

ANNEX A

TITLE 25. ENVIRONMENTAL PROTECTION
PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION
SUBPART D. ENVIRONMENTAL HEALTH AND SAFETY
ARTICLE VI. GENERAL HEALTH AND SAFETY
CHAPTER 250. ADMINISTRATION OF LAND RECYCLING PROGRAM

Subchapter A. GENERAL PROVISIONS

§ 250.1. Definitions.

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MDL – Method detection limit - The instrument-specific minimum measured concentration of a substance that can be reported with 99% confidence to be distinguishable from the method blank result.

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Volatile compound – A chemical compound with either a boiling point less than 200°centigrade at 1 atmosphere or a Henry’s law constant greater than or equal to 1×10^{-5} atm-m³/mol and a molecular weight less than 200 g/mol, where:

atm = standard atmosphere

m³ = cubic meter

mol = mole

g = gram

g/mol = molar mass

§ 250.4. Limits related to PQLs.

(a) The PQLs shall be selected from the PQLs **or EQLs** specified by the EPA [as EQLs] in the most current version of [the] EPA’s [RCRA Manual SW-846 (U. S. EPA, 1990. *Test Methods for Evaluating Solid Waste, Physical/Chemical Methods*. Third Edition. Office of Solid Waste and Emergency Response) for soil listed as “low level soil” and for groundwater listed as “groundwater” in accordance with the following:] **drinking water or solid waste analytical methods.**

[(1) For inorganic compounds, the PQLs under this chapter shall be the values listed for methods associated with analysis by Inductively Coupled Plasma (ICP) with the following exceptions:

(i) For lead, cadmium, arsenic and selenium, values listed for the atomic absorption graphite furnace methods for water shall be used.

(ii) Mercury shall be the value listed for the cold vapor method.

(2) For organic compounds, the PQLs shall be the EQLs listed for the GC/Mass spec methods—for example, Method 8240 for volatile organic compounds.

(b) If the PQL selected under subsection (a) is higher than the MCL or HAL for an organic regulated substance in groundwater, the PQLs shall be derived from the analytical methodologies [published under the drinking water program in the most current version of *Methods for the Determination of Organic Compounds in Drinking Water* (U. S. EPA, 1988, Environmental Monitoring Systems Laboratory, EPA/600/4-88/039) If a PQL determined under this subsection is not below a HAL, the methodologies in subsection (c)(1) or (2) shall be used unless those quantitation limits are higher than the PQL determined under this subsection.]

[(c)] (b) For regulated substances when PQLs or EQLs set by the EPA exceed an MCL or HAL or have a health risk that is greater (less protective) than the risk levels set in sections 303(c) and 304(b) and (c) of the act (35 P. S. § § 6026.303(c) and 6026.304(b) and (c)) [or] and for substances when no EQL has been established by the EPA, the [limits related to the] PQL shall be [the quantitation limits] established by the methodologies in paragraph (1) or (2).

(1) A level set by multiplying 3.18 by the published method detection limit (MDL) of the most recently approved EPA methodology.

(2) A level [representing the lowest calibration point that can consistently be determined to have a percent relative standard deviation (%RSD) of less than 30% or correlation coefficient of greater than 0.995 using reagent water.] set by multiplying 3.18 by the instrument-specific MDL. If multiple instruments are used, then the PQL is set by averaging the instrument-specific MDL's and multiplying that value by 3.18.

[(d)] (c) For regulated substances which have no limits related to PQLs identified in subsection [(c)] (b)(1) or (2), a person shall demonstrate attainment under the site-specific standard or the background standard.

[(e)] (d) When a minimum threshold MSC is used as a Statewide health standard, the minimum threshold MSC is the Statewide health standard regardless of whether it is higher or lower than a quantitation limit established by this section.

[(f)] (e) Nothing in this section restricts the selection of valid and generally accepted methods to be used to analyze samples of environmental media.

§ 250.6. Public participation.

