



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region 9
75 Hawthorne Street
San Francisco, CA 94105

MEMORANDUM

July 9, 2014

Subject: EPA Region 9 Response Action Levels and Recommendations to Address Near-Term Inhalation Exposures to TCE in Air from Subsurface Vapor Intrusion

From: Enrique Manzanilla
Director
Superfund Division

A handwritten signature in blue ink, appearing to read "Enrique Manzanilla".

To: Region 9 Superfund Division Staff and Management

At my request, Gerry Hiatt and Dan Stralka have prepared the attached memorandum with their technical assessment and recommendations regarding action levels, investigation approaches and response measures to address "inhalation exposures to trichloroethylene (TCE) in indoor air from the subsurface vapor intrusion pathway." The memorandum contains a useful operational framework and point of departure for Region 9 Superfund staff and management, in particular for Remedial Project Managers (RPMs) and On-Scene Coordinators (OSCs). I am asking each of you to consider this technical assessment and the resulting recommendations in making site-specific decisions regarding the investigation of and response to TCE vapor intrusion.

Addressing vapor intrusion at our Superfund sites is one of the top priorities for the Superfund Division. When a completed vapor intrusion pathway exists, current exposure can potentially result in risks to human health (both long term cancer risks and near term non-cancer hazards). The recommendations set forth in the attached memorandum address a particular concern for TCE focusing on protecting sensitive and vulnerable populations, especially women in the first trimester of pregnancy (because of the potential for cardiac malformations to the developing fetus). We have been in regular communication with OSWER regarding these issues and our toxicologists consulted with their peers in OSWER in developing their memorandum.

Numerous resources are available within the Superfund Division to help RPM's and OSC's evaluate and manage the many issues that arise when investigating or responding to vapor intrusion at a site. Our Technical Support Section, including Dan and Gerry, is available to provide assistance and advice. And the Division has established the Vapor Intrusion Core Team that can be an important resource that is available to all of you. Over the coming months, the VI Core Team will be sharing their recommendations and insights regarding investigation approaches/techniques, mitigation approaches and innovative pilots/treatability work building on our experience within Region 9 (e.g., MEW, Omega, SEMOU, Amco, the South Bay sites etc.).



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region 9
75 Hawthorne Street
San Francisco, CA 94105

MEMORANDUM

June 30, 2014

Subject: EPA Region 9 Interim Action Levels and Response Recommendations to Address Potential Developmental Hazards Arising from Inhalation Exposures to TCE in Indoor Air from Subsurface Vapor Intrusion

From: Gerald Hiatt, Ph.D. *Gerald Hiatt*
Senior Regional Toxicologist

Daniel Stralka, Ph.D. *Daniel J Stralka*
Regional Toxicologist

Through: John Kennedy *John Kennedy*
Chief, Technical Support Section

Angeles Herrera *Angeles Herrera*
Chief, Federal Facilities & Site Cleanup Branch

To: Enrique Manzanilla
Director, Superfund Division

We recommend that the EPA Region 9 Superfund program establish health protective response action recommendations to address inhalation exposures to trichloroethylene (TCE) in indoor air from the subsurface vapor intrusion pathway. The purpose of these interim action levels and response action recommendations is to be protective of sensitive and vulnerable populations, especially women in the first trimester of pregnancy, because of the potential for cardiac malformations to the developing fetus. This approach is consistent with recommendations provided by Region 10¹ and with previous actions taken at Region 9 Superfund sites.

Issue:

EPA identifies an inhalation level of concern for non-cancer hazards based on the ratio of the exposure concentration in air to a reference concentration ("RfC", which includes a margin of safety such that at the RfC and below there is little chance of an adverse effect).² This ratio is

¹ Memo: "OEA Recommendations Regarding Trichloroethylene Toxicity in Human Health Risk Assessments." JC Kelly, Office of Environmental Assessment, U.S. EPA Region 10, Dec 13 2012.

² The RfC represents an estimate of the continuous inhalation exposure (with uncertainty spanning perhaps an order of magnitude) to the human population (including sensitive sub-groups) that is likely to be without appreciable risk of deleterious effects during a lifetime. See on-line glossary at: <http://www.epa.gov/ncea/iris/index.html>

Interim Action Levels & Response Recommendations – TCE Exposures From Vapor Intrusion

defined as a Hazard Quotient and abbreviated "HQ". EPA's Integrated Risk Information System (IRIS) 2011 toxicity assessment concluded that TCE exposure poses potential human health hazards for noncancer toxicity to multiple organs and systems and to the developing fetus, including fetal cardiac malformations. This and other findings in the IRIS assessment of TCE indicates that women in the first trimester of pregnancy are one of the most sensitive populations to TCE inhalation exposure. For fetal cardiac malformations, a specific developmental effect, the critical period for exposure is considered to be the approximate 3-week period in the first trimester of pregnancy during which the heart develops. The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) and Superfund guidance provide for early or interim actions where warranted by the hazards posed by site-related contamination.³

EPA Region 9 Interim TCE Indoor Air Response Action Levels - Residential and Commercial TCE Inhalation Exposure from Vapor Intrusion		
<i>Exposure Scenario</i>	<i>Accelerated Response Action Level (HQ=1)</i>	<i>Urgent Response Action Level (HQ=3)⁴</i>
Residential *	2 µg/m ³	6 µg/m ³
Commercial/Industrial ** (8-hour workday)	8 µg/m ³	24 µg/m ³
Commercial/Industrial ** (10-hour workday)	7 µg/m ³	21 µg/m ³

* The residential HQ=1 accelerated response action level is equivalent to the inhalation reference concentration (RFC) since exposure is assumed to occur continuously.

