] to 0.078[r]. Under the Class II column change the value from 0.02[r] to 0.078[r].

For the chemical 2,4,5-TP (Silvex) remove the footnote "i" in the Class I and Class II columns.

For the chemical Trichloroethylene change the Construction Worker Outdoor Inhalation value from 8.8[e] to 2.9[b].

For the chemical 2,4-Dinitrophenol add a footnote "i" after the value in the Class I and Class II columns.

For the chemical MCPP (mecoprop) add a footnote "i" after the value in the Class I and Class II columns.

For the chemical Arsenic make the following change in the Class I column: 0.01[m,r] ~~0.05[m,r]~~.

Appendix B, Table E	For the chemical Nitrobenzene make the following change in the Class I column: 0.014[c] ~~0.0035~~[e]. Under the Class II column make the following change: 0.014[c] ~~0.0035~~[e].
Appendix B, Table F	For the chemical Nitrobenzene change the Class I value from 0.0035[c] to 0.014[c]. Change the Class II value from 0.0035[c] to 0.014[c].
Appendix B, Table G	The chemical Isopropylbenzene is not in alphabetical order and should be moved one row up (above Mercury). For the chemical Nitrobenzene change the Soil Residential value from 140[b] to 4.0[d]. Change the Soil Industrial/Commercial value from 380[c] to 30[d]. Change the Groundwater Residential value from 770[b] to 23[d]. Change the Groundwater Industrial/Commercial value from 2,100[h] to 160[d]. Change the Soil Gas Residential value from 310[b] to 9.0[d]. Change the Soil Gas Industrial/Commercial value from 1,700[g] to 66[d].
Appendix C, Table B	In the Source column for the Symbols RfC, RfD_o, SF_o, and URF add the following link after "Illinois EPA": http://www.epa.state.il.us/land/taco/toxicity-values.xls. Strike footnote a: ~~USEPA, Office of Solid Waste and Emergency Response. EPA/SQO/R-95/036. Updated Quarterly~~.
Appendix C, Table D	In the Source column for the Symbols RfD_i, RfD_o, SF_i, and SF_o add the following link after "Illinois EPA": http://www.epa.state.il.us/land/taco/toxicity-values.xls. Strike footnote a: ~~USEPA Office of Solid Waste and Emergency Response. EPA/SQO/R-95/036. Updated Quarterly~~.
Appendix C, Table E	Add a footnote "e" after the table's heading: Section 742.Table E: Default Physical and Chemical Parameters[e]. At the end of the table the new footnote will read as follows: [e] The values in

this table were taken from the following sources (in order of preference): SCDMS online database (http://www.epa.gov/superfund/sites/npl/hrsres/tools/scdm.htm); CHEMFATE online database (http://www.srcinc.com/what-we-do/databaseforms.aspx?id=381); PhysProp online database (http://www.srcinc.com/what-we-do/databaseforms.aspx?id=386); Water9 (http://www.epa.gov/ttn/chief/software/water/) for diffusivity values; and *Handbook of Environmental Degradation Rates* by P.H. Howard (1991) for first order degradation constant values.

Appendix C, Table L

Replace equation J&E 1 with the following equation:

$$RO_{indoor-air} = \frac{TR \times AT_c \times 365\,\frac{\text{days}}{\text{yr}}}{ED \times EF \times URF \times 1000\,\frac{\mu\text{g}}{\text{g}}}$$

Replace equation J&E2 with the following equation:

$$RO_{indoor\text{-}air} = \frac{THQ \times AT_{nc} \times 365\,\frac{days}{yr} \times RfC}{ED \times EF}$$

Add a note under the equation J&E3 as follows: Note: 24.45 equals the molar volume of air in liters at normal temperature (25°C) and pressure (760 mm Hg).

Replace equation J&E5 with the following equation:

$$RO_{soil} = \frac{RO_{soilgas} \times \left(\theta_w + K_d \times \rho_b + H'_{TS} \times \theta_a\right)}{H'_{TS} \times \rho_b \times \frac{10^6\,\text{cm}^3}{\text{m}^3} \times \frac{\text{kg}}{10^3\,\text{g}}}$$

Replace equation J&E7 with the following equation:

$$RO_{gw} = \frac{RO_{soilgas}}{H'_{TS} \times 1000 \frac{\mathrm{L}}{\mathrm{m}^3}}$$

Replace equation J&E13 with the following equation:

$$Q_{bldg} = \left(\frac{L_B \times W_B \times H_B \times ER}{3600 \frac{\mathrm{sec}}{\mathrm{hr}}} \right)$$

Appendix C, Table M

For the symbol C_v^{sat} in the column entitled "Parameter" change "Soil vapor concentration" to "Soil vapor saturation concentration."

Delete the notes at the end of the table: SSL "Technical Background Document for Draft Soil Screening Level Framework, Review Draft", July 1994 SSG "Soil Screening Guidance: User's Guide" EPA/540/R-96/018, April 1996. US EPA, 2004a. User's Guide for Evaluating Subsurface Vapor Intrusion into Buildings. February 2004.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

By: Kimberly A Geving
Kimberly A. Geving
Assistant Counsel
Division of Legal Counsel

DATE: February 20, 2009

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PRE-FILED TESTIMONY OF HEATHER NIFONG

At the request of the Illinois Pollution Control Board during the January 27, 2009 hearing on amendments to 35 Ill. Adm. Code Part 742, Illinois EPA has reviewed the existing definition of "residential property" and considered the inclusion of new definitions for "capillary fringe," "saturated zone," and "water table."

Illinois EPA agrees that the definition of "residential property" should be revised to clarify the addition of the indoor inhalation exposure route. The amended definition now reads as follows:

"Residential property" means any real property that is used for habitation by individuals, or where children have the opportunity for exposure to contaminants through soil ingestion or inhalation (indoor or outdoor) at educational facilities, health care facilities, child care facilities, or ~~outdoor~~ recreational areas.

Next, Illinois EPA agrees that regulatory definitions for "capillary fringe," "saturated zone," and "water table" should be included in 35 Ill. Adm. Code 742. Additionally, the Illinois EPA proposes that a fourth term, "unconfined aquifer," be included. The new definitions set forth below have been taken from the United States Geological Survey, *Water Basics Glossary of Terms*. The citation for this document will be added to the Illinois EPA's list of studies referenced during the Agency's indoor inhalation rulemaking development.

"Capillary Fringe" means the zone above the water table in which water is held by surface tension. Water in the capillary fringe is under a pressure less than atmospheric.

"Saturated Zone" means a subsurface zone in which all the interstices or voids are filled with water under pressure greater than that of the atmosphere.

"Water Table" means the top water surface of an unconfined aquifer at atmospheric pressure.

"Unconfined Aquifer" means an aquifer whose upper surface is a water table free to fluctuate under atmospheric pressure.

To describe the relationship between these terms, Illinois EPA directs the Board to page four of the following document: *Basic Ground-Water Hydrology*, United States Geological Survey Water-Supply Paper 2220 (Exhibit 1 to my testimony). This single page contains both a narrative description and a figure illustrating the capillary fringe, saturated zone and water table. The citation for this document will be added to the Illinois EPA's list of studies referenced during the Agency's indoor inhalation rulemaking development.

Lastly, Illinois EPA would like to amend its response to pre-filed question #7 from the Illinois Environmental Regulatory Group. As originally written, the answer could be interpreted to conclude that the Agency would not take into account the length of time needed for contaminants to migrate horizontally. Such an interpretation would not be correct. Compliance determinations in regards to sample adequacy will be made by the program under which the site is being remediated; no changes to Part 742 are necessary. The amended language is located at final paragraph of the Agency's answer to Question 7.

Question 7) Will the Agency require actual data or allow modeling of groundwater to evaluate the vapor intrusion pathway to an off-site building?

Answer: To determine if off-site properties are at risk from indoor inhalation route exposures, site evaluators have the option of running TACO equation R26, collecting groundwater samples, or collecting soil gas samples at the down gradient property boundary. With respect to the indoor inhalation route, soil gas data trumps groundwater sample data and R26 modeling results. Groundwater sample data trumps R26 modeling results when addressing the indoor inhalation route.

If R26 predicts groundwater impacts will migrate off-site at concentrations above the groundwater indoor inhalation remediation objectives, but soil gas concentrations at the source or down gradient property boundary of the remediation site are below the soil gas remediation objectives, no further analysis of off-site properties is necessary in regards to the indoor inhalation route.

If R26 predicts groundwater impacts will migrate off-site at concentrations above the groundwater indoor inhalation remediation objectives, but groundwater samples at the down gradient property boundary are below the indoor inhalation remediation objectives, no further analysis is necessary in regards to the indoor inhalation route.

Using both the J&E and the R26 models to predict down gradient risks associated with the indoor inhalation route is an extremely conservative, but allowable, option.

When either soil gas or groundwater data are used to demonstrate compliance, the number of sampling rounds required will be determined by the program under which the site is being remediated. This is because soil gas or groundwater samples collected after a recent spill or release may not represent the actual impact from contaminants migrating in groundwater. Repeat samples may be necessary to address this time lapse and ensure that the migration of the contaminant plume is fully evaluated.

This concludes my testimony.

EXHIBIT

1

Basic Ground-Water Hydrology

United States
Geological
Survey
Water-Supply
Paper 2220

Prepared in
cooperation with the
North Carolina
Department of Natural
Resources and
Community Development

U.S. DEPARTMENT OF THE INTERIOR
March 3, 1849

DEFINITIONS OF TERMS

[Number in parentheses is the page on which the term is first mentioned]

AQUIFER (6): A water-bearing layer of rock that will yield water in a usable quantity to a well or spring.

BEDROCK (2): A general term for the consolidated (solid) rock that underlies soils or other unconsolidated surficial material.

CAPILLARY FRINGE (4): The zone above the water table in which water is held by surface tension. Water in the capillary fringe is under a pressure less than atmospheric.

CONE OF DEPRESSION (30): The depression of heads around a pumping well caused by the withdrawal of water.

