Ohio Administrative Code

Rule 3745-300-09 Property-specific risk assessment procedures.

Effective: October 17, 2019

[Comment: For dates of non-regulatory government publications, publications of recognized organizations and associations, federal rules, and federal statutory provisions referenced in this rule, see rule 3745-300-15 of the Administrative Code titled "Incorporation by reference - voluntary action program."]

(A) Applicability. The volunteer may use the property-specific risk assessment procedures in this rule to determine applicable standards in place of, or in addition to, generic numerical standards in accordance with rule 3745-300-08 of the Administrative Code.

(1) If radioactive materials are identified at a property, the property may be subject to the Atomic Energy Act and regulations adopted thereunder and Chapters 3701. and 3747. of the Revised Code and rules adopted thereunder. If radionuclides or radioactive materials are present at a property, the volunteer shall conduct the cleanup of the radionuclides or radioactive material in compliance with requirements of the Ohio department of health. Remedy approval by the Ohio department of health are sufficient to meet applicable standards for radionuclides or radioactive materials for the voluntary action.

(2) Elective application. If a volunteer elects not to apply one or more of the generic numerical standards established under rule 3745-300-08 of the Administrative Code to a chemical of concern (COC), the volunteer shall use a property-specific risk assessment to develop an applicable standard for that COC.

(3) Mandatory application. A volunteer shall conduct a property-specific risk assessment in accordance with this rule to determine applicable standards instead of, or in addition to, use of the generic numerical standards in rule 3745-300-08 of the Administrative Code if any of the following apply to the property:

(a) The complete exposure pathways identified in accordance with paragraph (F)(1) of rule 3745-

300-07 of the Administrative Code include exposure pathways that are not considered in the development of standards listed in the appendices to rule 3745-300-08 of the Administrative Code.

(b) The exposure factors for the receptors identified in paragraph (E)(6) of rule 3745-300-07 of the Administrative Code are not considered in the development of standards listed in the appendices to rule 3745-300-08 of the Administrative Code.

(c) COCs that originate from the property, as follows:

(i) The COCs consist of hazardous substances or petroleum that do not have generic numerical standards included in the appendices to rule 3745-300-08 of the Administrative Code.

(ii) If only some of the COCs identified have a generic numerical standard listed in the appendices to rule 3745-300-08 of the Administrative Code, a volunteer may use the applicable generic numerical standards for the COC that has listed standards, and may conduct a property-specific risk assessment in accordance with this rule.

(iii) When a combination of generic numerical standards and applicable standards determined by a property-specific risk assessment conducted in accordance with this rule is used, the volunteer shall adjust the concentrations of the applicable standards to meet the human health risk and hazard levels described in paragraph (B) of this rule.

(d) Concentrations of COCs in surface water or sediment exceed applicable standards determined in accordance with rule 3745-300-08 of the Administrative Code.

(e) There are complete exposure pathways to important ecological resources (IERs) other than sediment or surface water, such as soil.

(f) There are persistent, bioaccumulative, and toxic (PBT) COCs that are determined to be from the property that do not have or that exceed applicable standards as determined in accordance with rule 3745-300-08 of the Administrative Code. A list of PBTs can be found in Ohio EPA's "Ecological Risk Assessment Guidance."

(B) Applicable risk and hazard levels for human receptors. The volunteer shall determine the applicable standards for human receptors developed from a property-specific risk assessment in accordance with the following risk and hazard levels:

(1) Carcinogenic risk. For COCs which have carcinogenic effects, the cumulative human health carcinogenic risk shall not exceed the following risk levels based on the reasonably anticipated use of the property:

(a) For all residential and commercial property land uses, the cumulative carcinogenic risk, which is attributable to the COCs, shall not exceed an excess upper bound lifetime cancer risk to an individual of one in one hundred thousand ($1x10^{-5}$).

(b) For industrial property land use, the cumulative carcinogenic risk shall not exceed an excess upper bound lifetime cancer risk to an individual, which is attributable to the COCs, of one in ten thousand ($1x10^{-4}$) provided that a demonstration that the cumulative cancer risk to off-property receptors, which is attributable to COCs, is less than an excess upper bound lifetime cancer risk to an individual of one in one hundred thousand ($1x10^{-5}$):

(2) Non-carcinogenic hazard. For COCs which have non-carcinogenic effects, the cumulative human health hazard, which is attributable to the COCs, shall not exceed a hazard index of one.

