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March 25, 2021

Christine Haag Program Director Remediation and Redevelopment Program Wisconsin Department of Natural Resources 101 S. Webster Street, P.O. Box 7921 Madison, WI 53707-7921

Subject: DHS response to Request for Assistance: Actions for Trichloroethylene at Acute Risk Levels

Dear Ms. Haag:

The Wisconsin Department of Health Services (DHS) received your letter dated October 18, 2019 requesting clarification on the definition of acute risk and timeline justifications for responding to various scenarios where the acute risk is related to volatile organic compounds (VOCs) and vapor intrusion (VI).

This request for clarification is intended to augment a December 7, 2017 DHS letter to the Wisconsin Department of Natural Resources (DNR) providing recommendations for when immediate action is needed in response to written comments on proposed revisions to the RR-800 document. Specifically, DHS concurred with DNR's position that immediate action is justified when indoor air is found to be present at three (3) times the indoor air vapor action level (VAL) or sub-slab vapor risk screening level (VRSL) for a non-carcinogen or ten (10) times the VAL or VRSL for a carcinogen. In addition, DHS supported the DNR's position that immediate action be taken when trichloroethylene (TCE) is present in indoor air above the VAL and when women of child-bearing age are present.

DHS response:

DHS clarification statements defining acute risk and justifying timelines for responding to acute risk follow for each of the DNR scenarios presented in the request letter:

1. Clarification from DHS that acute risk necessitates immediate action as defined in s. NR 700.03(28), Wis. Admin. Code.

To reinforce the finding in the December 7, 2017 letter, DHS is in agreement that DNR's immediate action as defined in s. NR 700.03(28), Wis. Admin. Code is warranted when acute risk is observed as discussed in DNR's Vapor Intrusion Guidance RR800 (2018). For all contaminants with the exception of trichloroethylene (TCE) when women of childbearing years (age 15 to 44) are present, acute risk is defined as indoor air concentrations that are three times over the vapor action limit (VAL) for non-carcinogens

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or ten times over the VAL for carcinogens. For TCE where people who are or may become pregnant occupy a dwelling, acute risk is defined as indoor air concentrations that are equal to or over the VAL (HI \geq 1). These immediate action guidelines are in agreement with EPA guidance. The following statement is from the EPA OSWER Technical Guide for Assessing and Mitigating the Vapor Intrusion Pathway from Subsurface Vapor Sources to Indoor Air (EPA 2015): "Although the indoor air concentrations may vary temporally, an appropriate exposure concentration estimate (e.g., time-integrated or time-averaged indoor air concentration measurement in an occupied space) that exceeds the health-protective concentration levels for acute or shortterm exposure (i.e., generally considered to be a hazard quotient (HQ) greater than one for an acute or short-term exposure period) indicates vapor concentrations that are generally considered to pose an unacceptable human health risk."

2. Clarification from DHS that trichloroethylene (TCE) present in indoor air above the applicable VAL qualifies as an acute risk to women of child-bearing years.

DNR basis its VAL and VRSL values on EPA regional screening levels (RSLs) for indoor air. These values are developed using reference concentrations (RfCs) from EPA's toxicological assessments developed for its Integrated Risk Information System (IRIS). The non-cancer chronic inhalation RfC of $2x10^{-3}$ mg/m³ in EPAs toxicological assessment for TCE (2011) is based upon two rodent drinking water exposure studies. One study (Kiel et al., 2009) reported an immunotoxic effect of TCE presenting as a reduced thymus weight in female mice. The other study reported an increased incidence of fetal cardiac malformations (Johnson et al., 2003). The cardiac malformation developmental endpoint drives the concern over short term exposure to TCE. Although some limitations were reported with the Johnson et al. study (2003), the cardiac malformations finding has been confirmed by several reviews since, including the EPA Office of Solid Waste and Emergency Response (2014), ATSDR (2014), the Massachusetts Department of Environmental Protection (MADEP, 2014), a group of EPA researchers (Makris et al, 2016), and the North Carolina Department of Environmental Quality (NC DEQ, 2018). These reviews found that a two- to three-fold increase in congenital heart defects were observed in multiple animal studies and that the most frequently observed heart defects were also reported in humans exposed to TCEcontaining VOCs in several epidemiological studies (Brender et al. 2014, Dawson et al. 1993). These reviews also found that mechanistic support exists with studies in avian and mammalian cells demonstrating that TCE exposure alters processes that are critical to normal valve and septum formation. Although a recent EPA TSCA Risk Evaluation for TCE (2019) used the immunotoxic end point and not the fetal cardiac malformation end point for their risk determinations, the EPA Science Advisory Committee on Chemicals (SACC) was split on whether to use the fetal heart malformations endpoint for risk consideration and the TSCA Risk Evaluation was not allowed to consider epidemiological evidence or the effects of TCE exposure from air, contaminated waste sites, groundwater used for drinking water, and food in their evaluation.

