

Appendix A

Highlights of document revisions

February 2005 Public Comment Draft → October 2006 Final Guidance

- Throughout: Revised language to clarify that the guidance is not a rule, regulation or requirement, and to eliminate text that might create a contrary impression.
- Preface: Revised to clarify that the guidance was developed in consultation with the NYSDEC and that it represents the State's methodology and our experience. Added notes for special considerations (e.g., naturally-occurring subsurface gases).
- Section 1: Replaced image in Figure 1.1. Identified additional factors in Table 1.1. Added section on conceptual site models. Provided additional information regarding the applicability of the guidance to specific scenarios (such as residential and non-residential settings and petroleum hydrocarbon sites).
- Section 2: Revised the discussion in Section 2.2.1 to clarify the use of soil vapor samples. Included crawl space air samples. Expanded the discussion on time of year in which to sample. Revised text to emphasize the importance of selecting methods that meet the data quality objectives. Clarified which information is highly recommended to gather at the time of sampling. Included liquid tracers in the section on tracer gas. Added QA/QC considerations. Revised text on target analyte lists. Relocated guidance on applicability in non-residential settings to Section 1.7.
- Section 3: Revised text and removed summary table in Section 3.2.4 to clarify that background levels are not defined as levels within a 25th to 75th percentile range. Added a summary of a recently published Health Effects Institute database to the discussion on background databases. Included "resampling" as one of the potential recommended actions in Section 3.3.2 and 3.3.3. Added text to clarify who is responsible for implementing recommended actions. Revised the outdoor air evaluation section to clarify that outdoor air samples are not collected and evaluated as part of a comprehensive assessment of outdoor air.
- Matrix 1: Based on comments received on the NYSDOH's TCE Criteria Document (NYSDOH 2006), the following two revisions were made to Matrix 1: changed the boundary between the indoor air concentration ranges in Columns 2 and 3 from 2.5 to 1 mcg/m³ and added "Monitor/Mitigate" as a recommended action in Box 10 (see memorandum from N. Kim to R. Tramontano dated October 12, 2006, provided on p. A-3 for additional information). Removed Monitor action from Box 3. Removed Mitigate and Monitor actions from Box 4. Revised the definitions of actions and the additional notes, including a definition of "Monitor/Mitigate" and a recommendation that resampling may be necessary to demonstrate the effectiveness of actions taken to reduce exposures.
- Matrix 2: Removed Monitor action from Box 3. Removed Mitigate and Monitor actions from Box 4. Added Monitor/Mitigate action to Box 6 (see memorandum from N. Kim to R. Tramontano dated October 12, 2006, provided on p. A-3 for additional information). Similar to Matrix 1, revised the definitions of actions and the additional notes.
- Section 4: Revised text to clarify that we are emphasizing preferred mitigation methods and not precluding the use of other mitigation methods. Added text to Section 4.3 about post-mitigation indoor air sampling in buildings with basements. Replaced EPA's *Radon Mitigation Standards* with ASTM E-2121. Replaced references to Operation, Maintenance and Monitoring Plans to Site Management Plans.
- Section 5: Replaced image in Figure 5.2.

- Appendix C: Added a discussion on a recently published Health Effects Institute database. Added tables for each database with additional volatile chemicals and statistical measures of background levels.
- Appendix E: Removed EPA's *Radon Mitigation Standards*. Provided EPA's web site explaining how to get copies of the recommended ASTM E-2121.

The reader is also referred to the NYSDOH's complementary document titled "Response to Comments received on the New York State Department of Health's *Guidance for Evaluating Soil Vapor Intrusion in the State of New York* (Public comment draft dated February 2005)."