(3) Carcinogenic risk and non-carcinogenic hazard. For COCs which have both carcinogenic and non-carcinogenic effects, the concentration of the COCs shall not exceed the risk and hazard levels established in paragraphs (B)(1) and (B)(2) of this rule. If more than one complete exposure pathway exists to each receptor population, the incremental cancer risk and hazard indices determined for each exposure pathway shall be summed to calculate a cumulative cancer risk and hazard index to each receptor population. All final cumulative human health carcinogenic risk and non-carcinogenic hazard levels are based on one significant figure.

(C) Petroleum standards.

(1) COCs that are required to be evaluated are dependent on the petroleum fraction of the released product. The volunteer shall evaluate additional petroleum constituents or typical impurities to

ensure applicable standards are met. The volunteer shall assess and evaluate the risk indicator compounds for each appropriate petroleum fraction including the following:

(a) For light petroleum fractions, such as natural gasoline, gasohol, or naphtha solvents, the volunteer shall analyze environmental media for benzene, toluene, ethylbenzene, methyl tert-butyl ether, total xylenes, naphthalene, and 1,2,4-trimethylbenzene.

(b) For middle petroleum fractions, such as kerosene, diesel fuel, or jet fuel, the volunteer shall analyze environmental media for benzene, toluene, ethylbenzene, total xylenes, acenaphthene, anthracene, chrysene, benzo[a]anthracene, benzo[a]pyrene, benzo[b]fluoranthene, benzo[k]fluoranthene, dibenzo[a,h]anthracene, fluoranthene, fluorene, indeno[1,2,3-cd]pyrene, naphthalene, and pyrene.

(c) For heavy petroleum fractions, such as hydraulic oil, lube oil, or residual fuel oils, the volunteer shall analyze environmental media for acenaphthene, anthracene, chrysene, benzo[a]pyrene, benzo[a]anthracene, benzo[b]fluoranthene, benzo[k]fluoranthene, dibenzo[a,h]anthracene, fluoranthene, fluorene, indeno[1,2,3-cd]pyrene, naphthalene, and pyrene. Where the heavy petroleum is used motor oil, used cutting oil, or hydraulic oil, the volunteer shall identify additional COCs that may be typical impurities of the used heavy petroleum fractions product, and the volunteers shall include such COCs in the analysis, as appropriate.

(d) For releases of automotive gasoline formulated before January 1, 1996, racing fuel, or aviation gasoline, the volunteer shall analyze environmental media for the constituents listed in paragraph (C)(1)(a) of this rule as well as 1,2-dichloroethane and 1,2-dibromoethane (ethylene dibromide).

(e) For petroleum from an unknown source, the volunteers shall analyze environmental media for benzene, ethylbenzene, toluene, total xylenes, methyl tert-butyl ether, acenaphthene, anthracene, chrysene, benzo[a]anthracene, benzo[a]pyrene, benzo[b]fluoranthene, benzo[k]fluoranthene, dibenzo[a,h]anthracene, fluoranthene, fluorene, indeno[1,2,3-cd]pyrene, naphthalene, and pyrene. The volunteer shall identify additional COCs that may be typical impurities of used petroleum fractions, and the volunteer shall include such additional COCs in the analysis, as appropriate.

(2) Evaluation of compliance with applicable standards. The concentrations of COCs evaluated in

accordance with paragraph (D)(3)(a) of this rule on or from the property shall meet applicable standards for the media and exposure pathways evaluated. As appropriate, the volunteer shall evaluate applicable standards for petroleum and petroleums constituents or impurities in the following manner:

(a) The volunteer shall conduct a human health property-specific risk assessment that includes derivation of applicable standards in accordance with paragraph (D) of this rule, or shall use generic numerical standards provided in rule 3745-300-08 of the Administrative Code. The volunteer may use generic numerical standards for the exposure pathways included in rule 3745-300-08 of the Administrative Code. The volunteer shall evaluate other exposure pathways in accordance with paragraph (D) of this rule. The volunteer shall conduct an evaluation of cumulative risks in accordance with paragraphs (B) and (D)(3)(d) of this rule.

(b) The volunteer shall determine soil saturation concentrations of total petroleum hydrocarbons utilizing the vertical hydraulic conductivity of the unsaturated soil or otherwise demonstrate the soil type most representative of the soils impacted by petroleum. The corresponding petroleum fraction shall meet the residual saturation concentration in table I of this rule.

	Residual Saturation Concentrations for:		Sand and Gravel; Unknown Soil Type
Silty or Clayey Sand	Glacial Till and Silty Clay	Petroleum Fraction	K_V : 10^{-3} - 10^{-4} cm/s
K_V : 10^{-4} - 10^{-5} cm/s	K_V : < 10^{-5} cm/s	Light (C_6 - C_{12})	1,000
5,000	8,000	Middle (C_{10} - C_{20})	2,000
10,000	20,000	Heavy (C_{20} - C_{34})	5,000

(c) Free product exceeds applicable standards for unrestricted potable use of ground water. Ground water with free product shall meet the appropriate ground water response requirements in accordance with rule 3745-300-10 of the Administrative Code.