CONFINING BED (6): A layer of rock having very low hydraulic conductivity that hampers the movement of water into and out of an aquifer.

DATUM PLANE (10): An arbitrary surface (or plane) used in the measurement of ground-water heads. The datum most commonly used is the National Geodetic Vertical Datum of 1929, which closely approximates sea level.

DISPERSION (19): The extent to which a liquid substance introduced into a ground-water system spreads as it moves through the system.

DRAWDOWN (34): The reduction in head at a point caused by the withdrawal of water from an aquifer.

EQUIPOTENTIAL LINE (21): A line on a map or cross section along which total heads are the same.

FLOW LINE (21): The idealized path followed by particles of water.

FLOW NET (21): The grid pattern formed by a network of flow lines and equipotential lines.

GROUND WATER (4): Water in the saturated zone that is under a pressure equal to or greater than atmospheric pressure.

HEAD *See* **TOTAL HEAD.**

HYDRAULIC CONDUCTIVITY (12): The capacity of a rock to transmit water. It is expressed as the volume of water at the existing kinematic viscosity that will move in unit time under a unit hydraulic gradient through a unit area measured at right angles to the direction of flow.

HYDRAULIC GRADIENT (10): Change in head per unit of distance measured in the direction of the steepest change.

POROSITY (7): The voids or openings in a rock. Porosity may be expressed quantitatively as the ratio of the volume of openings in a rock to the total volume of the rock.

POTENTIOMETRIC SURFACE (6): A surface that represents the total head in an aquifer; that is, it represents the height above a datum plane at which the water level stands in tightly cased wells that penetrate the aquifer.

ROCK (2): Any naturally formed, consolidated or unconsolidated material (but not soil) consisting of two or more minerals.

SATURATED ZONE (4): The subsurface zone in which all openings are full of water.

SOIL (4): The layer of material at the land surface that supports plant growth.

SPECIFIC CAPACITY (58): The yield of a well per unit of drawdown.

SPECIFIC RETENTION (8): The ratio of the volume of water retained in a rock after gravity drainage to the volume of the rock.

SPECIFIC YIELD (8): The ratio of the volume of water that will drain under the influence of gravity to the volume of saturated rock.

STORAGE COEFFICIENT (28): The volume of water released from storage in a unit prism of an aquifer when the head is lowered a unit distance.

STRATIFICATION (18): The layered structure of sedimentary rocks.

TOTAL HEAD (10): The height above a datum plane of a column of water. In a ground-water system, it is composed of elevation head and pressure head.

TRANSMISSIVITY (26): The rate at which water of the prevailing kinematic viscosity is transmitted through a unit width of an aquifer under a unit hydraulic gradient. It equals the hydraulic conductivity multiplied by the aquifer thickness.

UNSATURATED ZONE (4): The subsurface zone, usually starting at the land surface, that contains both water and air.

WATER TABLE (4): The level in the saturated zone at which the pressure is equal to the atmospheric pressure.

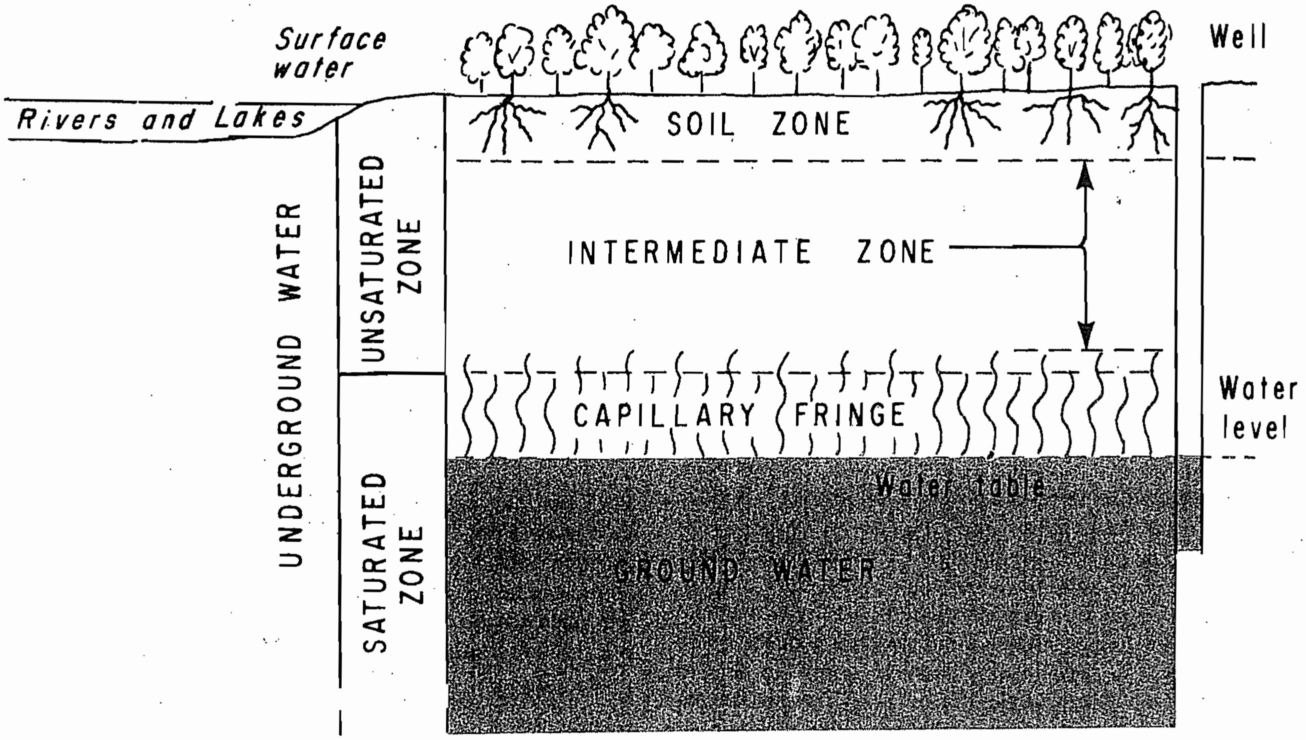
UNDERGROUND WATER

All water beneath the land surface is referred to as *underground water* (or subsurface water). The equivalent term for water on the land surface is *surface water*. Underground water occurs in two different zones. One zone, which occurs immediately below the land surface in most areas, contains both water and air and is referred to as the *unsaturated zone*. The unsaturated zone is almost invariably underlain by a zone in which all interconnected openings are full of water. This zone is referred to as the *saturated zone*.

Water in the saturated zone is the only underground water that is available to supply wells and springs and is the only water to which the name *ground water* is correctly applied. Recharge of the saturated zone occurs by percolation of water from the land surface through the unsaturated zone. The unsaturated zone is, therefore, of great importance to ground-water hydrology. This zone may be divided usefully into three parts: the soil zone, the intermediate zone, and the upper part of the capillary fringe.

The soil zone extends from the land surface to a maximum depth of a meter or two and is the zone that supports plant growth. It is crisscrossed by living roots, by voids left by decayed roots of earlier vegetation, and by animal and worm burrows. The porosity and permeability of this zone tend to be higher than those of the underlying material. The soil zone is underlain by the *intermediate zone*, which differs in thickness from place to place depending on the thickness of the soil zone and the depth to the capillary fringe.

The lowest part of the unsaturated zone is occupied by the *capillary fringe*, the subzone between the unsaturated and saturated zones. The capillary fringe results from the attraction between water and rocks. As a result of this attraction, water clings as a film on the surface of rock particles and rises in small-diameter pores against the pull of gravity. Water in the capillary fringe and in the overlying part of the unsaturated zone is under a negative hydraulic pressure—that is, it is under a pressure less than the atmospheric (barometric) pressure. The *water table* is the level in the saturated zone at which the hydraulic pressure is equal to atmospheric pressure and is represented by the water level in unused wells. Below the water table, the hydraulic pressure increases with increasing depth.



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(35 Ill. Adm. Code 742))

SUPPLEMENTAL TESTIMONY OF THOMAS HORNSHAW

This testimony is intended to describe proposed amendments to the Tier 1 table entries for two chemicals that have very recently had their toxicity criteria updated; to address issues that have arisen regarding averaging data to demonstrate compliance with remediation objectives for the indoor inhalation pathway; and to continue the process of correcting the text and tables of Part 742.

Toxicity criteria updates – Since the beginning of the year there have been changes in the toxicity criteria used by the Agency to derive the Tier 1 remediation objectives for Nitrobenzene and Trichloroethylene (TCE). USEPA has updated the entry for Nitrobenzene in its Integrated Risk Information System (IRIS), and has issued a memo to its Regional Administrators describing interim toxicity values recommended for use for TCE. A discussion of these updates and the corresponding changes to the Tier 1 tables follows.

Nitrobenzene – USEPA completely revised the IRIS entry for Nitrobenzene on February 6, 2009. In this revision, the chronic Reference Dose (RfD) was changed from 0.0005 mg/kg/d to 0.002 mg/kg/d, a chronic Reference Concentration (RfC) was added for the first time at 0.009 mg/m3, the previous weight-of-evidence cancer classification of Group D, "not classifiable as to human carcinogenicity," was changed to " likely to be carcinogenic to humans" under the 2005 revised *Guidelines for Carcinogen Risk Assessment* (equivalent to Group B in the old classification system), and an inhalation cancer Unit Risk Factor of 4E-05 per ug/m3 was added (there are insufficient data to derive an oral Slope Factor at this time). Following our hierarchy for developing subchronic RfDs and RfCs, the Toxicity Assessment Unit also updated the previous subchronic RfD of 0.005 mg/kg/d (from the 1997 Health Effects Assessment Summary Tables, HEAST) to 0.006 mg/kg/d (derived from the chronic RfD), and updated the previous subchronic RfC of 0.02 mg/m3 (also from HEAST) to 0.009 mg/m3 (same as the new chronic RfC).