**STATE OF NEW YORK - DEPARTMENT OF HEALTH
INTEROFFICE MEMORANDUM**

TO: Ronald Tramontano, Director
Center for Environmental Health

FROM: Nancy K. Kim, Director *N.K.*
Division of Environmental Health Assessment

SUBJECT: Trichloroethene

DATE: October 12, 2006

Center for Environmental Health staff in the New York State Department of Health (DOH) have written several documents to address health concerns about exposure to trichloroethene (TCE) from soil vapor intrusion and are revising those documents in response to comments from a scientific review panel and the public. The documents and related reports are:

- Draft Report Trichloroethene Air Criteria Document (DOH, 2005)(contains the derivation of the TCE guideline),
- Comments of the Trichloroethene (TCE) Panel (letter from Henry Anderson, M.D. to Nancy K. Kim, Ph.D. dated November 1, 2005),
- Guidance for Evaluating Soil Vapor Intrusion in the State of New York, Public Comment Draft (DOH, 2005), which includes the
 - Soil Vapor/Indoor Air Matrix 1 and Matrix 2 (both are a decision making tool for soil vapor and indoor air levels), and
 - TCE in Indoor and Outdoor Air (fact sheet), and
- Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues, a report issued by the National Research Council (NRC) of the National Academy of Sciences (July, 2006).

After reviewing these materials, I am recommending that we change Matrix 1. The 2.5 micrograms of trichloroethene per cubic meter of indoor air ($2.5 \text{ mcg}/\text{m}^3$) in the column headings for Indoor Air Concentration of Compound in Matrix 1 should be reduced to $1.0 \text{ mcg}/\text{m}^3$. I am also recommending that mitigate be included as an option in Box 10 of Matrix 1 and Box 6 of Matrix 2.

Use of the Air Guideline

The purpose of the air guideline for TCE of $5 \text{ mcg}/\text{m}^3$ given in the fact sheet, "...is to help guide decisions about the nature of the efforts to reduce TCE exposures. Reasonable and practical actions should be taken to reduce TCE exposure when indoor air levels are above background, even when they are below the guideline of $5 \text{ mcg}/\text{m}^3$. The urgency to take actions increases as indoor air levels increase, especially when air

levels are above the guideline. In all cases, the specific corrective actions to be taken depend on a case-by-case evaluation of the situation. The goal of the recommended action is to reduce TCE levels in indoor air to as close to background as practical.” This general advice applies to all situations including the following:

an individual wants to know if he should keep a closed bottle of TCE in his house,
a school asks DOH if it has a problem with a bottle of TCE being in a shop, and
an office wants to know if it should do anything about residual exposure from past TCE use.

DOH also uses the guideline to make decisions about the need for remedial actions because of state regulated sources or sites. DOH would use this value to decide if it needs to work with the New York State Department of Environmental Conservation to reduce outdoor air levels of TCE. DOH also uses this value in Matrix 1, a decision making tool for responding to soil vapor intrusion problems; for this use, the guideline is considered to be a TCE concentration that should not be exceeded in indoor air.

Indoor Air Concentrations

Several different studies provide information about background levels of TCE in indoor air. These data differ because of a number of factors such as the criteria for choosing sampling locations, the time period of the studies, etc. Three studies give a 50th percentile (less than 0.25 mcg/m³, less than 1.4 mcg/m³ and 0.12 mcg/m³) and a 95th percentile (less than 0.25 mcg/m³, 1.36 mcg/m³ and 4.2 mcg/m³). Two studies provide a 75th percentile (less than 0.25 mcg/m³ and 1.2 mcg/m³). One way to characterize these values is to state that background values are mostly less than 1 mcg/m³ and frequently less than 0.25 mcg/m³. (References: DOH 2003, USEPA 2001, and HEI, 2005)

Peer Review of the Derivation of the TCE Air Guideline

After receiving the TCE panel’s comments, the Department considered changes in the guideline or Matrix 1. The TCE panel was asked to answer technical questions about the derivation of the guideline and a specific question on the guideline itself (Is the summary transparent and does it adequately justify the guideline of 5 mg/m³?). In responding to the latter question, several panel members voiced their opinion about what they would select as a guideline. The consensus comment from the panel was “Some panel members suggested that additional consideration be given to lowering the guideline value.”

The panel also commented on aspects of the guideline when answering questions about cancer risk estimates.

One of the panel’s consensus comment was:

“The fact that TCE is a multi-species and multi-site carcinogen with a combination of both malignant and benign tumors should be further emphasized in the document

because these data coupled with the human data have led several authoritative bodies (EPA, NTP, & IARC) to the conclusion that TCE is on the cusp between a known and probable (likely, reasonably anticipated to be) human carcinogen. Thus, the NYSDOH should have flexibility in using risk levels of both 1 in 10^{-6} and 1 in 10^{-5} ." (Part of response to question 4 of the TCE Panel's comments.)