** Commercial/Industrial accelerated response action levels are calculated as a time-weighted average from the RFC, based on the length of a workday and rounding to one significant digit (e.g., for an 8-hour workday: Accelerated Response Action Level = (168 hours per week/40 hours per week) x 2 µg/m³ = 8 µg/m³). Time-weighted adjustments can be made as needed for workplaces with longer work schedules.

Note: Indoor air TCE exposures corresponding to these accelerated response action levels would pose cancer risks near the lower end of the Superfund target cancer risk range, considering the IRIS toxicity assessment; thus, the health protective risk range for both accelerated response actions and long-term exposures becomes truncated to: 0.5 – 2 µg/m³ for residential exposures and 3 – 8 µg/m³ for 8-hour/day commercial/industrial exposures.

³ The NCP preamble states (55 FR 8704): "EPA expects to take early action at sites where appropriate...to eliminate, reduce, or control the hazards posed by a site...In deciding whether to initiate early actions, EPA must balance the desire to definitively characterize site risks and analyze alternative remedial approaches for addressing those threats in great detail with the desire to implement protective measures quickly. Consistent with today's management principles, EPA intends to perform this balancing with a bias for initiating response actions necessary or appropriate to eliminate, reduce, or control hazards posed by a site as early as possible." Consistent with CERCLA and the NCP, early actions may be appropriate using CERCLA authority to carry out removal actions (emergency response, time critical response, or non-time critical response) or remedial actions based on the site-specific situation (see, for example, 40 CFR 300.415 (b)(1)-(3) and 300.430 (a)(1)(ii)(A)). See also U.S. EPA (2/14/2000), Use of Non-Time Critical Removal Authority in Superfund Response Actions (OSWER, OERR; OECA, OSRE).

⁴ There is a need to identify those TCE exposures that exceed the RFC by a magnitude sufficient enough that a more urgent response is prudent; it is generally Region 9 practice to immediately initiate response action to address exposures at or above an HQ=3 level.

Interim Action Levels & Response Recommendations – TCE Exposures From Vapor Intrusion

Based upon the above information from EPA's 2011 *Toxicological Review of Trichloroethylene in Support of the Integrated Risk Information System (IRIS)*, we recommend Region 9 establish interim action levels and response action recommendations to protect against potential non-cancer outcomes, including developmental effects such as cardiac malformations. These recommendations identify women of reproductive age as the sensitive population of concern, rather than only pregnant women, because some women may not be aware of their pregnancy during the critical period of the first trimester.

Recommendations for Assessment of TCE Inhalation Vapor Intrusion Exposure in Residential and Commercial/Industrial Buildings and Accelerated and Urgent Response Actions

The following recommendations should be used for assessing and responding to inhalation exposures to TCE in residential and non-residential/commercial/industrial settings caused by subsurface vapor intrusion at Region 9 Superfund sites. We also recommend consultation with an EPA Regional Toxicologist for implementation of these recommendations.

Sampling Considerations:

Generally, EPA recommends time-integrated air sampling methods to account for temporal variability in vapor intrusion. Time-integrated samples provide a direct measurement of the average TCE concentration over a fixed period of time (e.g., 8 hours, 24 hours, 4 days, 1 week, 2 weeks, etc.), which should be compared to the accelerated and urgent response action levels.

Considerations for When to Expedite Turn-around Time for TCE Analytical Results:

In determining the advisability of contracting for rapid (e.g., 24-72 hour) turn-around time for TCE analytical results for indoor air samples, the following factors should be taken into consideration:

- **Exposure of women of reproductive age** – Are women of reproductive age (or known pregnancy status) exposed or reasonably expected to be exposed?
- **Existing data** – Are there any existing data (e.g., from subsurface media) which indicate or suggest that indoor air TCE concentrations can exceed the accelerated response action level?
- **Multiple lines of evidence** – Are there other types of existing information, data or analytical results which indicate or suggest that indoor air TCE concentrations exceed or can exceed the accelerated response action level?
- **Confirmation sampling** - If previous TCE indoor air concentrations exceeded the accelerated response action level, and early or interim mitigation measures were taken, rapid turn-around time of TCE analytical results should be considered to verify TCE concentrations have been reduced sufficiently to below HQ=1.