Using these updated toxicity criteria, we calculated the revised remediation objectives listed for Nitrobenzene for Appendix B, Tables A, B, E, F, and G in Errata Sheet Number 3. We also updated Nitrobenzene's entry in Appendix A, Table E (for similar-acting noncarcinogens) and added Nitrobenzene to Appendix A, Table F (for similar-acting carcinogens) as presented in Errata Sheet Number 3. Since the 2005 revised *Guidelines*, cited above, have not previously been included in TACO, we are also now including the revised definition for "Carcinogen" and adding the 2005 *Guidelines* to the Incorporations by Reference as shown in Errata Sheet Number 3. Finally, it should be noted that the revised RfD will require a change in the proposed updates to the Part 620 Groundwater Standards, in which the proposed new standards of 0.0035 mg/l for both Class I and II groundwater should be changed to 0.014 mg/l for both classes.

<u>Trichloroethylene</u> – USEPA issued a memo from Assistant Administrator Susan Parker Bodine to its Regional Administrators on January 15, 2009, entitled "Interim Recommended Trichloroethylene (TCE) Toxicity Values to Assess Human Health Risk and Recommendations

for the Vapor Intrusion Pathway Analysis." (See Exhibit 1 to my this testimony) In the interest of promoting consistency with its earlier Toxicity Hierarchy memo from the Office of Solid Waste and Emergency Response (OSWER; discussed in my previous testimony in the Part 620 Groundwater Quality Standards hearing on pages 2-4), EPA in this January 15, 2009 memo recommends that the California EPA' s cancer oral Slope Factor of 0.013 per mg/kg/d and Inhalation Unit Risk of 2.0E-06 per ug/m3 be used to assess cancer risks-- values that the Toxicity Assessment Unit has been using since the Toxicity Hierarchy memo was issued. However, the January 15, 2009 memo now contains two recommendations for assessing noncancer inhalation risks (the previously recommended California EPA Reference Exposure Level (REL) of 600 ug/m3 and the New York State Dept. of Health's air criterion of 10 ug/m3).

These two values presented the Toxicity Assessment Unit with a dilemma, since they are over an order-of-magnitude different. Therefore, we reviewed the derivation of both values and decided that the New York air criterion was a more appropriate value for three reasons: (1) the California value evaluated studies published prior to 2000 whereas the New York value includes studies published prior to 2007; (2) the California value is based on a study that includes data from 19 workers whereas the New York value is based on data from 99 workers; and (3) the California value is based on self-reported neurological effects, whereas the New York value is based on objective clinical neurological measurements. Since we have been using the California cancer values already, all but one of the many TCE remediation objectives in the Tier 1 tables do not require updating because the values based on cancer risk are lower than the corresponding value for noncancer effects. This was also true for the soil objective for outdoor inhalation for the construction worker at the time we initially proposed these TACO amendments, since the objective for this pathway based on noncancer effects were calculated from the California value. However, the noncancer objective calculated from the smaller New York value now is lower than the objective based on cancer. Therefore, we are proposing to change the construction worker inhalation objective from 8.8 mg/kg to 2.9 mg/kg.

Averaging for the indoor inhalation pathway – One issue left unresolved after the first hearing for this TACO update was whether to allow averaging of sample results to demonstrate compliance with remediation objectives for the indoor inhalation pathway. Members of the Site Remediation Advisory Committee (SRAC) had asserted in meetings prior to the hearing that averaging results for this pathway made sense and that there should be no differences between this pathway and the other pathways for which averaging is already allowed. On the other hand, the Agency had expressed concern about the well-demonstrated variability in results for soil vapors, and to a lesser extent in groundwater samples, that made this pathway different from the other pathways, and also noted concerns about the possibility of missing "hot spot s" when calculating averages.

This issue remained unresolved prior to the hearing, and was only briefly touched upon at the hearing. It was then decided that the SRAC would try to develop proposed language to further address this issue. However, the SRAC was not able to develop a proposal for including averaging in the update by the time that testimony and comments were due to the Board for the second hearing, although they did state that they were amenable to limiting averaging to only soil samples, and not for soil vapors or groundwater samples. After receiving this information, the Agency had further internal discussions about allowing averaging only for soil samples and decided that this could be an appropriate way to demonstrate compliance for the indoor inhalation pathway. Further, the existing language at Section 742.225(d) would allow for this if the proposed new language creating Section 742.225(b)(5), which prohibits averaging for indoor inhalation for all pathways except through a plan approved in Tier 3, were to be removed from the proposed amendments. At a meeting with the SRAC on February 18, 2009 the Agency proposed to do this, and it was accepted by the SRAC. Thus, we now propose to delete the proposed Section 742.225(b)(5), and change the existing Section 742.225(d) to read (changes underlined):

"If a person chooses to composite soil samples or average soil sample results to demonstrate compliance relative to the indoor and outdoor inhalation exposure routes ~~route~~ or ingestion exposure route, the following requirements apply:"

Correcting text and tables - As the Agency and others continue to view and review the text and tables of this update, the need for additional corrections continues. The latest batch of corrections follows, with any needed explanations in parentheses.

- Section **742.510(b)**, last sentence should read, "...as set forth in Sections ~~Section~~ 742.505 (b)(3) and (b)(4)." (both 742.505(b)(3) and (b)(4) pertain to noncarcinogens mixtures).
- **Appendix A, Table A:** The 2-Chlorophenol superscript should be "c".
- **Appendix A, Table I:** The Class I groundwater remediation objective for Arsenic should be 0.01 mg/L.

Appendix A, Table L:

- A new footnote "c" needs to be added, "C_{sat} for pH of 6.8. If soil pH is other than 6.8, a site-specific C_{sat} should be calculated using equations S19 and J&E 6a and the pH-specific Koc values in Appendix C Table I."
- This footnote "c" should be applied to 2-Chlorophenol (because it is an ionizable organic).
- In footnote "b" the word "was" should be added before "calculated."

Appendix B, Table A:

- The compound 2-Chlorophenol should be moved to the "Ionizable Organics" section.
- The Class I and II migration to groundwater remediation objectives for Di-n-octyl phthalate should be "5.2" (for consistency in using two significant figures).
- The Class II migration to groundwater objective for Isopropylbenzene should be corrected from "460^{r}" to "400^{d}" (the risk-based value exceeds the subsurface C_{sat} value listed in Appendix A, Table A).
- The proposed update for Methoxychlor of 14 mg/kg with a "d" footnote for the Outdoor Inhalation pathway should be removed and the existing entry of "---^{c}" should be retained (the proposed entry is based on C_{sat} but Methoxychlor is a solid at 30 C with a melting point of 87 C, so C_{sat} should not be considered as a remediation objective); also, the proposed updates of 14 mg/kg for migration to Class I and II groundwater should be replaced with updated risk-based values of 80 mg/kg for Class I and 400 mg/kg for Class II, with an "r" footnote (for the same reason discussed above).
- Remove the "i" superscripts from the migration to groundwater objectives for 2,4,5-TP (updated physical/chemical data changes this chemical to non-ionizing).
- Change the superscript "b" to superscript "r" for Vanadium for the Class I migration to groundwater objective (a new Groundwater Standard is proposed for this chemical).
- Add the superscript "i" to the migration to groundwater remedial objectives for 2,4-Dinitrophenol.
- Add the superscript "i" to the migration to groundwater remedial objectives for MCPP.
- Correct the Arsenic Class I migration to groundwater remediation objective to 0.01 mg/L.

Appendix B, Table B:

- Correct the Class II migration to groundwater objective for Bis(2-ethylhexyl)phthalate from “200^{d}” to “68^{d}” (the Outdoor Inhalation C_{sat} was mistakenly listed).

- Correct the Class I and Class II migration to groundwater objectives for Butyl benzyl phthalate from “1,000^{d}” to “340^{d}” (the Outdoor Inhalation C_{sat} was mistakenly listed).

- The compound 2-Chlorophenol should be moved to the “Ionizable Organics” section.

- The Class I and II migration to groundwater remediation objectives for Di-n-octyl phthalate should be “5.2” (for consistency in using two significant figures).

- The remediation objective for Isopropylbenzene for migration to Class II groundwater should be corrected from “460^{r}” to “400^{d}” (same reason as above for Table A).

- The same changes specified above for Methoxychlor’s entries in Appendix B, Table A should also be made in Table B.

- Errata Sheet #1 instructs that a superscript “a” be added to the construction worker inhalation remediation objective for 2-Methylphenol, but this notation is inappropriate for this situation; footnote “b” should be used.

- The superscript “i” should be removed from the migration to groundwater remediation objectives for 2,4,5-TP (same reason as above for Table A).

- Add the superscript “i” to the migration to groundwater remediation objectives for 2,4-Dinitrophenol.

- Add the superscript “i” to the migration to groundwater remediation objectives for MCPP.

- Correct the Arsenic Class I migration to groundwater RO to 0.01 mg/L.

Appendix B, Table G: The entry for Isopropylbenzene should be placed in alphabetical order.

Appendix C, Tables B & D: Endnote “a” is no longer needed.

This concludes my supplemental testimony.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EXHIBIT
1

JAN 15 2009

MEMORANDUM

OFFICE OF
SOLID WASTE AND
EMERGENCY RESPONSE

SUBJECT: Interim Recommended Trichloroethylene (TCE) Toxicity Values to Assess Human Health Risk and Recommendations for the Vapor Intrusion Pathway Analysis

Susan Parker Bodine

FROM: Susan Parker Bodine
Assistant Administrator

TO: Regional Administrators

The purpose of this memorandum is two-fold. First, consistent with OSWER's chemical toxicity hierarchy guidance we recommend interim use of existing toxicity values developed by other regulatory agencies for trichloroethylene (TCE) for evaluating potential site-specific risks from inhalation or oral exposures to protect for both cancer and non- cancer effects. Second, we recommend an approach for assessing human health risk for the vapor intrusion (VI) pathway for sites addressed under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) or the Resource Conservation and Recovery Act (RCRA). This guidance is intended to facilitate better decisions by Regions in Superfund, RCRA, and Federal Facility assessments addressing risks due to exposure to TCE from vapor intrusion, and other pathways are addressed in the EPA Regions.