(d) The volunteer shall evaluate sediment, surface water, and ecological exposure pathways in accordance with this rule and rule 3745-300-08 of the Administrative Code as appropriate.

(D) Procedures for human health risk assessments.

(1) For a human health property-specific risk assessment conducted in accordance with this rule the volunteer shall demonstrate that the concentrations of COCs on or from a property meet the applicable risk and hazard levels under paragraph (B) of this rule.

(2) Voluntary action activities affecting the property-specific risk assessment. For the property-specific risk assessment, the volunteer shall take into account the following:

(a) The classification and use of the ground water determined in accordance with rule 3745-300-10 of the Administrative Code.

(b) The implementation of remedial activities other than institutional controls or engineering controls that address the COCs and are consistent with rule 3745-300-11 of the Administrative Code.

(c) The use of institutional controls including, without limitation, activity and use limitations in the environmental covenant. Institutional controls shall meet the following criteria:

(i) Be effective at eliminating or mitigating exposures to all receptor populations sufficient to meet the risk and hazard levels in paragraph (B) of this rule.

(ii) Be capable of being monitored, maintained, and enforced by the owner or operator of the property during the period of time which the control is used to achieve and maintain applicable standards.

(iii) Be transferrable with the property and recorded with the county recorder during the period of time which the control is used to achieve and maintain applicable standards.

(d) The existence of engineering controls including, without limitation, fences, cap systems, cover systems, and landscaped controls. Engineering controls shall meet the following criteria:

(i) Be effective at eliminating or mitigating exposures to all receptor populations sufficient to meet the risk and hazard levels or applicable standards in this rule.

(ii) Be effective and reliable for the climatic conditions and activities at the property to which the control is applied.

(iii) Be reliable during the period of time which the control is used to achieve and maintain applicable standards.

(iv) Be capable of being monitored and maintained as required by an operation and maintenance plan or agreement developed in accordance with rule 3745-300-11 of the Administrative Code in order to ensure that the control remains effective.

(e) The physical and chemical characteristics of the COCs at the property, identified under rules 3745-300-06 and 3745-300-07 of the Administrative Code, as either individual chemicals or as chemical mixtures whenever such chemical mixture data are available.

(f) Relevant exposure pathway information for a property. Property-specific information includes the following:

(i) As identified following the procedures under rules 3745-300-06 and 3745-300-07 of the Administrative Code, the physical characteristics of the property or properties that describe and define complete exposure pathways determined in accordance with paragraph (F)(1) of rule 3745-300-07 of the Administrative Code. Physical characteristics shall include, at a minimum, topography, climate, native soils and fill material characteristics, consolidated and unconsolidated geological units, hydrogeological conditions and zones of saturation, surface water bodies, engineered structures (e.g., buildings, roads, retaining walls, constructed fills), and subsurface utilities.

(ii) The spatial distribution of the COCs in identified areas or exposure units on the property, which are determined in accordance with the procedures under rule 3745-300-07 of the Administrative Code. The physical distribution information shall include the relative concentrations of the COCs in identified areas on the property.

(3) The property-specific risk assessment is comprised of four parts: selection of chemicals of concern, exposure assessment, toxicity assessment, and characterization of risk. These four parts are

as follows:

(a) Selection of COCs. Hazardous substances or petroleum identified on or from the property are considered COCs and the volunteer shall evaluate such COCs pursuant to all the appropriate risk assessment calculations and methods referenced in paragraph (D)(3) of this rule if such hazardous substances or petroleum fall into one of the following categories:

(i) Do not meet the applicable standards established for background pursuant to paragraph (H) of rule 3745-300-07 of the Administrative Code.

(ii) Do not constitute contamination in de minimis or previously addressed areas pursuant to paragraph (E) of rule 3745-300-06 of the Administrative Code.

(iii) Cannot be removed from the list of COCs pursuant to paragraph (F)(5)(f) of rule 3745-300-07 of the Administrative Code.

(b) Exposure assessment. The exposure assessment shall determine the reasonably anticipated magnitude, frequency, duration, and routes of exposure. The exposure assessment shall include consideration of the information obtained or activities performed under paragraph (D)(2) of this rule for the known and reasonably anticipated land use.