The EPA identifies that a single exposure at any of several developmental stages may be sufficient to produce an adverse developmental effect (EPA, 1991). In humans, the cardiac system is the second to develop following fertilization, with cardiac development beginning at approximately 3 weeks following implantation. Substantial cardiac system development continues through 8 to 9 weeks post implantation, with the most sensitive period of cardiac development occurring in 3 to 6 weeks (Smart and Hodgson, 2018). These critical fetal heart development windows occur during a time period when an individual may not yet know they are pregnant. Rapid actions should be taken to minimize the potential for TCE exposures during these timeframes (EPA 2014, EPA Region V, 2020).

- 3. Health-based recommended responses including the definition of critical exposure windows with scientific justification to help inform DNR determination of time lines for immediate (s. NR 700.03(28), Wis. Admin. Code) and interim (s. NR 700.03(29), Wis. Admin. Code) actions in the following scenarios:
 - a. TCE is present beyond the envelope of a building at or above the applicable Vapor Risk Screening Level (VRSL);

DHS recommends an evaluation of the demographics for the building. If persons of childbearing years occupy the dwelling, indoor air samples should have a quick turnaround time (24 to 72 hours, EPA Region 9, 2014). Women in the sensitive demographic should be consulted about the potential TCE developmental toxicity risk so they may make informed decisions in terms of staying in the dwelling during the timeframe of the indoor air assessment. DHS or local health can assist with this consultation. If the indoor air TCE sample result exceeds the VAL, DHS recommends interim action (carbon filter unit) and rapid installation of sub-slab depressurization system within two weeks. If the indoor air TCE sample result is less than the VAL, mitigate and monitor indoor air in interim to ensure exposure is not occurring and move toward installation of a mitigation system within 4 to 8 weeks, depending upon the building's complexity and need for system design.

b. Non-carcinogenic compounds are present beyond the envelope of a building at or above three (3) times the applicable VRSL;

The U.S. EPA defines a reference concentration (RfC) as an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure of a chemical to the human population through inhalation (including sensitive subpopulations), that is likely to be without an appreciable risk of deleterious effects during a lifetime (IRIS Glossary, 2020). When a non-carcinogenic VOC is three times above the applicable VRSL, the risk of that VOC being present in indoor air at levels that can cause an adverse health effect is high enough to warrant urgent action including indoor air sampling with 24 to 72 hour turnaround time and mitigation within 4 to 8 weeks, or sooner where indoor air sampling results indicates a VAL exceedance.

c. Carcinogenic compounds are present beyond the envelope of a building at or above ten (10) times the applicable VRSL;

VRSLs are established in Wisconsin with a 10⁻⁵ cancer risk. When a carcinogenic compound is present in indoor air at or above ten times the applicable VRSL, the cancer risk exceeds 10⁻⁴ cancer risk. The risk of cancer occurrences from continuous exposure is therefore high enough to warrant the installation of a mitigation system within 4 to 8 weeks, depending upon the building's complexity and need for system design.

d. TCE is present in indoor air below the applicable VAL

Review sub-slab results when available. If sub-slab TCE data is also below VRSL, additional assessment should take place with normal laboratory turnaround time to confirm results are below action levels. If women of childbearing years occupy the building, an additional sampling round should take place as soon as feasible to ensure levels above VAL/VRSL is not present.

e. Non-carcinogenic compounds are present in indoor air between the applicable VAL and three (3) times the applicable VAL;

Move toward mitigation system installation within 4 to 8 weeks, depending upon complexity and need for system design. Perform indoor air sampling to confirm mitigation system is effective.

f. Carcinogenic compounds are present in indoor air between the applicable VAL and ten (10) times the applicable VAL;

Move toward mitigation with a recommended timeframe of 4 to 8 weeks, depending upon complexity and need for system design. Perform indoor air sampling to confirm mitigation system is effective.

g. TCE is present in indoor air at or above the applicable VAL;

DHS recommends an evaluation of the demographics for the building. If women of childbearing years occupy the building, implement interim actions such as carbon filtration units to interrupt the TCE exposure. Move toward installation of a mitigation system within two weeks. Women in the sensitive demographic should be consulted about the potential TCE developmental toxicity risk so they may make informed decisions in terms of staying in the dwelling during the timeframe of the indoor air assessment.