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(c) If a public involvement plan has been initiated, the person proposing remediation shall, at a minimum, provide:

(1) Public access at convenient locations for document review.

(2) Designation of a single contact person to address questions from the community.

(3) A location near the remediation site for any public hearings and meetings that may be part of the public involvement plan.

(4) Measures to involve the public in the development and review of the remedial investigation report, risk assessment report, cleanup plan and final report.

(d) If a public involvement plan has been requested, **[it shall be submitted with one of the following:] the person proposing the remediation shall notify the Department and submit the plan to the municipality and the Department prior to its implementation.**

[(1) A remedial investigation report under a site-specific remediation.

(2) A baseline environmental report under an SIA cleanup.]

§ 250.10. Measurement of regulated substances in media.

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(d) For groundwater where monitoring is being performed at a drinking water well, samples for metals analysis shall be field acidified and unfiltered in accordance with the most current version of **[Groundwater Monitoring Guidance Manual] Land Recycling Program Technical Guidance Manual, Appendix A: Groundwater Monitoring Guidance,** Department of Environmental Protection, [3610-BK-DEP1973] **document number 261-0300-101.**

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§ 250.12. Professional Seal.

Reports submitted to satisfy this subchapter containing information or analysis that constitutes professional geologic or engineering work as defined by the Engineer, Land Surveyor and Geologist Registration Law (63 P.S. § § 148—158.2) must be sealed by a professional geologist or engineer who is in compliance with that statute.

Subchapter C. STATEWIDE HEALTH STANDARDS

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§ 250.304. MSCs for groundwater.

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(c) The MSCs for regulated substances contained in groundwater in aquifers used or currently planned to be used for drinking water or for agricultural purposes are the MCLs as established by the Department or the EPA in § 109.202 (relating to State MCLs, MRDLs and treatment technique requirements). For regulated substances where no MCL has been established, the MSCs are the Lifetime Health Advisory Levels (HAL) set forth in Drinking Water Standards and Health Advisories (DWSHA), EPA Office of Water Publication No. EPA [822-S-12-001 (April 2012)822-F-18-001 (March 2018 or as revised), except for substances designated in the DWSHA with cancer descriptor (L) “Likely to be carcinogenic to humans” or (L/N) “Likely to be carcinogenic above a specific dose but not likely to be carcinogenic below that dose because a key event in tumor formation does not occur below that dose.” New or revised MCLs or HALs promulgated by the Department or the EPA shall become effective immediately for any demonstration of attainment completed after the date the new or revised MCLs or HALs become effective.

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(g) The references referred to in subsection (f) are:

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(19) ATSDR (Agency for Toxic Substances and Disease Registry). 2015. *Toxicological Profile for Perfluoroalkyls. Draft for Public Comment. Agency for Toxic Substances and Disease Registry, Public Health Service, U.S. Department of Health and Human Services, Atlanta, GA. Accessed May 2016. <http://www.atsdr.cdc.gov/ToxProfiles/tp200.pdf>.*

(20) Hekster, F.M., R.W. Laane, and P. de Voogt. 2003. *Environmental and toxicity effects of perfluoroalkylated substances. Reviews of Environmental Contamination and Toxicology 179:99–121.*

(21) HSDB (Hazardous Substances Data Bank). 2012. U.S. National Library of Medicine, Bethesda, MD. Accessed May 2016. <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB>.

(22) Kauck, E.A., and A.R. Diesslin. 1951. *Some properties of perfluorocarboxylic acids. Industrial & Engineering Chemistry Research 43(10):2332–2334.*

(23) SRC (Syracuse Research Corporation). 2016. PHYSPROP Database. Accessed May 2016. <http://www.srcinc.com/what-we-do/environmental/scientific-databases.html>.

(24) OECD (Organisation for Economic Co-operation and Development). 2002. *Hazard Assessment of Perfluorooctane Sulfonate (PFOS) and its Salts*. ENV/JM/RD (2002) 17/FINAL. Report of the Environment Directorate, Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, Co-operation on Existing Chemicals, Paris, November 21, 2002.