Another consensus comment was:

"The rationale to utilize the human epidemiologic studies for weight of evidence support for the animal carcinogenicity studies rather than as the primary for the quantitative cancer risk assessment is appropriate. The weaknesses of the exposure estimates and potential confounding exposures support this decision. However, the DOH may want to consider the human studies to a greater extent when weighting the cancer evidence to establish a guideline." (Part of response to question 5 of the TCE Panel's comments)

Other, individual comments on the guideline follow.

George Lucier, Ph.D.

"Based on the available data, especially the cancer data, a guideline in the range of 1-5 mcg/m³ could be justified. After all, a linear model cannot be rejected, for some sites acceptable risk levels are less than 5 mcg/m³ and in some cases less than 1 mcg/m³ and EPA has stated that TCE is highly likely to be a human carcinogen. The NYSDOH may wish to consider an acceptable risk level to be 3-5 cancers per million since TCE appears to be on the cusp between a known human carcinogen and a probable human carcinogen."

James Dix, Ph.D.

"The extensive review of the cancer literature in the draft document seems to indicate TCE levels giving 1×10^{-6} increased cancer risk can be in the range 0.1-1 mcg/m³ (e.g., p. 132, 133, 141, 147, 149, and 150 of the draft document), which prima facia (sic) would support an air criterion of below 1 μ /m³(sic). The DOH weighted these studies less. However, given the support on this scientific review panel for weighting the non-Hodgkin's lymphoma more strongly, an air criterion of less than 1 μ g/m³ might be justified."

NRC Report on Trichloroethene

In July 2006, the NRC released its report on TCE. We have reviewed that report. The approaches and methods we used to derive health-based air criteria for TCE are consistent with the recommendations of the NRC Committee. For example, both NRC and DOH identified kidney cancer, liver cancer, central nervous system effects, reproductive problems and developmental problems as human health endpoints that might be sensitive to the effects of TCE. NRC recommended that animal data, not human health data, be used to derive quantitative estimates of human cancer risks from TCE exposure and that the available human data be used only for validation. DOH used this approach in evaluating cancer risks.

Integration, Matrix 1 and Matrix 2

The attached tables compare the TCE criteria in the draft document with the revised TCE criteria in the final document. These data indicate that the guideline of 5 mcg/m³ is below the recommended health-based criteria for non-cancer effects and that the excess lifetime cancer risks at the guideline are in the lower end of the risk range that is generally used by regulatory agencies when setting guidelines or standards. However, Matrix 1 is a major determinant for remediation in the soil vapor intrusion program, a state program addressing involuntary risks, and two revisions would help to align decisions in that program with the goals stated in the DOH TCE fact sheet and with the requirements of the Brownfields legislation.

In the current state program, mitigation is recommended when the potential for soil vapor intrusion to affect indoor air is high (sub-slab levels are equal to or greater than 250 mcg/m³) regardless of the measured indoor air levels. However, when the potential for soil vapor intrusion to affect indoor air is moderate (sub-slab concentrations are equal to or greater than 50 mcg/m³, but less than 250 mcg/m³), mitigation is only recommended when an indoor air level is equal to or greater than 2.5 mcg/m³. The excess risk levels associated with 2.5 mcg/m³ range from 0.3 to 8 x 10⁻⁶; the upper end of this range exceeds the 3 to 5 cancers per million recommended by Dr. Lucier and the 1 x 10⁻⁶ risk level given in the Brownfields legislation. This concentration also exceeds most background concentrations for TCE, a goal stated in the TCE fact sheet. Reducing 2.5 mcg/m³ to 1.0 mcg/m³ in Matrix 1 would result in recommending remediation at levels above most background levels and at risk levels of 0.1 to 3 x 10⁻⁶.