h. Non-carcinogenic compounds are present in indoor air at or above three (3) times the applicable VAL;

The U.S. EPA defines a reference concentration (RfC) as an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure of a chemical to the human population through inhalation (including sensitive subpopulations), that is likely to be without an appreciable risk of deleterious effects during a lifetime (IRIS Glossary, 2020). When a non-carcinogenic VOC is three times above the applicable VAL, the risk of adverse health effects occurring from continuous exposure is high enough to warrant the installation of a mitigation system within 4 to 8 weeks, depending upon the building's complexity and need for system design. Depending upon how far above the VAL the concentration is, more urgent actions may be needed, and the local health officer should be consulted for potential abatement orders, placarding, and temporary relocation of occupants per Section 254 Wis. Admin. Code.

i. Carcinogenic compounds are present in indoor air at or above ten (10) times the applicable VAL.

When a carcinogenic compound is present in indoor air at or above ten times the applicable VAL, the cancer risk exceeds 10^{-4} cancer risk. The risk of cancer occurrences from continuous exposure is therefore high enough to warrant the installation of a mitigation system within 4 to 8 weeks, depending upon the building's complexity and need for system design. Depending upon how far above the VAL the concentration is, more urgent actions may be needed, and the local health officer should be consulted for potential abatement orders, placarding, and temporary relocation of occupants per Section 254 Wis. Admin. Code.

4. Health-based recommendations for when sampling indoor air at commercial or industrial businesses is necessary in light of the recent Department of Defense study on sewers and utility tunnels as preferential pathways (Sewers and Utility Tunnels as Preferential Pathways for Volatile Organic Compound Migration into Buildings: Risk Factors And Investigation Protocol, ESTCP Project ER-201505).

DHS agrees with the finding in the DoD study that indoor air should be part of the VI assessment where evidence of preferential pathways might be feasible. This evidence may include detection of VOCs in sewer lines or utility corridors. Recent experience has shown instances where indoor air levels are found at high levels due to preferential pathway contamination through open sumps, openings in foundations, and poorly sealed conduits. DHS also recommends sampling indoor air when environmental sampling (groundwater, soil, or soil gas) indicates that indoor air action levels could be exceeded. When TCE is the contaminant of concern, indoor air should always be evaluated to assist with the risk assessment and be able to interrupt exposures as soon as possible to sensitive populations to prevent the known reproductive/developmental endpoint. When commercial or industrial businesses are users of the VOCs being studied, those chemicals may need to be temporarily removed prior to the indoor air assessment, where feasible.

Thank you for the opportunity to provide feedback on this topic. Please contact me at (608) 266-6677, or <u>curtis.hedman@wisconsin.gov</u> if you have any follow up questions or comments about this response.

Sincerely,

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Curtis Hedman, Ph.D. Toxicologist Bureau of Environmental and Occupational Health

Cc: Jennifer Borski, Vapor Intrusion Team Leader, DNR R&R Program Judy Fassbender, NR Program Manager, DNR R&R Program Roy Irving, Chief, DHS Hazard Assessment Section, BEOH Mark Werner, Chief, DHS BEOH

Enc: Summary of DHS response to Request for Assistance: Actions for Trichloroethylene at Acute Risk Levels