Implementation of Early or Interim Measures to Mitigate TCE Inhalation Exposure:

When selecting a response to reduce or avoid inhalation exposures to TCE, we recommend the following early or interim response actions (mitigation measures) be considered, along with how quickly they can be implemented:

- Increasing building pressurization and/or ventilation
- Sealing potential conduits where vapors may be entering the building
- Treating indoor air (carbon filtration, air purifiers)

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- Installing and operating engineered exposure controls (sub-slab/crawlspace, depressurization systems)
- Temporarily relocating occupants

Tiered Response Actions:

- **TCE Indoor Air Concentration \leq Accelerated Response Action Level (HQ=1):** If indoor air TCE concentrations are observed to be equal to or less than the accelerated response action level, then we recommend routine periodic confirmatory sampling and/or monitoring be conducted as appropriate for conditions at the site, including evaluation of the potential for subsurface vapor intrusion into indoor air exceeding health-based screening levels for long-term exposure.
- **TCE Indoor Air Concentration $>$ Accelerated Response Action Level (HQ=1):** In the event indoor air TCE concentrations are observed to be greater than the accelerated response action level, we recommend early or interim mitigation measures be evaluated and implemented quickly, and their effectiveness (defined as a reduction of the TCE indoor air concentration to below HQ=1 level) confirmed promptly (e.g., all actions completed and confirmed within a few weeks).
- **TCE Indoor Air Concentration $>$ the Urgent Response Action Level (HQ=3):** In the event indoor air TCE concentrations are observed to be greater than the urgent response action level, we recommend mitigation measures be initiated immediately and their effectiveness (defined as a reduction of the indoor air TCE concentration to below HQ=1 level) confirmed before any additional exposure is allowed to occur (e.g., all actions completed and confirmed within a few days). Note that temporary relocation may be indicated under these circumstances because of the need to prevent additional exposure.

Basis for Tiered Response Actions:

The *Toxicological Review of Trichloroethylene in Support of the Integrated Risk Information System (IRIS)* (EPA 2011a) established an inhalation Reference Concentration (RfC) at $2 \mu\text{g}/\text{m}^3$ to be protective for sensitive populations, including the developing fetus with regard to the potential for congenital heart defects arising due to maternal TCE exposure during fetal development. Identification of this developmental effect as a critical toxic end-point and the method of calculation of the RfC were the subjects of peer review by the EPA Science Advisory Board, which supported both.

This RfC in the 2011 TCE IRIS Assessment applies to continuous (24 hours per day) exposures and is therefore directly relevant to a reasonable maximum exposure in a residential exposure scenario. We recommend health protective inhalation concentrations for less-than-continuous exposures, such as in a commercial/industrial setting, be adjusted based on the number of hours per day of exposure.

Application of the RfC in the present context allows calculation of Hazard Quotient (HQ) concentrations for exposures equivalent to the RfC (HQ=1) and exceeding the RfC by a factor of 3-fold (HQ=3). Note: It is appropriate for the resultant HQ to be adjusted to a time-weighted average for exposures that are less than continuous. Thus:

- **Indoor Air Exposure Concentrations \leq HQ=1:** Indoor air exposures equal to or below (less than) the relevant HQ=1 level are protective for inhalation exposure.

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- **Indoor Air Exposure Concentrations > HQ=1:** For some exposure above the HQ=1 level, the non-cancer hazard begins to increase. This hazard generally increases as the exposure (considering concentration, time, and frequency) exceeds the HQ=1 level. Because of the increased potential risk of a developmental effect, we recommend reducing exposure to below HQ=1 using an accelerated time-frame.
- **Indoor Air Exposure Concentrations HQ=3:** The HQ=3 level is the level of exposure at which the increased risk of developmental effects is high enough that Region 9 considers an urgent response is warranted to reduce exposure for sensitive population to below HQ=1.

References:

Agency of Toxic Substances Disease Registry (ATSDR). 2013. Addendum to the Toxicological Profile for Trichloroethylene. Currently available online at:

http://www.atsdr.cdc.gov/ToxProfiles/tce_addendum.pdf

U.S. Environmental Protection Agency (EPA). 2011a. Toxicological Review of Trichloroethylene in Support of the Integrated Risk Information System (IRIS). EPA/635/R-09/011F. National Center for Environmental Assessment. Washington, DC. Currently available online at:

<http://www.epa.gov/iris/toxreviews/0199tr/0199tr.pdf>

U.S. Environmental Protection Agency (EPA). 2011b. IRIS Toxicity Profile for Trichloroethylene (CASRN 79-01-6). Washington DC, USEPA. <http://www.epa.gov/iris/subst/0199.htm>

U.S. Environmental Protection Agency, Science Advisory Board (EPA-SAB). 2011. *Review of EPA's Draft Assessment entitled — Toxicological Review of Trichloroethylene // (October 2009)*. EPA-SAB-11-002. Office of the Administrator. Washington, DC. January 11.

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Abbreviations:

HQ Hazard Quotient (HQ = Exposure Concentration / RfC)

IRIS Integrated Risk Information System

RfC Reference concentration (inhalation)

TCE Trichloroethylene

µg/m³ micrograms per cubic meter