The Office of Solid Waste and Emergency Response (OSWER) recommends using its 2003 Toxicity Hierarchy[1] in the development of a preliminary remediation goal (PRG) for TCE.[2]. We generally recommend the use of the California Environmental Protection Agency's (Cal EPA's) inhalation unit risk value[3] (IUR) of 2.0E-06$(ug/m^3)^{-1}$

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[1] *Human Health Toxicity Values in Superfund Risk Assessments* (OSWER Directive 9285.7-53, December 5, 2003), referred to in this document as the 2003 Toxicity Hierarchy, recommends using a tiered approach for identifying toxicity values. As discussed in the 2003 guidance, Tier 1 refers to IRIS, Tier 2 refers to EPA's Provisional Peer Reviewed Toxicity Values, and Tier 3 refers to other sources.
http://www.epa.gov/oswer/riskassessment/pdf/hhmemo.pdf

[2] We note that this hierarchy is generally consistent with the application of the criteria developed by the Environmental Council of the States (ECOS). Environmental Council of States (ECOS) issue paper; *Identification and Selection of Toxicity Values/Criteria for CERCLA and Hazardous Waste Site Risk Assessments in the Absence of IRIS Values*. This issue paper was developed by a task force comprised of State and DOD. EPA provided technical support to the effort under the auspices of an ECOS/DOD work group on emerging contaminants.
http://www.ecos.org/files/2733_file_FINAL_ECOS_PV_Paper_4_23_07.doc

[3] California Environmental Protection Agency (Cal EPA). *Air Toxics Hot Spot Program Risk Assessment Guidelines, Part II. Technical Support for Describing Available Cancer Potency Factors*., Office of Environmental Health Hazard Assessment, December 2002. http://www.oehha.ca.gov/air/cancer_guide/TSD2.html

and oral cancer slope factor[4] of 0.013 (mg/kg-day)$^{-1}$ for evaluating the carcinogenic effects of TCE in site-specific risk assessments at sites addressed under CERCLA and RCRA. Acceptable air exposure levels are generally concentration levels that represent an upper bound life-time cancer risk to an individual between 10^{-6} (1.2 ug/m^3) and 10^{-4} (120 ug/m^3)[5]. Consistent with the National Contingency Plan (NCP), OSWER recommends using 1.2 ug/m^3 as the point of departure for determining preliminary remediation goals (see 40 CFR 300 Section 430(e)(2)(i)(A)(2)); this generally is the air concentration representing a 10^{-6} excess cancer risk using the Cal EPA inhalation unit risk. For assessing non carcinogenic effects of TCE, OSWER has identified two values that can be considered in evaluating systemic toxicity at sites: the 10 ug/m^3 air criterion developed by the New York State Department of Health[6] and the 600 ug/m^3 Chronic Reference Exposure Level developed by Cal EPA[7]. OSWER believes that both of these values may be appropriate Tier 3 toxicity values under the OSWER Toxicity Hierarchy.

As discussed in the OSWER Toxicity Hierarchy guidance, draft toxicity assessments generally are not appropriate for use until they have been through peer review, the peer review comments have been addressed in a revised draft, and the revised draft is publicly available. The toxicity values in this guidance may be appropriate for Regions to use to assess risks at least until toxicity values for TCE are available in the Environmental Protection Agency's (EPA's) Integrated Risk Information System (IRIS) database, or until further scientific analysis indicates a more appropriate value is available. When a new IRIS toxicity assessment is available, OSWER may review sites to ensure that sites addressed under this interim approach remain protective given revised toxicity values. If new scientific information representing the best available science becomes available before a new IRIS toxicity assessment is available, OSWER may revisit the toxicity values provided in this guidance.

This guidance supersedes previous guidance on TCE toxicity values found in OSWER's "Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils" (EPA 530-D-02-004, November 2002). This guidance is consistent with our 2003 guidance on using a hierarchy of existing chemical toxicity sources; it does not represent a new, independent review of TCE toxicity, which EPA has currently underway as part of the IRIS program.

This guidance recommends an oral cancer slope factor for use in risk assessments and is designed to help provide an estimate of the cumulative risk at sites and make other

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[4] California Environmental Protection Agency (Cal EPA) *Public Health Goal for Trichloroethylene*, Office of Environmental Health Hazard Assessment, Cal EPA, February 1999. http://www.oehha.ca.gov/water/phg/pdf/tce_f.pdf

[5] These acceptable air levels (concentrations) were derived based on a residential scenario of continuous exposure (24 hrs./day and 350 d/yr), for 30 years averaged over a 70 year lifetime (equation presented in Figure 2 of appendix). Site specific exposure assumptions may be different and then could lead to different acceptable air exposure levels.

[6] NYSDOH. 2006. Center for Environmental Health, Bureau of Toxic Substances Assessment, Trichloroethene Air Criteria Document, October. http://www.health.state.ny.us/environmental/chemicals/trichloroethene/docs/cd_tce.pdf

[7] Chronic Toxicity Summary: Trichloroethylene. Documentation for a chronic Reference Exposure Level for Trichloroethylene, California EPA Office of Environmental Health Hazard Assessment, April 2000. www.oehha.ca.gov/air/chronic_rel.

cleanup decisions; this guidance does not affect or replace statutory or regulatory requirements. (for example, meeting applicable or relevant and appropriate requirements (ARARs)) under CERCLA or RCRA. For example, the maximum contaminant level (MCL) for TCE, 5 ug/l, (or a lower concentration if required by a state ARAR) generally should continue to be considered as an ARAR for the cleanup under CERCLA of ground water that may be used as drinking water. OSWER recommends the same approach be taken under RCRA. However, when other ground water exposure pathways may be complete (such as vapor intrusion into indoor air) or multiple contaminants are present, site-specific conditions should be evaluated to ensure that use of the MCL would be sufficiently protective of human health and the environment.

Application of Toxicity Hierarchy for TCE

Background

As discussed in the 2003 Toxicity Hierarchy[8], OSWER recommends using a hierarchy of sources of toxicological information that Regional risk assessors and managers should consider for site-specific risk assessments. Generally, Regions should first look for toxicity information in the Integrated Risk Information System (IRIS) developed by EPA's Office of Research and Development; as discussed in the 2003 guidance, these are considered Tier 1 values in the hierarchy. If quantitative information is not available there, generally Regions should next look to Provisional Peer Reviewed Toxicity Values (PPRTVs) developed by EPA's National Center for Environmental Assessment/Superfund Technical Health Risk Support Center (STSC); as discussed in the 2003 guidance, these are considered Tier 2 values in the hierarchy. If toxicity values are not available from either Tier 1 or 2, generally Regions should look to other high quality sources of toxicity information developed by other regulatory or health agencies that can be used for risk assessment; as discussed in the 2003 guidance, these are considered Tier 3 values in this hierarchy.

It should be noted that the 2003 Toxicity Hierarchy states:

> "In general, draft toxicity assessments are not appropriate for use until they have been through peer review, the peer review comments have been addressed in a revised draft, and the revised draft is publicly available."

Thus, the cancer and non-cancer toxicity values presented in EPA's 2001 draft risk assessment for TCE are not recommended as appropriate Tier 3 values nor are they discussed in this document based on their "draft status," consistent with the 2003 Toxicity Hierarchy.

A consensus issue paper from the Department of Defense, EPA, and the Environmental Council of States (ECOS) supported OSWER's hierarchy and recommended a set of preferences for evaluating potential toxicity values that largely mirror EPA's. These preferences include transparent assessments that have received internal and external peer review that are derived using an established methodology, that incorporate current best scientific practice, and that consider the quality of the studies, including statistical power, as well as considering assessments that corroborate data amongst pertinent studies. In addition, both the values and supporting documentation should be publicly available and a preference should be given to toxicity values that are

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[8] See footnote 1

consistent with the duration of exposure being assessed. Selection of a toxicity value should include an understanding of the available sources of toxicity data and the strengths and weaknesses of each source in order to select the most appropriate toxicity value for use in a risk assessment. Because there is no toxicity value for TCE either in IRIS (Tier 1) or as a PPRTV (Tier 2), EPA evaluated other high quality sources of toxicity information (Tier 3) developed by other regulatory or health agencies.

Consistent with CERCLA and the NCP, protection of human health and the environment is a threshold requirement for selected remedies (see e.g., 40 CFR §300.430(f)(1)(i)(A)). In the CERCLA remedy selection process, preliminary remediation goals (PRGs) typically are developed as a site-specific tool when setting cleanup levels. At CERCLA sites, PRGs typically are "statements of the desired endpoint concentrations or risk levels" (see e.g., 55 Fed. Reg. 8713; March 8, 1990); generally they are conservative, default endpoint concentrations used in screening and initial development of remedial alternatives before consideration of more detailed information from the site-specific risk assessment.

The NCP states:

> Remediation goals shall establish acceptable exposure levels that are protective of human health and the environment and shall be developed by considering the following:
>
> (A) Applicable or relevant and appropriate requirements under federal environmental or state environmental or facility siting laws, if available, and the following factors:
> (*1*) For systemic toxicants, acceptable exposure levels shall represent concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, incorporating an adequate margin of safety;
> (*2*) For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6} using information on the relationship between dose and response. The 10^{-6} risk level shall be used as the point of departure for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of the presence of multiple contaminants at a site or multiple pathways of exposure;
> (*3*) Factors related to technical limitations such as detection/quantification limits for contaminants;
> (*4*) Factors related to uncertainty; and
> (*5*) Other pertinent information."

40CFR§300.430(e)(2)(i)(A).