(i) Identification of receptor populations. The exposure assessment shall evaluate the risk and hazard potential to all receptor populations as identified in paragraph (E)(6) of rule 3745-300-07 of the Administrative Code that are reasonably anticipated to be exposed to COCs on or from the property. The exposure assessment shall evaluate populations for the magnitude and frequency of exposure for each exposure period.

(ii) Evaluation of exposure pathways, as follows:

(a) The property-specific exposure assessment shall evaluate all complete exposure pathways in accordance with paragraph (F)(1) of rule 3745-300-07 of the Administrative Code.

(b) The exposure assessment shall include a written justification for all exposure pathways

eliminated or mitigated through the use of institutional controls or engineering controls. The written justification shall include a description of the efficacy of such controls. The volunteer shall implement the described institutional controls or engineering controls in accordance with rules 3745-300-11 and 3745-300-13 of the Administrative Code.

(c) The volunteer shall evaluate complete exposure pathways in accordance with the procedures in the following sources, as incorporated by reference in rule 3745-300-15 of the Administrative Code:

(i) U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part A)."

(ii) U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment."

(iii) U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment)."

(iv) U.S. EPA's "Exposure Factors Handbook," 2011 Edition and 2017 Chapter 5 updates.

(v) U.S. EPA's "Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors."

(iii) Quantification of chemical-specific intake. The volunteer shall calculate chemical-specific intakes to quantify the exposure of each receptor population as identified in accordance with paragraph (E)(6) of rule 3745-300-07 of the Administrative Code, to COCs on or from the property as identified in accordance with paragraph (D)(3)(a) of this rule, and for each medium identified in a phase II property assessment.

(a) The volunteer shall calculate the chemical-specific intakes using formulas identified in the following sources, as incorporated by reference in rule 3745-300-15 of the Administrative Code:

(i) U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part A)."

(ii) U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment."

(iii) U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment)."

(iv) U.S. EPA's "Exposure Factors Handbook," 2011 Edition and 2017 Chapter 5 updates.

(v) U.S. EPA's "Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors."

(vi) Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures."

(b) The volunteer shall determine the numerical values for the exposure factor terms in formulas in accordance with paragraphs (D)(3)(b)(iii)(c) and (D)(3)(b)(iii)(d) of this rule.

(c) Exposure factors.

(i) The volunteer shall determine the exposure factor values either as point values or as the output value from a probabilistic simulation of twenty thousand or more iterations which solve for the chemical-specific intake equation. A probabilistic simulation output value for the intake shall be the ninetieth per centile or greater value.

(ii) For risk-derived unrestricted potable use ground water, the volunteer shall obtain exposure factor values using the reasonable maximum exposure point values in Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures," which are the basis for the development of the generic unrestricted potable use standards listed in appendix A to rule 3745-300-08 of the Administrative Code. Distributions developed by the volunteer shall adequately describe the parameter in question following U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part A)."

(iii) For all other pathways, the volunteer shall obtain the exposure factor values using one of the following methods:

(A) Exposure factor values not determined from property-specific information. For exposure factors represented by a point value, these values shall be upper bound or central tendency with an estimate of upper-bound exposures obtained in accordance with U.S. EPA's "Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors" and Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures" for the complete exposure pathway which contributes most substantially to risk, and for any other complete exposure pathways for which upper-bound exposures are deemed likely. For all other complete exposure pathways, exposure factor point values shall be the values representative of central tendency, upper bound or other appropriate exposures as defined in Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures." When exposure factor values are represented by probability distributions as input for a probabilistic simulation, the volunteer shall derive the probability distributions using guidance in U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume III Part A: Process for Conducting a Probabilistic Risk Assessment."

(B) Exposure factor values determined from property-specific information. For the complete exposure pathway which contributes most substantially to risk, and for any other complete exposure pathways for which upper-bound exposures are deemed likely, the property-specific exposure factor value shall reasonably represent the upper bound value or central tendency value from a distribution of property-specific data, as appropriate. Exposure factor values shall be consistent with an estimate of upper-bound exposures as described in U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part A)," and Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures." For all other complete exposure pathways, the property-specific exposure factor values shall reasonably represent either an upper-bound or central tendency value from a distribution of property-specific data for that exposure factor term. Property-specific exposure factor distributions and, if used, the upper bound or central tendency values derived from property-specific exposure factor distributions, shall meet the criteria for property-specific data described in paragraph (D)(3)(b)(iv) of this rule.

(d) Exposure point concentration. The volunteer shall determine exposure point concentrations for each complete exposure pathway and shall represent the concentration of COCs from each of the identified areas or exposure units. This representation of exposure point concentration shall be consistent with concentrations of the COCs determined in accordance with paragraph (F)(6) of rule 3745-300-07 of the Administrative Code, and the exposure factor values as determined in accordance with paragraph (D)(3)(b)(iii)(c) of this rule.