§ 250.305. MSCs for soil.

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(c) For the residential standard, the MSC for regulated substances contained in soil is one of the following:

(1) The lowest of the following:

(i) The ingestion numeric value throughout the soil column to a depth of up to 15 feet from the existing ground surface as determined by the methodology in § 250.306 (relating to ingestion numeric values), using the appropriate default residential exposure assumptions contained in § 250.306(e)(d).

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(g) A person conducting a remediation of soils contaminated with a substance having a secondary MCL **and no MSC** will not be required to comply with the soil-to-groundwater pathway requirements for those substances to protect groundwater in aquifers for drinking water.

§ 250.306. Ingestion numeric values.

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(d) The default exposure assumptions used to calculate the ingestion numeric values are as follows:

<i>Term</i>		<i>Residential</i>		<i>Nonresidential (Onsite Worker)</i>
		<i>Systemic¹</i>	<i>Carcinogens^{2,6}</i>	
THQ	Target Hazard Quotient	1	N/A	1
RfD _o	Oral Reference Dose (mg/kg-day)	Chemical-specific	N/A	Chemical-specific
BW	Body Weight (kg)		N/A	
	Soil	15		80
	Groundwater	80		80
AT _{nc}	Averaging Time for systemic toxicants (yr)			
	Soil	6	N/A	25
	Groundwater	30	N/A	25
Abs	Absorption (unitless) ³	1	1	1
EF	Exposure Frequency (d/yr)			
	Soil	250	250	180
	Groundwater	350	350	250
ED	Exposure Duration (yr)			
	Soil	6	N/A	25
	Groundwater	30	N/A	25
IngR	Ingestion Rate			
	Soil (mg/day)	100	N/A	50
	GW (L/day)	[2] <u>2.4</u>	N/A	[1] <u>1.2</u>

Term		Residential		Nonresidential (Onsite Worker)
		Systemic ¹	Carcinogens ^{2,6}	
CF	Conversion Factor Soil (kg/mg) GW (unitless)	1×10^{-6} 1	1×10^{-6} 1	1×10^{-6} 1
TR	Target Risk	N/A	1×10^{-5}	1×10^{-5}
CSF _o	Oral Cancer Slope Factor (mg/kg-day) ⁻¹	N/A	Chemical-specific	Chemical-specific
AT _c	Averaging Time for carcinogens (yr)	N/A	70	70
IFadj ⁴	Ingestion Factor Soil (mg-yr/kg-day) GW (L-yr/kg day)	N/A	55 [1] 1.2	15.6 [0.3] 0.38
AIFadj ⁵	Combined Age-Dependent Adjustment Factor and Ingestion Factor Soil (mg-yr/kg-day) GW (L-yr/kg-day)	N/A	241 [3.23] 3.45	N/A
CSFo _k	TCE oral cancer slope factor for kidney cancer (mg/kg/day) ⁻¹		9.3×10^{-3}	
CSFo _l	TCE oral cancer slope factor for non-Hodgkin lymphoma and liver cancer (mg/kg/day) ⁻¹		3.7×10^{-2}	

Notes:

⁴The Ingestion Factor for the residential scenario is calculated using the equation $If_{[adj]adj} = ED_c \times IR_c / BW_c + ED_a \times IR_a / B[w]W_a$, where $ED_c = 6$ yr, $IR_c = 100$ mg/day for soils and 1 L/day for groundwater, $BW_c = 15$ kg, $ED_a = 24$ yr, $IR_a = 50$ mg/day for soils and [2] **2.4** L/day for groundwater, and $BW_a = 80$ kg. The ingestion factor for the nonresidential scenario is calculated using the equation $If_{[adj]adj} = ED \times IR / BW$, where $ED = 25$ yr, $IR = 50$ mg/day for soils and [1] **1.2** L/day for groundwater, and $BW = 80$ kg.