Cancer Toxicity Values for TCE

After analyzing potential Tier 3 human health toxicity values using the preferences described in the ECOS paper, OSWER believes that the Cal EPA IUR of

2.0E-06 $(ug/m^3)^{-1}$ presented in the Air Toxics Hot Spots Program (Cal EPA, 2002) and an oral cancer slope factor of 0.013 $(mg/kg\text{-}day)^{-1}$ presented in the "Public Health Goal for Drinking Water" (Cal EPA, 1999) generally are appropriate for use in site specific risk assessments at least until a revised IRIS value is available or until further scientific analysis identifies a more appropriate value. These values were developed specifically for use in risk assessments and are consistent with the 2003 Toxicity Hierarchy

The Cal EPA IUR is derived from the geometric mean of the unit risks from four inhalation studies on mice and includes liver cancers, lung cancer, and lymphoma endpoints [9] (see appendix for a more detailed discussion). The Cal EPA oral cancer slope factor was based on the geometric mean of four values based on the occurrence of hepatocellular carcinomas and adenocarcinomas in mice in two studies, in both sexes, by inhalation and oral routes of administrations and a linear dose response approach.[10] OSWER believes the IUR and oral cancer slope factor developed by Cal EPA are reasonably consistent with values developed by other researchers and regulators, also discussed in more detail in the appendix. OSWER believes the Cal EPA IUR and oral cancer slope factor provide an appropriate interim approach, based on information currently available. These recommended toxicity values can be used to evaluate lifetime excess cancer risk from TCE exposure at least until toxicity values for TCE are available in EPA's IRIS database or until further scientific analysis indicates a more appropriate value is available.

Consistent with the National Contingency Plan (NCP) (40 CFR §300.430(e)(2)(i)(A)(2)), OSWER recommends using a concentration of 1.2 ug/m3, corresponding to the 10^{-6} cancer risk level using the Cal EPA IUR, as the point of departure for determining remediation goals. OSWER also recommends using 1 ug/m^3 to 120 ug/m^3 as the generally acceptable concentration levels corresponding to 10^{-6} to 10^{-4} cancer risk (See footnote 5).

Systemic, Non cancer Toxicity Value for TCE

After analyzing existing potential Tier 3 human health toxicity values, OSWER has identified two values as appropriate for consideration: Cal EPA's reference exposure level (REL) and NYSDOH's non-cancer air criterion. The National Research Council (NRC, 2006), in its comments on the non cancer studies analyzed in EPA's 2001 draft risk assessment noted that several neurotoxicity studies reported common effects in humans and rats at similar concentrations. The studies included reports in humans of changes in trigeminal nerve function and motor incoordination (Ruijten et al. 1991; Rasmussen et al. 1993) and symptoms including nausea, drowsiness, and fatigue (Okawa and Bodner 1973; Vandervort and Polakoff 1973). Studies in rats showed changes at similar levels (adjusted for human equivalence) in heart rate and wakefulness (Arito et al. 1994). Furthermore, the NRC also noted that new information on neurological effects of TCE published since 2001 "is limited and thus may offer little in the way of amendment" to the current understanding of non cancer effects. These comments support the studies

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[9] Trichloroethylene. In: Technical Support Document for Describing Available Cancer Potency Factors., California EPA Office of Environmental Health Hazard Assessment., December 2002. pp 522-530.

[10] Public Health Goal for Trichloroethylene in Drinking Water, California EPA Office of Environmental Health Hazard Assessment, February 1999., www.oehha.ca.gov

cited in the development of these values as representing noteworthy and current understanding regarding these systemic effects.

The Cal EPA reference exposure value (REL) is based on a pre-2000 review of literature and used the 1973 Vandervort and Polakoff study to develop a chronic REL [11] (similar to a reference concentration) of 600 ug/m^3 based on self reported neurological effects (drowsiness, fatigue, headache) and eye irritation in workers. This study looked at self-reported symptoms in 19 workers, who had an average of 8 years of exposure, with exposure concentrations extrapolated from one day of personal air concentration measurements. The lack of reproductive and developmental toxicity studies and the lack of a no effect level were identified by Cal EPA as major areas of uncertainty. In addition, OSWER identified the use of self-reported symptoms as a limitation of the study. Cal EPA used an estimated LOAEL of 60 mg/m^3 and an uncertainty factor of 100 to account for intraspecies differences and the use of an LOAEL.

NYSDOH is based on a pre-2007 review of the literature on the non-cancer health effects of TCE and includes studies published more recently than those cited in the Cal EPA REL. NYSDOH used the 1993 Rasmussen et al. study to derive a potential non-cancer air criterion (similar to a reference concentration) of 10 ug/m^3 based on neurological effects (as measured by coordination tests) among 99 Danish metal degreasers exposed for 11 years. Limitations of the study include some uncertainty about the actual long-term exposure levels of the workers to TCE during their employment, and that 25 of 99 subjects were exposed primarily to CFC 113. The appendix provides further discussion of these points.

The NYS DOH assessment is limited by gaps in the data on developmental effects and immunotoxicity, and concerns about adequacy of methods for evaluating health risks to children (limitations it shares with the CalEPA assessment). NYSDOH used an estimated LOAEL of 11 mg/m^3 and an uncertainty factor of 1000 to account for intraspecies differences, use of an LOAEL, and extrapolation from 11 years of exposure to a lifetime. The NYSDOH analysis also indicated that this air criterion of 10 ug/m^3 is only slightly lower than the air criterion of 20 ug/m^3 they estimated based on developmental and reproductive effects.

Both CalEPA and NYS DOH had an external peer review process and allowed for public comment before finalizing their respective assessments. The NYS DOH assessment was finalized in 2006 and the CalEPA assessment was finalized in 2000, but only the NYSDOH assessment discussed the Rasmussen et al. study. Comparing the Rasmussen et al. study underlying the NYSDOH air criterion to the Vandervort and Polakoff study underlying the Cal EPA REL, the LOAEL for the Rasmussen et al. (1993) study is about 1/6th of the LOAEL from the study Cal EPA used. OSWER also found that the Rasmussen study was based on a significantly larger number of subjects (99 compared to 19) and used objective clinical neurological measurements compared to self-reported symptoms.

While both the NYSDOH value and the Cal EPA REL should be considered as

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[11] Chronic Toxicity Summary: Trichloroethylene. Documentation for a chronic Reference Exposure Level for Trichloroethylene, California EPA Office of Environmental Health Hazard Assessment, April 2000. http://www.oehha.ca.gov/air/chronic_rels/pdf/79016.pdf.

Tier 3 toxicity values under the OSWER Toxicity Hierarchy, OSWER notes that the NYSDOH criterion is based on a more extensive presentation of health endpoints and a more recent evaluation of the available health effects literature.

Other exposure scenarios (e.g., commercial/industrial) may result in a different concentration range based on different exposure assumptions. OSWER recommends that the Regions implementing RCRA corrective action take this analysis into consideration for those settings as well.

Vapor Intrusion Recommendations

The Agency often evaluates TCE inhalation risks arising from the vapor intrusion pathway; this is a potentially significant exposure pathway associated with volatile contaminants at wastes sites. While this guidance focuses on TCE, the following recommendations relating to vapor intrusion are relevant and useful for other volatile organic compounds as well.

Considerable information, primarily empirically-based, has been generated regarding evaluation of the VI pathway since the pathway emerged as a national issue in the late 1990s and especially since publication of EPA's draft vapor intrusion guidance in November 2002.[12] . Our experience with vapor intrusion investigations indicates that no single media data set, whether it be ground water, soil gas, sub-slab gas or indoor air, can be used reliably to fully evaluate the potential for risks from VI above health risk-based levels due to the large number of variables affecting the transport of vapors from the subsurface to indoor air and the confounding influence of indoor sources of common subsurface contaminants. Our investigations have found that spatial and temporal impacts on volatile organic chemical (VOC) concentrations are highly variable. Some of this variability is due to vertical and horizontal differences in subsurface conditions and the differences in structural conditions, such as foundation cracks, and ventilation rates from one building to another. Variation in weather conditions, such as rainfall and barometric pressure, can also have a significant impact. All these factors strongly suggest that multiple lines of evidence are important to evaluate VI as an exposure pathway of concern at sites where hazardous VOCs have been released to the subsurface[13].

Lines of evidence to evaluate the VI pathway may include: site history and geology, groundwater data, soil gas data, sub-slab soil gas data, crawlspace sample data, preferential pathway sample data, indoor air data, outdoor air data, tracer compound data, chemical ratio data, modeling results, building/home surveys, chemical use inventory, and other supporting information, as appropriate. By using the multiple lines of evidence approach, project managers usually have been successful in determining whether the VI exposure pathway for TCE is complete and whether any elevated levels of TCE in indoor

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[12] OSWER Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion Guidance), EPA 530-D-02-004, November 2002.

[13] We note that based on an evaluation of the evidence and experience at numerous sites with VI, the Interstate Technology and Regulatory Council also recommended a multiple lines of evidence approach in their document entitled, Vapor Intrusion Pathway: A Practical Guideline (January 2007) Interstate Technology and Regulatory Council. Vapor Intrusion Pathway: A Practical Guideline, VI-1. Washington, DC., January 2007. www.itrcweb.org

air are likely caused by subsurface VI, an indoor source (consumer product), or an outdoor source. Generally, site conditions will determine the number of lines of evidence that provide enough information for decision making. For example, where ground water and sub-slab soil gas concentrations are low, project managers could determine that the VI exposure pathway is not complete with relatively few lines of evidence. Coordination with a risk assessor and hydrogeologist generally will be very useful in evaluating the multiple lines of evidence.

OSWER believes it is often useful to collect sufficient data to evaluate two or more of these lines of evidence in parallel. For example, Regions should consider, it may be more expeditious and cost-effective to sample indoor air for TCE directly where there is existing ground water or sub-slab soil gas data that suggest the potential for a VI problem. If the decision is made to sample indoors for TCE, we generally recommend the collection of sub-slab soil gas samples along with indoor and outdoor air samples. Collecting sub-slab samples along with air samples often can provide a more complete evaluation and allow a more definitive conclusion to be drawn regarding the VI pathway for TCE at a particular site. However, sub-slab sampling may not be necessary when collecting indoor air samples for degradation products, such as cis-1,2-dichloroethene or 1,1-dichloroethene, that have few or no indoor or outdoor sources. Also, when a building is built on concrete reinforced with pressure tension cables, sub-slab sampling may not be feasible.