(iv) Criteria for use of property-specific data. Property-specific data used in the identification of receptor populations described in paragraph (D)(3)(b)(i) of this rule, the identification of exposure pathways as described in paragraph (D)(3)(b)(ii) of this rule, or the quantification of chemical-specific intake as described in paragraph (D)(3)(b)(iii) of this rule, shall meet the following criteria:

(a) The volunteer shall collect property-specific physical data in accordance with paragraph (E) of rule 3745-300-07 of the Administrative Code.

(b) Property-specific information used to define any parameter which requires the prediction of human use and activity patterns on a property, or the physical, physiological, and behavioral characteristics of the receptor populations shall be representative of the reasonably anticipated land use category and the actual property characteristics, and shall be included in an institutional control or engineering control that complies with rule 3745-300-11 of the Administrative Code.

(c) Peer-reviewed literature sources may be used for the express intent to define property-specific data for paragraphs (D)(3)(b)(i), (D)(3)(b)(ii), and (D)(3)(b)(iii) of this rule. Literature-based data shall be consistent with property-specific conditions.

(c) Toxicity assessment.

(i) Information hierarchy. The volunteer shall obtain the toxicity information used in a property-specific risk assessment from the following hierarchy:

(a) U.S. EPA toxicity values [i.e., "Integrated Risk Information System" (IRIS)]. The volunteer shall obtain the most current toxicity information from the IRIS for COCs that are being evaluated in the property-specific risk assessment.

(b) Ohio EPA toxicity information. If the toxicity information required to be used in a property-specific risk assessment is not in the IRIS, or is not listed in Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures," the volunteer shall consult Ohio EPA to obtain appropriate toxicity information.

(ii) Absorption factors and adjustment of toxicity values, as follows:

(a) The volunteer shall evaluate the toxicity values selected for use in the property-specific risk assessment as described in paragraph (D)(3)(c)(i) of this rule for each of the COCs in conjunction with the quantification of chemical-specific intake as described in paragraph (D)(3)(b)(iii) of this rule for each complete exposure pathway, in accordance with the procedures described in U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part A)," and U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)."

(b) The volunteer shall perform the risk characterization in accordance with the procedures described in paragraph (D)(3)(d) of this rule so that chemical-specific intake and toxicity values are both expressed as the absorbed dose or both expressed as the administered dose.

(c) The volunteer shall obtain default and chemical-specific absorption factor and bioavailability values in accordance with U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part A)," and U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)" or from Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures."

(d) Risk characterization. Risk characterization shall integrate the exposure and toxicity assessments in order to quantitatively determine the risk or hazard posed by the COCs on or from the property. The risk characterization shall evaluate carcinogenic risks and non-carcinogenic hazard separately.

(i) Cancer risk characterization. The volunteer shall estimate cancer risks as an incremental probability of an individual member of a receptor population developing cancer over a lifetime as a

result of exposure to carcinogenic COCs on or from the property; hereafter, this estimation of cancer risk is referred to as incremental cancer risk. The volunteer shall calculate separately an incremental cancer risk, at a minimum, for each receptor population identified in accordance with the procedures described in paragraph (D)(3)(b)(i) of this rule. An estimate of incremental cancer risk for each receptor population shall not exceed the applicable carcinogenic risk goal in paragraph (B)(1) of this rule. An estimate of incremental cancer risk is calculated as follows:

(a) A volunteer shall determine incremental cancer risk in accordance with the procedures described in this rule and in U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part A)" for each carcinogenic COC and for each complete exposure pathway identified in accordance with paragraphs (D)(3)(a) and (D)(3)(b)(ii) of this rule, respectively.

(b) If incremental cancer risk is determined for a receptor population for more than one carcinogenic COC, the volunteer shall calculate separately, as appropriate, the cumulative incremental cancer risk posed by these multiple COCs, for each complete exposure pathway in accordance with the procedures described in U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part A)."

(c) If incremental cancer risk is determined for a receptor population for more than one complete exposure pathway, the volunteer shall calculate the cumulative incremental cancer risk posed by an estimate based on the complete exposure pathways in accordance with the procedures described in paragraph (D)(3)(d) of this rule and in U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part A)."