⁵ The Combined Age-Dependent Adjustment Factor and Ingestion Factor (AIFadj) for the residential scenario is calculated using the equation $AIFadj = [(ADAF_{2} \times ED_{2}) + (ADAF_{2-6} \times ED_{2-6})] \times IR[c]_g / BW[c]_g + [(ADAF_{16-16} \times ED_{16-16}) + (ADAF_{16} \times ED_{16-16})] \times IR[a]_a / BW[a]_a$, where $ADAF_{2} = 10$, $ED_{2} = 2$

yr, ADAF₂₋₆ = 3, ED₂₋₆ = 4 yr, IR[c]_g = 100mg/day for soils and 1 L/day for groundwater, BW[c]_g = 15 kg, ADAF_[16-16] = 3, ED_[16-16] = 10 yr, ADAF_{,16} = 1, ED_{,16} = 14 yr, IR[a]_a = 50 mg/day for soils and [2] 2.4 L/day for groundwater, and BW[a]_a = 80 kg.

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(e) The residential ingestion numeric value for lead in soil was developed using the [**Uptake Biokinetic (UBK) Model for Lead (version 0.4)**] **Integrated Exposure Uptake Biokinetic Model for Lead in Children, Windows® version (IEUBKwin v1.1 build 11) 32-bit version** developed by the EPA (U.S. Environmental Protection Agency. (**[1990] February 2010**)) [**Uptake Biokinetic (UBK) Model for Lead (version 0.4). U.S. EPA/ECAO. August 1990,**] in lieu of the algorithms presented in subsections (a) and (b). Default input values are identified in Appendix A, Table 7. Because the **IEUBK** model is applicable only to children, the nonresidential ingestion numeric value was calculated [**according to the method developed by the Society for Environmental Geochemistry and Health (Wixson, B. G. (1991)). The Society for Environmental Geochemistry and Health (SEGH) Task Force Approach to the Assessment of Lead in Soil. *Trace Substances in Environmental Health.* (11-20), using the following equations:**

$$S = \frac{1000 \left[\left(\frac{T}{G^n} \right) - B \right]}{\delta}$$

using EPA’s Adult Lead Methodology (ALM) in accordance with the guidance, exposure factors, equations, and spreadsheets provided in EPA’s *Recommendations of the Technical Review Workgroup for Lead for an Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil* (EPA-540-R-03-001, OSWER Dir #9285.7-54, January 2003), *OLEM Directive 9285.6-56 “Update to the Adult Lead Methodology’s Default Baseline Blood Lead Concentration and Geometric Standard Deviation Parameters”* (May 2017) and the associated June 14, 2017, version of the *Calculations of Preliminary Remediation Goals (PRGs) for Soil in Nonresidential Areas U.S. EPA Technical Review Workgroup for Lead, Adult Lead Committee spreadsheets.* Table 7 identifies each of the variables [in this equation] used to calculate the nonresidential ingestion numeric value for lead.

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§ 250.307. Inhalation numeric values.

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(g) For a regulated substance which is a carcinogen and is a volatile compound, the numeric value for the inhalation of volatiles from groundwater shall be calculated by using the appropriate residential or nonresidential exposure assumptions from subsection (h) according to the following equations:

(1) For regulated substances not identified as a mutagen in § 250.301(b):

$$MSC = \frac{TR \times AT_c \times 365 \text{ days/year} \times \mathbf{24 \text{ hr/day}}}{IUR \times ET \times EF \times ED \times TF \times CF}$$

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§ 250.308. Soil to groundwater pathway numeric values.

(a) A person may use the soil-to-groundwater pathway numeric values listed in Appendix A, Tables 3B and 4B, as developed using the methods contained in paragraph (1), (2) or (4), may use a concentration in soil at the site which does not produce a leachate in excess of the MSC for groundwater contained in Appendix A, Tables 1 and 2, when subjected to the Synthetic Precipitation Leaching Procedure (Method 1312 of SW-846, Test Methods for Evaluating Solid Waste, promulgated by the U. S. EPA), or may use the soil-to-groundwater pathway soil buffer criteria in subsection (b) or may use the soil-to-groundwater pathway equivalency demonstration in subsection (d).