We recognize that some states and facilities have found it expeditious in some situations to implement remediation rather than do extensive indoor air sampling; however, the cost of oversight, monitoring, operations, and maintenance should be factored into the decision to remediate.

The potential for VI should be considered at sites that may involve new development projects overlying contaminated soil or shallow ground water. Property developers, regulators, city planners and others involved in redevelopment and Brownfields projects and sites addressed under the Base Realignment and Closure Act (BRAC) should consider designing engineering controls to mitigate for the potential of VI before new buildings are constructed. This recommended approach can have multiple benefits:

- Engineering controls may be used to address the uncertainty in both site characterization and the toxicity of contaminants;
- It is often more cost-effective to mitigate potential VI in advance of construction than to conduct the extensive sampling necessary to determine whether VI might result in unacceptable health risk at the site, and
- It is typically more cost-effective to incorporate VI mitigation measures during the design/build phase than to retrofit an existing building.

Conclusion

We recommend that Regions use the approach described in this guidance to evaluate sites with potential VI of TCE and monitor developments with regard to TCE.

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APPENDIX

Supplemental Information and Discussion

The US Environmental Protection Agency's (EPA's) Office of Research and Development (ORD) developed a draft health risk assessment in 2001 (U.S. EPA, 2001); however, external peer review commenters raised several important issues. As a result, ORD developed a series of issue papers on various aspects of trichloroethylene (TCE) toxicology based on the comments from the external peer reviewers, which were then submitted as background information to the National Academy of Science (NAS) for review (U. S. EPA, 2005 a, b, c, d). NAS was asked to examine issues critical to developing an objective, realistic, scientifically based health risk assessment for TCE. The National Research Council (NRC) released their report in 2006 (NRC, 2006), providing ORD with further insights as they develop a revised health risk assessment. Given the Office of Solid Waste and Emergency Response's (OSWER's) policy not to use draft toxicology values until peer review comments have been addressed in a publicly available document and the further effort that ORD is continuing, OSWER will not rely upon the 2001 draft risk assessment and recommends that the Regions and others not utilize the 2001 draft risk assessment for quantifying the toxicity of TCE.

Because no Tier 1 (Integrated Risk Information System (IRIS)) or Tier 2 (Provisional Peer-Reviewed Toxicity Values (PPRTVs)) toxicity values are currently available, typical Tier 3 sources were inventoried and toxicity values evaluated. Typical Tier 3 sources include other federal agencies[14] and states that may develop toxicity values that would be useful for site-specific risk assessments. We identified three States (California, New York, and Indiana) with potentially relevant values. In addition, we identified one scientific research paper (Lewandowski and Rhomberg (2005)) that addressed the question of TCE toxicity and that had some form of cancer assessment for TCE.[15] These are discussed in the paragraphs below.

Cancer Assessments

To inform their development of an air guideline for TCE, NYSDOH developed an array of cancer slope factors and potential air criteria for kidney tumors in rats (Maltoni et al., 1986), liver tumors in mice (Maltoni et al, 1986), lung tumors in mice (Maltoni et al., 1986, Fukuda et al. 1983), testes tumors in rats (Maltoni et al., 1986), and lymphomas in mice and humans (Henschler et al., 1980, Hansen et al., 2001).

The NYSDOH analysis provides a good overview of the current data available on the carcinogenicity of TCE. From the available studies, they identified five cancer endpoints for which they developed potency factors. These five endpoints were rat kidney tumors, rat testes tumors, mouse lung tumors, mouse liver tumors, and mouse lymphoma, in order of increasing toxicity. These data are arrayed in Figure 1 at the end of the Appendix. NYSDOH also looked at human epidemiological data to check the relevance of the cancer endpoints to humans. If humans and animals develop cancer in the same target organs, then the endpoint is more relevant than if humans do not develop

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[14] ATSDR has neither cancer toxicity values nor chronic minimal risk levels in their Toxicological Profile for TCE (ATSDR, Dec 1997).

[15] We include the research paper of Lewandowski and Rhomberg for comparison and completeness only.

cancer in that organ. Human epidemiologic data do not support the conclusion that TCE is a risk factor for lung cancer, so this health endpoint was given less weight in the NYSDOH assessment (NYSDOH, 2006). NYSDOH also incorporated an age adjustment factor to account for potential increased susceptibility of children to the affects of TCE exposure, where their analysis determined it was appropriate. Figure 1 graphs their age adjusted cancer risk ranges for kidney and liver tumors.

Cal EPA has an inhalation unit risk (IUR), an oral cancer slope factor, and an inhalation cancer slope factor presented on the Office of Environmental Health Hazard Assessment website. http://www.oehha.ca.gov/risk/ChemicalDB/cancerpotency.asp?name=Trichloroethylene&number=79016. The IUR and the inhalation cancer slope factor represent the same analysis expressed in different units. Cal EPA based their oral cancer slope factor of 0.013 $(mg/kg\text{-}day)^{-1}$ on slope factors derived from liver tumor data for mice exposed orally (National Cancer Institute, 1976) or by inhalation (Maltoni et al., 1986, 1988) and from lung tumor data for mice exposed by inhalation (Fukuda et al., 1983). Human equivalent doses were calculated with three different dose metrics using physiologically-based pharmacokinetic (PBPK) modeling. The slope factor based on liver tumor incidence using a total TCE metabolism dose metric (AMET dose metric) was selected as the most appropriate based on model fitting criteria (Cal EPA, 1999).

The Cal EPA IUR of 2.0E-06$(ug/m^3)^{-1}$ was based on the geometric mean of the 95% upper confidence limit potency estimates from four inhalation studies (Bell et al., 1978; Henschler et al., 1980; Fukuda et al., 1983; and Maltoni et al., 1986) based on mouse liver carcinoma, mouse malignant lymphoma, mouse lung adenocarcinoma, and mouse hepatoma, respectively (Cal EPA, 1990).

Cal EPA looked at many of the same studies as NYS to develop their cancer potency values. The California evaluation is older, so some later studies were not available to them. California chose to calculate their IUR from four inhalation studies (Bell et al., 1978; Henschler et al., 1980; Fukuda et al., 1983; and Maltoni et al., 1986) based on mouse liver carcinoma, mouse malignant lymphoma, mouse lung adenocarcinoma, and mouse hepatoma, respectively. They determined that approach would result in the most protective and supportable cancer potency factor. Their IUR incorporates several of the more potent potential IURs identified by NYSDOH. Air concentrations associated with the 10^{-6} to 10^{-4} lifetime excess cancer risk range using the Cal EPA IUR can be found on Figure 1.

The Indiana Department of Environmental Management (IDEM) conducted a focused review of the toxicity studies cited in the 2001 ORD draft TCE risk assessment, with the primary goal of selecting a single cancer slope factor from within the range of slope factors presented in the 2001 ORD draft TCE risk assessment. IDEM did not consider studies published after 2001; although their review was peer reviewed, it is not recommended because of its more limited focus. Because of the specific, narrow focus of the IDEM review (i.e., a predetermined range of cancer potency values derived from studies considered in the 2001 ORD draft TCE risk assessment) and its reliance on the 2001 ORD draft TCE risk assessment, which as we noted earlier is still considered a draft document, we determined that the IDEM review was not the best source for establishing an interim Tier 3 toxicity value. However, their analysis is germane and we will present the results of their analysis for comparison. IDEM (2005) based their cancer potency value on mouse bioassays (NCI, 1976; NTP, 1990) and developed an oral cancer slope factor of 0.034 (mg/kg-day)$^{-1}$ adjusted to 0.1 (mg/kg-day)$^{-1}$ to protect children. For inhalation exposures, they developed an inhalation cancer slope factor of 0.018 (mg/kg-day)$^{-1}$ adjusted to 0.054 (mg/kg-day)$^{-1}$ to protect children, based on the same studies.

IDEM based their inhalation cancer slope factor on an evaluation of mouse liver tumors. They developed cancer slope factors independently for each sex from the NCI (1976) and NTP (1990) studies of the mouse liver tumor endpoint. From PBPK modeling and a goodness of fit analysis, IDEM determined that the data were best represented as a lognormal distribution, from which they calculated the harmonic mean of the four datasets for their inhalation cancer slope factor. To this inhalation cancer slope factor, they applied a factor of three to account for children's exposure. Figure 1 includes the air concentrations associated with the cancer risk range using the IDEM cancer slope factor. The 1x 10^{-6} cancer risk equates to a concentration of 0.15 ug/m^3.

Finally, Lewandowski and Rhomberg (2005) undertook an analysis to derive an interim unit cancer risk for low-dose inhalation exposure based on available scientific information. Based on accepted principles for evaluating scientific studies, they identify the most appropriate interim unit risk for low-level inhalation exposure as 9.0E-7 (ug/m^3)$^{-1}$ based on epidemiological data. The authors do not represent a regulatory agency, which typically EPA would rely on for Tier 3 assessments. However, we included the results of this paper for comparison and completeness.

Lewandowski and Rhomberg arrayed the available cancer studies, both human and animal, with the goal of identifying a plausible interim cancer endpoint. They asserted that the uncertainty introduced by using a human study with uncertain exposures was preferable to the uncertainty of interspecies extrapolation. As a result, they chose the Antilla (1995) study from which they quantified an IUR based on human liver cancers. Using this approach, they derived an IUR marginally less potent than, but within the rounding range of the Cal EPA IUR. A 1x 10^{-6} cancer risk equates to 2.7 ug/m^3 using the Lewandowski and Rhomberg recommendation and 1.2 ug/m^3 using the Cal EP IUR, which is close concordance in this field. However, the NAS indicated in their review that the available human exposure data were more uncertain than the interspecies extrapolation, which argues for using the animal data as the basis for quantification.

Non Cancer Assessments

Cal EPA also has a chronic inhalation reference exposure level of 600 ug/m^3. Cal EPA developed this value for risk assessment using established methodology. These values are peer-reviewed and are publicly available.