(ii) Noncancer hazard characterization. The volunteer shall calculate a hazard index value to determine the exposure which is not likely to cause noncancer adverse health effects posed by COCs to each receptor population at a property for the duration of that exposure in accordance with the applicable noncancer hazard goals described in paragraph (B)(2) of this rule. The volunteer shall calculate a separate hazard index for each receptor population over a specified exposure period (i.e., chronic or sub-chronic exposure) identified in accordance with the procedures described in paragraph (D)(3)(b)(ii) of this rule, as follows:

(a) The volunteer shall calculate a hazard quotient for each COC with noncancer effects described by a reference dose or reference concentration for each complete exposure pathway in accordance with the procedures described in this rule and in U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part A)."

(b) If the volunteer determines hazard quotient values representing noncancer hazards for one receptor population over a specified exposure period for more than one COC as described in paragraph (D)(3)(d)(ii)(a) of this rule, the volunteer shall calculate separately, as appropriate, the cumulative noncancer hazards posed by these COCs as a hazard index value for each complete exposure pathway in accordance with the procedures described in U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part A)." The volunteer may perform separate hazard index calculations based on the consideration of major non-carcinogenic toxic endpoints, which shall include, at a minimum, those toxic endpoints identified with the critical effect upon which the reference dose or reference concentration is based, for each non-carcinogenic COC. The volunteer shall submit a written justification for separate hazard index calculations in the property-specific risk assessment report.

(c) If the volunteer determines hazard index values representing noncancer hazard for one receptor population over a specified exposure period for more than one complete exposure pathway, the volunteer shall calculate cumulative noncancer hazard posed by one or more complete exposure pathways, as appropriate, as a hazard index value in accordance with the procedures described in this rule and in U.S. EPA's "Risk Assessment Guidance for Superfund (RAGs), Volume I: Human Health Evaluation Manual (Part A)." Exclusion of one or more non-carcinogenic COCs from the hazard index calculations performed in accordance with paragraph (D)(3)(d)(ii)(b) of this rule may be reconsidered with respect to the toxic endpoints, (including, as available, target organ, modes of action, or mechanisms of action) identified for the non-carcinogenic COCs associated with each complete exposure pathway considered in accordance with this paragraph.

(iii) Uncertainty analysis. The volunteer shall evaluate uncertainty associated with the property-specific risk assessment. The uncertainty analysis shall include a qualitative description or quantitative evaluation of uncertainty associated with any of the following:

(a) Selection of COCs and the exposure point concentration.

(b) Estimates of chemical-specific intake factors.

(c) Complete exposure pathways.

(d) Toxicity criteria.

(e) Additive or antagonistic effects of exposure to multiple COCs through one or more complete exposure pathways.

(f) Evaluation of site-specific, epidemiological, or health studies.

(E) Procedures for ecological risk assessment.

(1) For each complete exposure pathway to IERs from environmental media that contain COCs that are persistent, bioaccumulative, and toxic, the volunteer shall evaluate the environmental media using a food web model in accordance with Ohio EPA's "Ecological Risk Assessment Guidance Document," as incorporated by reference in rule 3745-300-15 of the Administrative Code. Further assessment is not needed if concentrations of COCs in sediment or surface water do not exceed the following:

(a) Ohio-specific metal sediment reference values by ecoregion in table I of appendix B to rule 3745-300-08 of the Administrative Code.

(b) Consensus-based threshold effect concentrations in "Development and Evaluation of Consensus-based Sediment Quantity Guidelines for Freshwater Ecosystems," as incorporated by reference in rule 3745-300-15 of the Administrative Code. These values are in table II of appendix B to rule 3745-300-08 of the Administrative Code.

(c) Surface water standards provided in Chapter 3745-1 of the Administrative Code, in accordance with paragraph (F)(2)(a) of rule 3745-300-08 of the Administrative Code, for all releases or source areas of hazardous substances on or from the property to surface waters of the state.

(2) If COCs are present for which there are no reference values in accordance with paragraph (E)(1) of this rule, then the volunteer shall determine such values in consultation with Ohio EPA.

(a) If concentrations of COCs do not exceed reference values, then no further evaluation is necessary.

(b) If concentrations exceed reference values, then the following apply:

(i) A qualitative property-specific ecological risk assessment may be appropriate, and the volunteer may conduct a qualitative property-specific ecological risk assessment in order to demonstrate that COCs on or from a property are not harmful to IERs in cases where toxicity is likely to be low based on the concentrations of such COCs, the land use, the habitat quality, contributions from upstream anthropogenic inputs, and the areal extent of the habitat.

(ii) The volunteer shall conduct a quantitative property-specific ecological risk assessment in accordance with Ohio EPA's "Ecological Risk Assessment Guidance Document" if complete exposure pathways from environmental media other than surface water or sediment exist to IERs and the provisions in paragraph (E)(1) or (E)(2) of this rule do not apply.