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DNR Ask	DHS Response	Supporting Reference(s)
1) Clarification from DHS that	A) Immediate action as defined in	A) December 7, 2017 DHS
acute risk necessitates	NR 700.03(28) warranted if: for	letter
immediate action as defined	compounds except TCE = 3x VAL, or	and EPA OSWER Tech Guide
in s. NR 700.03(28), Wis.	10x VAL carcinogens; TCE w/	(2015)
Admin. Code.	women age 15-44 = VAL	(2013)
2) Clarification from DHS that	A) VALs&VRSLs based on EPA RSLs	A) EPA tox assessment TCE
trichloroethylene (TCE)	B) RSL for TCE is based on	(2011)
present in indoor air above	immunotox. and fetal cardiac	B) Kiel et al. (2009) Johnson et
-	development endpoints	al. (2003)
the applicable VAL qualifies as an acute risk to women of		C)EPAOSWER (2014), ATSDR
	C) findings confirmed by reviews	(2014), MADEP (2014), Makris
child-bearing years	D) also consistent with epi study	et al (2016), NC DEQ (2018)
	findings	D) Brender et al. (2014), Dawson
	E) single exposure during	et al. (1993)
	development can have harmful	E) EPA (1991)
	effect	F) Smart and Hodgson (2018)
	F) critical development window 3 to	G) EPA 2014, EPA Region V (2020)
	6 weeks	(2020)
	G) rapid action warranted for TCE >	
	RSL	
-	responses including the definition of c	•
-	form DNR determination of time lines	-
	and interim (s. NR 700.03(29), Wis. Adı	nin. Code) actions in the
following scenarios:		B) 504 D : 0 (2014)
a) TCE is present beyond	A) evaluate demographics in	B) EPA Region 9, (2014)
the envelope of a	building	
building at or above	B) sample indoor air with 24-72	WI DNR RR800 (2018), EPA
the applicable Vapor	hour TAT	
Risk Screening Level		Reg V (2020)
_	C) consult w/ women 15-44 about	Reg V (2020)
(VRSL)	TCE	Reg V (2020)
_	TCE D) if TCE >VAL, carbon filtration	Reg V (2020)
_	TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system	Reg V (2020)
_	TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks	Reg V (2020)
_	TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks E) if TCE <val, another<="" perform="" th=""><th>Reg V (2020)</th></val,>	Reg V (2020)
_	TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks E) if TCE <val, another<br="" perform="">indoor air sample and sub-slab</val,>	Reg V (2020)
(VRSL)	TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks E) if TCE <val, another<br="" perform="">indoor air sample and sub-slab system w/in 4-8 weeks</val,>	
(VRSL) b) Non-carcinogenic	TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks E) if TCE <val, another<br="" perform="">indoor air sample and sub-slab system w/in 4-8 weeks A) RfC is estimate, ca. order of</val,>	Reg V (2020) C) EPA Region 9, (2014)
(VRSL) b) Non-carcinogenic compounds are	TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks E) if TCE <val, another<br="" perform="">indoor air sample and sub-slab system w/in 4-8 weeks A) RfC is estimate, ca. order of magnitude, of concentration w/o</val,>	C) EPA Region 9, (2014)
(VRSL) b) Non-carcinogenic compounds are present beyond the	 TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks E) if TCE <val, another<="" li="" perform=""> indoor air sample and sub-slab system w/in 4-8 weeks A) RfC is estimate, ca. order of magnitude, of concentration w/o harm over lifetime </val,>	C) EPA Region 9, (2014) WI DNR RR800 (2018), EPA
(VRSL) b) Non-carcinogenic compounds are present beyond the envelope of a building	TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks E) if TCE <val, another<br="" perform="">indoor air sample and sub-slab system w/in 4-8 weeks A) RfC is estimate, ca. order of magnitude, of concentration w/o harm over lifetime B) >3x that level cuts significantly</val,>	C) EPA Region 9, (2014)
(VRSL) b) Non-carcinogenic compounds are present beyond the envelope of a building at or above three (3)	 TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks E) if TCE <val, another<="" li="" perform=""> indoor air sample and sub-slab system w/in 4-8 weeks A) RfC is estimate, ca. order of magnitude, of concentration w/o harm over lifetime B) >3x that level cuts significantly into that safety factor </val,>	C) EPA Region 9, (2014) WI DNR RR800 (2018), EPA
(VRSL) b) Non-carcinogenic compounds are present beyond the envelope of a building at or above three (3) times the applicable	TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks E) if TCE <val, another<br="" perform="">indoor air sample and sub-slab system w/in 4-8 weeks A) RfC is estimate, ca. order of magnitude, of concentration w/o harm over lifetime B) >3x that level cuts significantly into that safety factor C) indoor air sampling with 24-72</val,>	C) EPA Region 9, (2014) WI DNR RR800 (2018), EPA
(VRSL) b) Non-carcinogenic compounds are present beyond the envelope of a building at or above three (3)	 TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks E) if TCE <val, another<="" li="" perform=""> indoor air sample and sub-slab system w/in 4-8 weeks A) RfC is estimate, ca. order of magnitude, of concentration w/o harm over lifetime B) >3x that level cuts significantly into that safety factor C) indoor air sampling with 24-72 hour TAT </val,>	C) EPA Region 9, (2014) WI DNR RR800 (2018), EPA
(VRSL) b) Non-carcinogenic compounds are present beyond the envelope of a building at or above three (3) times the applicable	 TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks E) if TCE <val, another<="" li="" perform=""> indoor air sample and sub-slab system w/in 4-8 weeks A) RfC is estimate, ca. order of magnitude, of concentration w/o harm over lifetime B) >3x that level cuts significantly into that safety factor C) indoor air sampling with 24-72 hour TAT D) sub-slab system w/in 4-8 weeks </val,>	C) EPA Region 9, (2014) WI DNR RR800 (2018), EPA
(VRSL) b) Non-carcinogenic compounds are present beyond the envelope of a building at or above three (3) times the applicable VRSL	TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks E) if TCE <val, another<br="" perform="">indoor air sample and sub-slab system w/in 4-8 weeks A) RfC is estimate, ca. order of magnitude, of concentration w/o harm over lifetime B) >3x that level cuts significantly into that safety factor C) indoor air sampling with 24-72 hour TAT D) sub-slab system w/in 4-8 weeks if >VAL</val,>	C) EPA Region 9, (2014) WI DNR RR800 (2018), EPA
(VRSL) b) Non-carcinogenic compounds are present beyond the envelope of a building at or above three (3) times the applicable	 TCE D) if TCE >VAL, carbon filtration w/in 48 hours and sub-slab system w/in 2 weeks E) if TCE <val, another<="" li="" perform=""> indoor air sample and sub-slab system w/in 4-8 weeks A) RfC is estimate, ca. order of magnitude, of concentration w/o harm over lifetime B) >3x that level cuts significantly into that safety factor C) indoor air sampling with 24-72 hour TAT D) sub-slab system w/in 4-8 weeks </val,>	C) EPA Region 9, (2014) WI DNR RR800 (2018), EPA