After thorough analysis, the Cal EPA chronic reference exposure level (REL) of 600 ug/m^3 was based on neurological effects (drowsiness, fatigue, headache) and eye irritation in workers (Vandervort and Polakoff, 1973). This study analyzed self-reported symptoms of 19 workers employed for an average of 8 years working with TCE as a degreaser, and included drowsiness, heart palpitations, weakness, and dizziness. Time-weighted 8-hour exposures to TCE, extrapolated from 1-day personal breathing zone and area samples ranged from 172-419 mg/m^3. The lack of reproductive and developmental toxicity studies and the lack of a no effect level were identified by Cal EPA as major areas of uncertainty. In addition, OSWER identified the use of self-reported symptoms as a limitation of the study.

NYSDOH also derived a number of potential air criteria based on studies of the non-cancer effects of TCE. After thorough analysis, NYSDOH selected 10 ug/m^3 as the most appropriate criterion to assess noncancer effects of TCE. (NYSDOH, 2006, page 81). The critical study for non-cancer endpoints that NYSDOH identified was a study by Rasmussen et al. (1993) which investigated clinical neurological effects among Danish metal degreasers. This study examined clinical neurological effects in 99 metal degreasers after long-term exposure to TCE. For 70 of the workers, the dominant exposure was to TCE for 35 hours/week, with a mean exposure duration of 7.1 years, while for 25 of the workers, dominant exposure was to 1,1,2-trichloro-1,2,2-trifluoroethane (CFC113) for 15.1 hours/week, with a mean exposure duration of 4.2 years. Evidence of air exposure was extrapolated from measurement of urinary metabolite TCA. Clinical measures of effect (as measured by coordination tests) show significant increase with increasing exposure duration. Limitations of the study include some uncertainty about the actual long-term exposure levels of the workers to TCE during their employment, and that 25 of 99 subjects were exposed primarily to CFC 113. However, as NYSDOH notes,

> "However, a separate, earlier report by the same investigators on the same cohort indicated that only 3 of the 99 workers showed slight signs of psychoorganic syndrome (i.e., reduced performance on tests evaluating motor coordination, psychomotor speed and memory) that the authors attributed solely to CFC 113 (Rasmussen et al., 1988). In limited short-term tests, CFC 113 has also been shown to be less potent than TCE in causing effects on psychomotor performance in humans, with the reported effect levels being about 12-fold higher (2500 ppm versus 200 ppm) (Stopps and McLaughlin et al., 1967). The greater potency of TCE compared to CFC 113, and the finding that only a small percentage of the Rasmussen et al. (1993) cohort was identified as having neurological deficits attributable to CFC 113, suggest that the observed deficits in motor coordination observed by Rasmussen et al. (1993) are primarily due to TCE exposure."

From this epidemiological data presented by Rasmussen et al., NYSDOH derived an air criterion for evaluating the non-cancer effects from exposure to TCE in ambient air (analogous to a reference concentration) of 10 ug/m^3. Ultimately, NYSDOH supported their evaluation by looking at the weight of scientific evidence, observing:

"Several other factors increased confidence in the CNS criterion as the basis of the TCE criterion for non-carcinogenic effects:
(1) inhaled TCE is unequivocally an animal and human neurotoxicant;
(2) comparison of the points-of-departure for the various endpoints indicates that CNS may be more sensitive to the toxic effects of inhaled TCE than other organ, systems, or lifestages;
(3) the characteristics of children were specifically addressed in the derivation;
(4) it is based on a good epidemiologic study (Rasmussen et al., 1993) for use in dose response assessment because although it had a relatively small cohort (n = 99), it did have an extended exposure duration, a dose-response relationship, and concurrent

biological monitoring data;
(5) a limitation of the study (the concomitant exposure to CFC 113) is not considered a major confounding factor because of its lower CNS potency compared to TCE and because only a small percentage of the cohort was identified as having effects related to CFC 113 exposure; and
(6) it is similar or lower than the potential criteria based on CNS effects, including effects in adult animals (Arito et al., 1994) and neurobehavioral effects in young animals (e.g., Isaacson and Taylor, 1989)."

The NYSDOH analysis indicates that 10 ug/m^3 is only slightly lower than potential criteria based on other non-cancer endpoints (e.g. developmental effects (Isaacson and Taylor, 1989; NTP, 1986) and reproductive effects (Land et al., 1981; Kumar et al., 2000, 2001). The NYS DOH assessment is limited by gaps in the data on developmental effects and immunotoxicity, and concerns about adequacy of methods for evaluating health risks to children (limitations it shares with the CalEPA assessment).

All of the studies discussed above were considered in developing the NYSDOH air guideline, but none were specifically selected as the best study upon which to base a toxicity value, since that was not their ultimate goal. However, they did identify the Rasmussen study as the critical study for CNS effects and stated "the recommended criterion for evaluating the risks of non-carcinogenic effects from chronic exposure to TCE in ambient air is 10ug/m^3" (NYSDOH, 2006, page 81). Ultimately, their air guideline was set at 5 ug/m^3, as a risk management decision, "based partly on residual concerns in three toxicologic areas: (1) gaps on the non-carcinogenic effects of TCE, including gaps in the data on developmental effects and immunotoxicity, (2) concerns about adequacy of methods for evaluating health risks to children, and (3) concerns about human carcinogenicity of TCE." (NYSDOH, 2006).

The NYSDOH analysis was based on current science, was peer-reviewed, and is publicly available. However, because NYSDOH's final TCE air guideline is a risk management value that considers factors other than systemic toxicity, such as practicality and analytical sensitivity, EPA has focused on its toxicity values, i.e., cancer slope factors and air criteria, in this review.

With respect to non-cancer endpoints, both Cal EPA and NYSDOH based their assessments on epidemiological studies. Cal EPA based their reference exposure level on Vandervort and Polankoff (1973). This study looked at self-reported endpoints in 19 subjects, who had an average of 8 years of exposure, with exposure concentrations extrapolated from one day of concentration measurements. The NYSDOH assessment identified Rasmussen et al. (1993) as their critical study. Rasmussen et al. is a more recent study, had a significantly larger number of subjects than Vandervort and Polankoff (99 compared to 19), had objective clinical neurological endpoints compared to a self-reported symptoms, and an LOAEL 1/6th that of the Cal EPA study. The NYSDOH report described the strengths and limitations of the Rasmussen study as follows: "Strengths of the Rasmussen et al. (1993) study include the fact that it evaluated TCE-related CNS effects in a reasonably-sized human cohort (which eliminates the uncertainty associated with interspecies extrapolation), the extended exposure duration (as long as 35 years), a statistically significant trend for increasing severity of a sensitive CNS effect (motor coordination deficits) with increasing exposure duration, and concurrent biological monitoring data (urinary TCA) that can be used with pharmacokinetic modeling to estimate a TCE air concentration at the LOEL. A limitation of the Rasmussen et al. (1993) study is the concomitant exposure to CFC 113, which, based on its lower neurological potency compared to TCE and that only a small percentage of the cohort was identified as having effects related to CFC 113 exposure, is not considered a major confounding factor."

Conclusions

As noted earlier, the purpose of this guidance is to recommend an appropriate interim toxicity value for TCE from among those developed by other regulatory agencies and specifically using the preferences described in the 2003 Toxicity Hierarchy and consistent with the ECOS white paper (*Identification and Selection of Toxicity Values/Criteria for CERCLA and Hazardous Waste Site Risk Assessments in the Absence of IRIS Value* (ECOS, 2007)). The following criteria were recommended in that paper:

1. There should be a preference for transparent assessments (in which toxicity values are derived), that clearly identify the information used and how it was used.
2. There should be a preference for assessments which have been externally and independently peer reviewed, where reviewers and affiliations are identified. Other things being equal, there should also be a preference for assessments with more extensive peer review. Panel peer reviews are considered preferable to letter peer reviews.
3. There should be a preference for assessments that were completed with a previously established and publicly available methodology. Methodologies that themselves were externally peer reviewed are preferred over those that were not externally peer reviewed.
4. While there should be a preference for assessments using established methodologies to derive toxicity values, these methodologies should also be informed by the current best scientific information and practices. New assessment methodologies should provide reproducible results and meet quality assurance and quality control requirements.
5. There should be a preference for assessments that consider the quality of studies used, including the statistical power or lack thereof to detect effects; that corroborate data amongst pertinent studies; and that make best use of all available science.
6. There should be a preference for assessments and values which are publicly available or accessible. There may be a further preference for toxicity assessments that invited and considered public comment (as well as, but not in lieu of, external peer review).
7. Other things being equal, there should be a preference for toxicity values that are consistent with the duration of human exposure being assessed. For example, an externally peer reviewed subchronic reference dose (RfD) should be preferred to an externally peer reviewed chronic RfD when assessing an exposure of 2 years for non-cancer toxicity.

These recommendations formed the criteria against which the identified values were evaluated. The ECOS paper also recommends against the use of risk management values for use in risk assessment.

In summary, the goal of this analysis is to choose the most appropriate interim toxicity values for assessing site-specific risks of TCE exposure from among available assessments. OSWER recommends that the Cal EPA values provide the most appropriate interim cancer potency factors for risk assessment. Specifically, Cal EPA developed them expressly for use in risk assessment. In addition, the Cal EPA assessment was based on a full review of the literature, unlike IDEM's assessment, which IDEM undertook specifically to determine an appropriate cancer slope factor within the draft ORD risk range, which narrowed the focus of their analysis. As can be seen from Figure 1, the Cal EPA IUR is consistent with many of the other assessments and other IURs that could be developed on individual cancer endpoints. Lymphoma, which was the effect that occurred at the lowest concentration identified in the NYSDOH analysis, was one of the cancers incorporated into the calculation of the Cal EPA IUR. The Cal EPA value is consistent with relevant age-adjusted IURs that were developed in the NYSDOH analysis. Because EPA's risk assessment for TCE is currently being developed, EPA has not determined that the weight of evidence for TCE supports a mutagenic mode of action for carcinogenicity as described in EPA's "Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens." Therefore, OSWER is not recommending any specific adjustments for childhood susceptibility in site-specific risk assessments for TCE.