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(2) For organic compounds, a generic value determined not to produce a concentration in groundwater in the aquifer in excess of the MSC for groundwater as calculated by the equation in paragraph (3).

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(ii) For soil in the zone of groundwater saturation, the **[standard] generic numeric value** is 1/10th of the generic value calculated by the equation in paragraph (3).

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Subchapter D. SITE-SPECIFIC STANDARD

§ 250.402. Human health and environmental protection goals.

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(d) If a person is using the site-specific standard to protect ecological receptors under this subchapter or **[in accordance with] as a result of selecting § 250.311(e)(4) when ecological receptors cannot be evaluated under the Statewide health standard,** the following shall be performed:

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(3) Implementation of the selected remedy, which may include mitigation measures under § **[230.311(f)] 250.311(f)**, that is protective of the ecological receptors.

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§ 250.404. Pathway identification and elimination.

(a) The person shall use **Department or** Department-approved EPA or ASTM guidance to identify any potential current and future exposure pathways for both human receptors and environmental receptors identified in § 250.402 (relating to human health and environmental protection goals).

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§ 250.409. Risk assessment report.

The risk assessment report shall conform to this subchapter and Subchapter F (relating to exposure and risk determinations), and shall include the following unless not required under § 250.405 (relating to when to perform a risk assessment):

(1) **Except when submitted in combination with a remedial investigation report, a[A]** risk assessment report that **uses site characterization information from an approved remedial investigation report to** describe[s] the potential adverse effects, including the evaluation of ecological receptors, under both current and planned future conditions caused by the presence of regulated substances in the absence of any further control, remediation or mitigation measures.

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§ 250.410. Cleanup plan.

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(d) **A cleanup plan is required when an institutional or engineering control is used as a remedy to address current and future exposure pathways or exposure pathways that existed prior to submitting an NIR.**

(e) A cleanup plan is not required and no remedy is required to be proposed or completed if no current or future exposure pathways exist.

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§ 250.412. Combined reports.

A person does not need prior Department approval of a remedial investigation report if the remedial investigation report is submitted together with either a risk assessment or a cleanup plan.

Subchapter E. SIA STANDARDS

§ 250.503. Remediation requirements.

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(e) A person that changes the use of the property from nonresidential to residential, or changes the use of the property to create substantial changes in exposure conditions to contamination that existed prior to the person's reuse shall notify the Department of the changes and may be required to **amend the baseline environmental report and** implement a remediation plan to address any new imminent, direct or immediate threats to human health and the environment resulting from the changes.

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Subchapter F. EXPOSURE AND RISK DETERMINATIONS

§ 250.603. Exposure factors for site-specific standards.

(a) A risk assessment for the site-specific standard shall use site-specific exposure factors under the EPA's [*Final Guidelines for Exposure Assessment, 1992 (57 FR 22888—22938)*] **Exposure Factors Handbook: 2011 Edition, 2011 (EPA/600/R-090/052F)** or exposure factors used in the development of the Statewide health standards identified in Subchapter C (relating to Statewide health standards).

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§ 250.605. Sources of toxicity information.

(a) For site-specific standards, the person shall use appropriate reference doses, reference concentrations, cancer slope factors and unit risk factors identified in Subchapter C (relating to Statewide health standards), unless the person can demonstrate that published data, available from one of the following sources, provides more current reference doses, reference concentrations, cancer slope factors or unit risk factors:

- (1) Integrated Risk Information System (IRIS).

(2) United States Environmental Protection Agency, National Center for Environmental Assessment (NCEA) Provisional Peer-Reviewed Toxicity Values (PPRTV).

(3) Other sources:

(i) Health Effects Assessment Summary Tables (HEAST)

(ii) Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles.

(iii) California EPA, California Cancer Potency Factors and Chronic Reference Exposure Levels.