In Matrix 1 of the draft soil vapor intrusion guidance, Box 10 (sub-slab vapor levels of 50 mcg/m³ or greater to less than 250 mcg/m³ and indoor air levels of 0.25 mcg/m³ or greater to less than 2.5 mcg/m³) recommends monitoring. (The recommendation in the previous paragraph would change 2.5 mcg/m³ to 1.0 mcg/m³.) Box 10 addresses situations where the potential for soil vapor to affect indoor air is moderate, but indoor air levels are in the range of most background levels. Recommending an option for mitigation in Box 10 when environmental factors for a specific site suggest a high potential for indoor air concentrations to increase is consistent with the goals outlined in the previous paragraph. A similar mitigation option is recommended for Box 6 of Matrix 2.

Attachments

Table 1. Non-Carcinogenic Effects: Draft and Final Criteria Used in Guideline Derivation.

Organ/System/ Lifestage	Study*	Recommended TCE Air Criteria (mcg/m ³)			
		Draft		Final	
		Study	System	Study	System
CNS	Arito et al. (1994)	40	40	4 (childhood)	10
	Rasmussen et al. (1993)	40		11 (adult)	
Liver	Kjellstrand et al. (1983)	160	160	160 (adult & childhood)	160
Kidney	Kjellstrand et al. (1983)	165	165	160 (adult & childhood)	160
Reproduction	Land et al. (1981)	32	32	32	20
	DuTeaux et al. (2004)	110		110	
	Kumar et al. (2000; 2001a)	not done		20	
	NTP (1986)	not done		110	
Developmental	Dawson et al. (1993)	11	11	11 (supporting study)	20
	Healy et al. (1982)	38		38	
	Isaacson & Taylor (1989)	19		19	
	NTP (1986)	not done		22	

*References from Trichloroethene Air Criteria Document.

Table 2. Carcinogenic Effects: Draft and Final Criteria Used in Guideline Derivation.

Cancer	Recommended TCE Air Criteria (mcg/m ³)*					
	Draft			Final		
	LADE		LADD (PBPK)	LADE		LADD (PBPK)
	Unadjusted	Adjusted**		Unadjusted	Adjusted**	
Animal Data (Fukuda et al., 1983; Henschler et al., 1980; Maltoni et al., 1986)***						
liver	1.8	not done	1.4	1.8	1.1	1.4
kidney	13	not done	3100	13	7.8	3100
lymphoma	not a recommended site			0.3	not done	not done given uncertainty in appropriate internal dose & mode of action
testes (benign)	not a recommended site					
lung	not a recommended site					
Human Data (Hansen et al., 2001)***						
esophagus	0.077 – 1.2#	not done	not done	0.36 – 1.2##	not done	not done
NHL	0.062 – 0.91#	not done	not done	0.29 – 0.91##	not done	not done

*Air concentrations associated with an excess lifetime human risk of 1×10^{-6} are provided for comparative purposes, air concentrations associated with excess risks 1×10^{-5} and 1×10^{-4} are 10X and 100X the given concentration.

**The LADE (lifetime average daily exposure) estimates based on linear low-dose extrapolation are unadjusted and adjusted for the potential increased sensitivity of children to the early-life TCE exposures following US EPA guidance. Adjusted values were not calculated using age-specific internal dose metrics (LADD, lifetime average daily dose) because validated TCE PBPK models for children are unavailable and because of additional uncertainties associated with estimating model parameter values for children. Adjusted values were not calculated based on lymphomas because the mode-of-action for those cancers is unknown, and in such cases, the US EPA guidance recommends using unadjusted values.

***References from Trichloroethene Air Criteria Document.

Range of values based on two measures of relative risk, two occupational exposure levels, and three estimates of exposure duration.

Range of values based on two measures of relative risk, one occupational exposure level, and three estimates of exposure duration.

Soil Vapor/Indoor Air Matrix 1

WORKING DRAFT 02.23.05

SUBJECT TO CHANGE

SUB-SLAB VAPOR CONCENTRATION of COMPOUND (mcg/m ³)	INDOOR AIR CONCENTRATION of COMPOUND (mcg/m ³)			
	< 0.25	0.25 to < 2.5	2.5 to < 5.0	5.0 and above
< 5	1. No further action	2. Take reasonable and practical actions to identify source(s) and reduce exposures	3. Take reasonable and practical actions to identify source(s) and reduce exposures — and — Monitor	4. MITIGATE — or — Take reasonable and practical actions to identify source(s) and reduce exposures — and — Monitor
5 to < 50	5. No further action	6. Monitor	7. Monitor	8. MITIGATE
50 to < 250	9. Monitor	10. Monitor	11. MITIGATE	12. MITIGATE
250 and above	13. MITIGATE	14. MITIGATE	15. MITIGATE	16. MITIGATE

No further action: Given that the compound was not detected in the indoor air sample and that the concentration detected in the sub-slab vapor sample is not expected to significantly affect indoor air quality, no additional actions are needed to address human exposures.