OSWER recommends using the criteria in the 2003 Toxicity Hierarchy in developing a preliminary remediation goal (PRG) for assessing systemic non-carcinogenic effects of TCE exposure. OSWER notes that both the NYSDOH value and the CAL EPA REL should be considered as Tier 3 toxicity values under the OSWER Toxicity Hierarchy. OSWER also notes that the NYSDOH analysis presented evaluation of more and different studies than the Cal EPA REL evaluation including the critical study NYSDOH identified (Rasmussen et al. (1993)) which was based on more subjects and had more objective endpoints than Vandervort and Polakoff (1973) and an LOAEL 1/6th that of the Cal EPA study.

Disclaimer

This guidance presents current OSWER technical and policy recommendations regarding the TCE human health values for site-specific risk assessments. While OSWER developed this guidance for facility response actions under CERCLA and RCRA corrective action, other regulators, including the states, may find it useful in their programs, although they may choose to develop alternative assessments, consistent with their own programs and policies. In addition, EPA may use and accept other technically sound approaches after appropriate review, either at its own initiative or at the suggestion of other interested parties. This guidance does not impose any requirements or obligations on EPA, the states, other federal agencies, or the regulated community. It is important to understand that this document does not substitute for statutes EPA administers or their implementing regulations, nor is it a regulation itself. Thus, this document does not impose legally binding requirements on EPA, the states, or the regulated community, and may not apply to a particular situation based upon the specific circumstances. Rather, the document suggests approaches that may be used at particular sites as appropriate, given site-specific circumstances.

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Figure 1: Air Concentrations associated with the 1 E-06 to 1E-04 lifetime excess cancer risk range for variety of Inhalation Unit Risks. This graph includes the risk range calculated for five cancer endpoints developed by NYSDOH, the Cal EPA IUR, the IDEM inhalation cancer slope factor converted to an IUR, the IUR recommended by Lewandowski and Rhomberg (2005), and U.S. EPA for comparison. OSWER recommends that the Cal EPA values provide the most appropriate interim cancer potency factors for risk assessment.

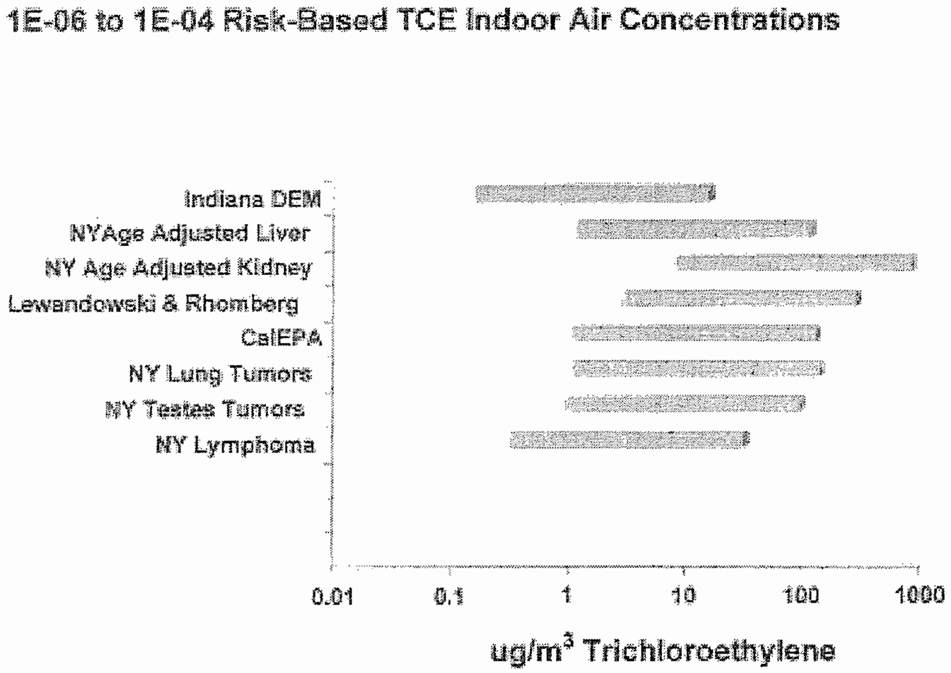

Figure 2: Example calculation of acceptable air level (concentration), or screening level, for a continuous residential exposure to a carcinogen.

$$SL_{res\text{-}air\text{-}ca}\left(\mu g/m^3\right)=\frac{TR\times AT_r\left(\frac{365\ \text{days}}{\text{year}}\times LT\ (70\ \text{years})\right)}{EF_r\left(\frac{350\ \text{days}}{\text{year}}\right)\times ED_r\ (30\ \text{years})\times ET_{ra}\left(\frac{24\ \text{hours}}{\text{day}}\right)\times\left(\frac{1\ \text{day}}{24\ \text{hours}}\right)\times IUR\left(\mu g/_{m^3}\right)^{-1}}$$

Where: $SL_{res\text{-}air\text{-}ca}$ = residential air for a carcinogen
TR = target risk (e.g., 10^{-6})
AT_r = averaging time - residential
LT = lifetime
EF_r = exposure frequency - residential
ED_r = exposure duration – residential
ET_{ra} = exposure time – residential air
IUR = inhalation unit risk

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STATE OF ILLINOIS
Pollution Control Board

BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:)
)
PROPOSED AMENDMENTS TO:)
TIERED APPROACH TO CORRECTIVE) R09-9
ACTION OBJECTIVES) (Rulemaking-Land)
(35 Ill. Adm. Code 742))

SUPPLEMENTAL TESTIMONY OF TRACEY HURLEY

This testimony responds to additional questions and requests made by the Illinois Pollution Control Board members during the January 27, 2009 hearing. As a result of the Board's questions and requests, we are proposing some changes, which are documented in Errata Sheet Number 3.

The Illinois EPA was asked to provide more information on the source of the toxicity parameters listed in Appendix C, Tables B and D. The toxicity parameters and their values and the sources of these values are listed on the Illinois EPA website. The tables on the website are updated on a quarterly basis. We will refer users of TACO to the website to ensure that they have the most current information. Therefore, we are proposing the following changes: For the symbols RfC, RfD_o, SF_o, URF in Appendix C, Table B, and the symbols RfD_i, RfD_o, SF_i, SF_o, in Appendix C, Table D, the Source column will now read "Illinois EPA (http://www.epa.state.il.us/land/taco/toxicity-values.xls)".

The Hearing Officer asked for the sources of the default physical and chemical parameters listed in Appendix C, Table E. In response to this request, we are proposing to add a footnote to the end of the title of this table, footnote "e". Footnote "e" will read: "The values in this table were taken from the following sources (in order of preference):

SCDMS online database (http://www.epa.gov/superfund/sites/npl/hrsres/tools/scdm.htm); CHEMFATE online database (http://www.srcinc.com/what-we-do/databaseforms.aspx?id=381); PhysProp online database (http://www.srcinc.com/what-we-do/databaseforms.aspx?id=386); Water9 (http://www.epa.gov/ttn/chief/software/water/) for diffusivity values; and *Handbook of Environmental Degradation Rates* by P.H. Howard (1991) for first order degradation constant values."

In my pre-filed testimony for the February 2009 hearing I referred to Rick Cobb's testimony in support of adding chemicals to the proposed Groundwater Quality Standards during the Part 620 hearings. The Hearing Officer asked that a specific portion of his testimony be referenced, not the entire testimony. The specific portions of Rick Cobb's testimony to which I was referring are pages 11 – 17 of his pre-filed testimony. I would also like to add a portion of Tom Hornshaw's pre-filed testimony from the Part 620 hearings, specifically pages 5 – 7. Lastly, I would like to add questions and responses numbers 2, 17, and 18 from the supplemental testimony of Richard P. Cobb and Thomas C. Hornshaw from the Part 620 hearings.

In Appendix C, Table M, the parameter column for the symbol C_v^{sat} should be corrected to read "Soil vapor saturation concentration." The word "saturation" was inadvertently omitted. Soil vapor saturation concentration is the term used in the Definitions section, 742.200.

We have received some questions about the conversion factors used in some of the J&E equations listed in Appendix C, Table L. In order to clear up any confusion, we are adding units and making the conversions more specific. In J&E1, the factor of 1000 in the denominator converts micrograms to milligrams. We are adding μg/mg after the 1000 conversion factor. The factor of 365 in the numerator converts days to years. We are adding the units of days/yr after the 365 conversion factor. This is similar to equation S6 in Appendix C, Table A.

To J&E2, we also are adding the units of days/yr to the factor of 365 in the numerator.

The factor of 24.45 in J&E3 is the molar volume of air in liters at normal temperature (25°C) and pressure (760 mm Hg). We are adding a note to this equation to explain this.

In J&E5, there are actually two conversions involved in the factor of 1000; cubic centimeters to cubic meters and grams to kilograms. To clarify this, we are changing the 1000 to 10^6 cm^3/m^3 x $kg/10^3$ g.

In J&E7, the conversion factor of 1000 is used to convert from cubic meters to liters. We are adding L/m^3 after the 1000 conversion factor in the denominator.

In J&E13, the conversion factor of 3600 is used to convert from hours to seconds. Therefore, we are adding sec/hr after the 3600 conversion factor in the denominator.

This concludes my testimony.

STATE OF ILLINOIS)
)
COUNTY OF SANGAMON)

PROOF OF SERVICE

I, the undersigned, on oath state that I have served the attached Motion for Leave from the Filing and Service Requirements, Supplemental Studies and Reports List, Errata Sheet Number 3, and Pre-filed Testimony of Heather Nifong, Thomas C. Hornshaw, and Tracey Hurley upon the persons to whom they are directed, by placing a copy of each in an envelope addressed to:

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Participants on the Service List

and mailing them (First Class Mail) from Springfield, Illinois on February 20, 2009, with sufficient postage affixed as indicated above.

SUBSCRIBED AND SWORN TO BEFORE ME
This __20th__ day of _February, 2009.

Brenda Boehner
Notary Public

BRENDA BOEHNER
MY COMMISSION EXPIRES 11-3-2009

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