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	present beyond the	B) >10x that exceeds 10 ⁻⁴ cancer	
	envelope of a building	risk	
	at or above ten (10)	C) sub-slab system w/in 4-8 weeks	
	times the applicable	if >10x VRSL	
	VRSL		
d)	TCE is present in	A) verify TCE in sub-slab is not	WI DNR RR800 (2018), EPA
	indoor air below the	>VRSL	Reg. V (2020)
	applicable VAL	B) If TCE also <vrsl; more<="" one="" p=""></vrsl;>	
		sampling event	
		C) do follow up samples soon as	
		possible if women age 15-44 live in	
		building	
e)	Non-carcinogenic	A) sub-slab system w/in 4-8 weeks	WI DNR RR800 (2018), EPA
	compounds are	B) sample to confirm system is	Reg. V (2020)
	present in indoor air	effective	
	between the		
	applicable VAL and		
	three (3) times the		
f)	applicable VAL Carcinogenic	A) sub-slab system w/in 4-8 weeks	WI DNR RR800 (2018), EPA
, v	compounds are	B) sample to confirm system is	Reg. V (2020)
	present in indoor air	effective	Reg. V (2020)
	between the	enective	
	applicable VAL and		
	ten (10) times the		
	applicable VAL		
g)	TCE is present in	A) evaluate demographics in	WI DNR RR800 (2018), EPA
0,	indoor air at or above	building	Reg. V (2020)
	the applicable VAL	B) consult w/ women 15-44 about	<u> </u>
		TCE	
		C) carbon filtration w/in 48 hours	
		and sub-slab system w/in 2 weeks	
h)	Non-carcinogenic	A) RfC is estimate, ca. order of	WI DNR RR800 (2018), EPA
	compounds are	magnitude, of concentration w/o	Reg. V (2020)
	present in indoor air	harm over lifetime	
	at or above three (3)	B) >3x that level cuts significantly	
	times the applicable	into that safety factor	
	VAL	C) sub-slab system w/in 4-8 weeks	
		D) if >>VAL, consult health officer for actions available under Section	
		254 WI Administrative Code	
i)	Carcinogenic	A) VRSLs est. w/ 10 ⁻⁵ cancer risk	WI DNR RR800 (2018), EPA
, "	compounds are	B) >10x that exceeds 10^{-4} cancer	Reg. V (2020)
	present in indoor air	risk	
	at or above ten (10)	C) sub-slab system w/in 4-8 weeks	
	at of above ten (10)	CJ SUD-SIAD SYSLEM W/IN 4-8 WEEKS	

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times the applicable	D) if >>VAL, consult health officer	
VAL	for actions available under Section	
	254 WI Administrative Code	
4) Health-based	A) DHS agrees with DOD study	US DOD ESTCP Project ER-
recommendations for when	findings	201505 (2018)
sampling indoor air at	B) DHS recommends sampling	
commercial or industrial	indoor air when soil gas results	
businesses is necessary in light	suggest indoor air levels may be	
of the recent Department of	exceeded	
Defense study on sewers and	C) Indoor air should always be	
utility tunnels as preferential	assessed where TCE is contaminant	
pathways (Sewers and Utility	of concern due to acute	
Tunnels as Preferential	reproductive endpoint	
Pathways for Volatile Organic	D) when assessing indoor air in	
Compound Migration into	commercial buildings, may need to	
Buildings: Risk Factors And	relocate COCs that are used in	
Investigation Protocol, ESTCP	production during sampling	
Project ER-201505)		