Take steps to identify source(s) and reduce exposures: The concentration detected in the indoor air sample is likely due to indoor and/or outdoor sources rather than soil vapor intrusion given the concentration detected in the sub-slab vapor sample. Therefore, steps should be taken to identify potential source(s) and to reduce exposures accordingly (e.g., by keeping containers tightly capped or by storing volatile organic compound-containing products in places where people do not spend much time, such as a garage or outdoor shed).

Monitor as appropriate: Monitoring is needed to confirm concentrations in the indoor air have not increased due to changes in pressure gradients (e.g., deterioration of building foundation) or to evaluate temporal trends for relevant environmental data. Monitoring may also be needed to verify that existing building conditions (e.g., positive pressure heating, ventilation and air-conditioning systems) are minimizing potential effects associated with soil vapor intrusion. The type and frequency of monitoring is determined on a site-specific basis, taking into account applicable environmental data and building operating conditions. Monitoring is considered a temporary measure implemented to address exposures related to soil vapor intrusion until contaminated environmental media are remediated.

Mitigate: Mitigation is needed to minimize current or potential exposures associated with soil vapor intrusion. The most common mitigation methods are sealing preferential pathways in conjunction with installing a sub-slab depressurization system, and changing the pressurization of the building in conjunction with monitoring. The type, or combination of types, of mitigation is determined on a building-specific basis, taking into account building construction and operating conditions. Mitigation is considered a temporary measure implemented to address exposures related to soil vapor intrusion until contaminated environmental media are remediated.

ADDITIONAL NOTES FOR MATRIX 1

This matrix provides guidance on actions that should be taken to address current and potential exposures related to soil vapor intrusion. To use the matrix accurately as a tool in the decision-making process, the following must be noted:

- [1] The matrix is generic. As such, it may be necessary to modify recommended actions to accommodate building-specific conditions (e.g., dirt floor in basement, crawl spaces, etc.) and/or site-specific conditions (e.g., proximity of building to identified subsurface contamination) for the protection of public health. Additionally, actions more conservative than those specified within the matrix may be implemented at any time. For example, the decision to implement more conservative actions may be based on a comparison of the costs associated with resampling or monitoring to the costs associated with installation and monitoring of a mitigation system.
- [2] Actions provided in the matrix are specific to addressing human exposures. Implementation of these actions does not preclude the need to investigate possible sources of vapor contamination, nor does it preclude the need to remediate contaminated soil vapors or the source of soil vapor contamination.
- [3] Extreme care should be taken during all aspects of sample collection to ensure that high quality data are obtained. Since the data are being used in the decision-making process, the laboratory analyzing the environmental samples must have current Environmental Laboratory Approval Program (ELAP) certification for the appropriate analyte and environmental matrix combinations. Furthermore, samples must be analyzed by methods that can achieve a minimum reporting limit of 0.25 microgram per cubic meter for indoor and outdoor air samples, and typically 1 microgram per cubic meter for subsurface vapor samples.
- [4] Sub-slab vapor and indoor air samples are typically collected during the heating season since soil vapor intrusion is more likely to occur when a building's heating system is in operation and air is being drawn into the building. If samples are collected during other times of the year, it may be necessary to resample during the heating season to evaluate exposures accurately.
- [5] When current exposures are attributed to sources other than vapor intrusion, the agencies must be provided documentation (e.g., applicable environmental data, completed indoor air sampling questionnaire, digital photographs, etc.) to support a proposed action other than that provided in the matrix box and to support agency assessment and follow-up.