(3) The volunteer shall collect data to assess ecological risk for both qualitative and quantitative ecological property-specific risk assessments in accordance with rule 3745-300-07 of the Administrative Code.

(F) Procedures for assessment and remediation of sediments.

(1) For each complete human health exposure pathway from source areas on the property to sediments, the volunteer shall determine if concentrations of COCs in sediments meet applicable standards in accordance with paragraph (G) of rule 3745-300-08 of the Administrative Code, or shall conduct a human health property-specific risk assessment following the methodology provided in paragraph (D) of this rule.

(2) For purposes of this rule and rule 3745-300-07 of the Administrative Code, an exposure pathway to humans is considered to exist if both of the following apply:

(a) The surface water which contains the sediments produces or can produce a consistent supply of edible-sized fish.

(b) COCs that are persistent, bioaccumulative, and toxic are present in the sediment or the surface water.

(3) An exposure pathway to humans is considered to exist if the surface water which contains the sediments is reasonably anticipated to support recreational activities such as wading, fishing, swimming, and boating.

(4) For each complete exposure pathway from sediments to IERs where applicable standards determined in accordance with paragraph (H)(2) of rule 3745-300-08 of the Administrative Code are not met or sediment samples are not compared to the appropriate values in accordance with paragraph (H) of rule 3745-300-08 of the Administrative Code, the volunteer shall evaluate the sediment toxicity according to the following methodology:

(a) For all surface waters that have an aquatic life use designation of warm-water habitat, exceptional warm-water habitat (excluding lakes and reservoirs), modified warm-water habitat, or cold-water habitat assigned under Chapter 3745-1 of the Administrative Code, the volunteer shall conduct a biological survey. The biological survey shall include the following:

(i) The volunteer shall use a fish and physical habitat survey to calculate the qualitative habitat evaluation index, the index of biotic integrity and, where applicable, a modified index of well-being for the surface water. To accomplish this, the volunteer shall follow the procedures in "Biological Criterial for the Protection of Aquatic Life" (hereinafter in this rule referred to as the "biocriteria manual") and Ohio EPA's division of surface water "Manual of Ohio EPA Surveillance Methods and Quality Assurance Practices," as both documents are incorporated by reference in rule 3745-300-15 of the Administrative Code. If possible, the sampling locations for the fish and physical habitat survey shall include the same locations where sediment samples are collected.

(ii) The volunteer shall use a quantitative macroinvertebrate survey to calculate the invertebrate community index for the surface waters. To accomplish this, the volunteer shall follow the

biocriteria manual unless the water body does not have sufficient depth and flow to conduct a quantitative macroinvertebrate study. If the water body does not have sufficient depth and flow to conduct a quantitative macroinvertebrate study, the volunteer shall conduct a qualitative macroinvertebrate study using the biocriteria manual and the instruction provided by the biocriteria certification and qualified data collector approval obtained in accordance with paragraph (D) of rule 3745-300-05 and paragraph (B) of rule 3745-4-03 of the Administrative Code. If possible, the sampling locations for the quantitative macroinvertebrate survey shall include the same locations established where sediment samples are collected.

[Comment: If the volunteer conducts a qualitative macroinvertebrate study, Ohio EPA recommends that the volunteer consult Ohio EPA regarding appropriate steps to perform the study.]

(b) For all surface waters with an aquatic life use designation of limited resource water assigned under Chapter 3745-1 of the Administrative Code, or that are a lake, reservoir, wetland, or pond, the volunteer shall conduct sediment bioassays using sediment samples taken from the surface waters to evaluate sediment toxicity. The volunteer shall determine sediment bioassay sampling locations in accordance with this rule and rule 3745-300-07 of the Administrative Code. At a minimum, sediment bioassays shall include the ten-day survival and growth test for Hyalella azteca and Chironomus tentans following the procedures in U.S. EPA's "Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates," as incorporated by reference in rule 3745-300-15 of the Administrative Code. Chironomus riparius may be substituted for Chironomus tentans if necessary.

(c) For all surface waters with an aquatic life use designation of limited warm-water habitat or with no aquatic life use designation assigned under Chapter 3745-1 of the Administrative Code, a volunteer shall either conduct a use attainability analysis as detailed in the biocriteria manual to assign the appropriate aquatic life use designation, or shall apply biocriteria for warm-water habitat. The volunteer shall consult Ohio EPA for assistance to make a determination on an aquatic life use designation for an unlisted water body.