(iv) EPA criteria documents, including drinking water criteria documents, drinking water health advisory summaries, ambient water quality criteria documents and air quality criteria documents.

(v) EPA Human Health Benchmarks for Pesticides (HHBP)

(vi) EPA PPRTV Appendix

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Subchapter G. DEMONSTRATION OF ATTAINMENT

§ 250.707. Statistical tests.

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(b) The following statistical tests may be accepted by the Department to demonstrate attainment of the Statewide health standard. The statistical test for soil shall apply to each distinct area of contamination. The statistical test for groundwater will apply to each compliance monitoring well. Testing shall be performed individually for each regulated substance identified in the final report site investigation as being present at the site for which a person wants relief from liability under the act. The application of a statistical method must meet the criteria in subsection (d).

(1) For soil attainment determination at each distinct area of contamination, subparagraph (i), (ii) or (iii) shall be met in addition to the attainment requirements in §§ 250.702 and 250.703 (relating to attainment requirements; and general attainment requirements for soil).

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(ii) As applied in accordance with EPA approved methods on statistical analysis of environmental data, as identified in subsection (e), the 95% UCL of the arithmetic mean shall be at or below the **[Statewide health standard] MSC**.

(iii) For sites with a petroleum release where full site characterization, as defined in § 250.204(b) (relating to final report), has not been done in association with an excavation remediation, attainment of the Statewide health standard shall be demonstrated using the following procedure:

(A) For sites regulated under Chapter 245 (relating to administration of the storage tank and spill prevention program) where there is localized contamination as defined in the document “Closure Requirements for Underground Storage Tank Systems” (DEP technical document 2530-BK-DEP2008), samples shall be taken in accordance with that document.

(B) For sites not covered by clause (A), including all sites being remediated under an NIR under this chapter, samples shall be taken from the bottom and sidewalls of the excavation in a biased fashion that concentrates on areas where any remaining contamination above the Statewide health standard would most likely be found. The samples shall be taken from these suspect areas based on visual observation and the use of field instruments. If a sufficient number of samples has been collected from all suspect locations and the minimum number of samples has not been collected, or if there are no suspect areas, the locations to meet the minimum number of samples shall be based on a random procedure. The number of sample points required shall be determined in the following way:

(I) For 250 cubic yards or less of excavated contaminated soil, five samples shall be collected.

(II) For each additional 100 cubic yards of excavated contaminated soil, one sample shall be collected.

(III) For excavations involving more than 1,000 cubic yards of contaminated soil, the remediator shall identify the number and locations of samples in a confirmatory sampling plan submitted to the Department. The remediator shall obtain the Department’s approval of the confirmatory sampling plan prior to conducting attainment sampling.

(IV) Where water is encountered in the excavation and no obvious contamination is observed or indicated, soil samples collected just above the soil/water interface shall be equal to or less than the applicable Statewide health MSC determined by § 250.308(a)(2)(ii) (relating to soil to groundwater pathway numeric values).

(V) Where water is encountered in the excavation and no obvious contamination is observed or indicated, a minimum of two samples shall be collected from the water surface in the excavation.

(VI) For sites where there is a release to surface soils resulting in excavation of 50 cubic yards or less of contaminated soil, samples shall be collected as described in this clause, except that two samples shall be collected.

(C) All sample results shall be equal to or less than the applicable Statewide health MSC as determined using Tables 1—4 and 6 in Appendix A.

(D) A vapor intrusion analysis is not necessary if the requirements of § 250.707(b)(1)(iii) are met in addition to the following:

(I) At least one soil sample is collected on the sidewall nearest an inhabited building within the appropriate proximity distance to a potential vapor intrusion source and there are not substantially higher field instrument readings elsewhere.

(II) Observations of obvious contamination and the use of appropriate field screening instruments verify that contamination has not contacted or penetrated the foundation of an inhabited building.

(III) Groundwater contamination has not been identified as a potential vapor intrusion concern.

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