Soil Vapor/Indoor Air Matrix 2

WORKING DRAFT 02.23.05

SUBJECT TO CHANGE

SUB-SLAB VAPOR CONCENTRATION of COMPOUND (mcg/m ³)	INDOOR AIR CONCENTRATION of COMPOUND (mcg/m ³)			
	< 3	3 to < 30	30 to < 100	100 and above
< 100	1. No further action	2. Take reasonable and practical actions to identify source(s) and reduce exposures	3. Take reasonable and practical actions to identify source(s) and reduce exposures — and — Monitor	4. MITIGATE — or — Take reasonable and practical actions to identify source(s) and reduce exposures — and — Monitor
100 to < 1,000	5. Monitor	6. Monitor	7. MITIGATE	8. MITIGATE
1,000 and above	9. MITIGATE	10. MITIGATE	11. MITIGATE	12. MITIGATE

No further action: Given that the compound was not detected in the indoor air sample and that the concentration detected in the sub-slab vapor sample is not expected to significantly affect indoor air quality, no additional actions are needed to address human exposures.

Take steps to identify source(s) and reduce exposures: The concentration detected in the indoor air sample is likely due to indoor and/or outdoor sources rather than soil vapor intrusion given the concentration detected in the sub-slab vapor sample. Therefore, steps should be taken to identify potential source(s) and to reduce exposures accordingly (e.g., by keeping containers tightly capped or by storing volatile organic compound-containing products in places where people do not spend much time, such as a garage or outdoor shed).

Monitor: Monitoring, including sub-slab vapor, basement air, lowest occupied living space air, and outdoor air sampling, is needed to determine whether concentrations in the indoor air or sub-slab vapor have changed. Monitoring may also be needed to determine whether existing building conditions (e.g., positive pressure heating, ventilation and air-conditioning systems) are maintaining the desired mitigation endpoint and to determine whether changes are needed. The type and frequency of monitoring is determined on a site-specific and building-specific basis, taking into account applicable environmental data and building operating conditions. Monitoring is an interim measure required to evaluate exposures related to soil vapor intrusion until contaminated environmental media are remediated.

Mitigate: Mitigation is needed to minimize current or potential exposures associated with soil vapor intrusion. The most common mitigation methods are sealing preferential pathways in conjunction with installing a sub-slab depressurization system, and changing the pressurization of the building in conjunction with monitoring. The type, or combination of types, of mitigation is determined on a building-specific basis, taking into account building construction and operating conditions. Mitigation is an interim measure implemented to address exposures related to soil vapor intrusion until contaminated environmental media are remediated.

ADDITIONAL NOTES FOR MATRIX 2

This matrix provides guidance on actions that should be taken to address current and potential exposures related to soil vapor intrusion. To use the matrix accurately as a tool in the decision-making process, the following must be noted:

- [1] The matrix is generic. As such, it may be necessary to modify recommended actions to accommodate building-specific conditions (e.g., dirt floor in basement, crawl spaces, etc.) and/or site-specific conditions (e.g., proximity of building to identified subsurface contamination) for the protection of public health. Additionally, actions more conservative than those specified within the matrix may be implemented at any time. More conservative actions are often cost-based (e.g., the cost of additional sampling versus the cost of mitigation) rather than health-based.
- [2] Actions provided in the matrix are specific to addressing human exposures. Implementation of these actions does not preclude the need to investigate possible sources of vapor contamination, nor does it preclude the need to remediate contaminated soil vapors or the source of soil vapor contamination.
- [3] Extreme care should be taken during all aspects of sample collection to ensure that high quality data are obtained. Since the data are being used in the decision-making process, the laboratory analyzing the environmental samples must have current Environmental Laboratory Approval Program (ELAP) certification for the appropriate analyte and environmental matrix combinations. Furthermore, samples must be analyzed by methods that can achieve a minimum reporting limit of 3 micrograms per cubic meter.
- [4] Sub-slab vapor and indoor air samples (basement and lowest occupied living space) are typically collected during the heating season since soil vapor intrusion is more likely to occur when a building's heating system is in operation and air is being drawn into the building. If samples are collected during other times of the year, it may be necessary to resample during the heating season to evaluate exposures accurately.
- [5] When current exposures are attributed to sources other than vapor intrusion, the agencies must be provided documentation (e.g., applicable environmental data, completed indoor air sampling questionnaire, digital photographs, etc.) to support a proposed action other than that provided in the matrix box and to support agency assessment and follow-up.