(5) Unless concentrations of COCs in sediments meet applicable standards in accordance with paragraph (H) of rule 3745-300-08 of the Administrative Code, applicable standards for sediments and surface water are as follows:

(a) For surface water that has an aquatic life use designation of warm-water habitat, exceptional warm-water habitat (excluding lakes and reservoirs), modified warm-water habitat, or cold-water habitat assigned under Chapter 3745-1 of the Administrative Code, the volunteer shall determine the applicable standards in accordance with the water quality standards established or developed under the Water Pollution Control Act and Chapter 6111. of the Revised Code and the regulations adopted thereunder.

[Comment: The applicable standards for releases or source areas of hazardous substances or petroleum include the water quality standards established or developed in accordance with Chapter 3745-1 of the Administrative Code. Examples of such standards include, but are not limited to, the general water quality criteria, water use designations and statewide water quality criteria, the criteria provided for the applicable drainage basin, the site-specific modifications to criteria and values, and the methodologies for the development of criteria and values.]

(b) For surface water with an aquatic life use designation of limited resource water assigned under Chapter 3745-1 of the Administrative Code and for surface waters which are wetlands, ponds, lakes, or reservoirs, the applicable standards are the absence of toxic effects to both organism groups as defined in U.S. EPA's "Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates."

(6) The volunteer shall take the following actions when applicable standards for sediments are not met in accordance with paragraphs (F)(5)(a) and (F)(5)(b) of this rule:

(a) Submit a written demonstration to be in a risk assessment report or a section of the phase II property assessment under paragraph (I) of this rule that substantiates the determination that hazardous substances or petroleum on or from the property did not cause the failure to meet the applicable standards in paragraph (F)(5) of this rule, taking into consideration upstream sources not related to releases from the property. Applicable standards for sediment are met if the volunteer demonstrates that hazardous substances or petroleum on or from the property are not contributing to the failure to meet the applicable standards in paragraph (F)(5) of this rule.

(b) Implement a remedy conducted in accordance with rule 3745-300-11 of the Administrative Code

to meet applicable standards.

(7) The volunteer may conduct a bioassay or biosurvey in accordance with paragraph (F) of this rule instead of applying paragraph (H)(1) of rule 3745-300-08 of the Administrative Code. If sediment bioassay or biosurvey does not demonstrate full compliance with applicable standards, the volunteer shall conduct sediment sampling according to rule 3745-300-07 of the Administrative Code in order to determine the concentrations of COCs in sediments.

(8) A volunteer may use historical biological data collected and interpreted by Ohio EPA or certified professionals approved as level 3 qualified data collectors in accordance with paragraph (D) of rule 3745-300-05 of the Administrative Code, as part of the demonstration that applicable standards are met, provided that the data are not collected more than ten years prior to the issuance of the no further action letter. Prior to the inclusion of historical data within an applicable standards demonstration, volunteers shall consider any changes in the watershed, release history, property characteristics, or knowledge of recent data collection.

(G) Surface water assessment. If concentrations of COCs in surface water exceed applicable standards in accordance with paragraph (F)(2)(a) of rule 3745-300-08 of the Administrative Code, then the standards for surface water in paragraphs (E) and (F)(5) of this rule are applicable.

(H) Determination of applicable standards from a property-specific risk assessment. If the volunteer elects or is required to apply risk derived standards determined in accordance with this rule, applicable standards from a property-specific risk assessment are one or more of the following:

(1) Concentrations of COCs which meet the risk and hazard levels for human health in accordance with paragraphs (B) and (C) of this rule and in accordance with paragraphs (D) and (F) of this rule.

(2) Concentrations of COCs that protect IERs in accordance with paragraph (E) of this rule.

(3) The applicable standards for sediments under paragraphs (F) of this rule.

(4) The applicable standards for surface water under paragraph (G) of this rule.

(5) The soil saturation concentrations, for all compounds which are not at solid phase at ambient soil temperatures, if such concentration are lower than the applicable standard concentrations determined in accordance with paragraphs (H)(1) to (H)(4) of this rule. The volunteer shall use the following equation, along with property-specific information, to calculate a property-specific soil saturation concentration:

$$C_{sat} = \frac{S}{\rho_b}\left(K_d\rho_b + \theta_w + H'\,\theta_a\right)$$

$$\begin{gathered}
Where: \\
C_{sat}\ is\ the\ soil\ saturation\ concentration\ \ (mg/kg) \\
S\ is\ the\ water\ solubility\ (mg/L\ water) \\
\rho_b\ is\ dry\ soil\ bulk\ density\ (kg/L) \\
K_d\ is\ the\ soil-water\ partition\ coefficient\ \ (L/kg)\ \ (default\ is\ K_d = K_{oc} \times f_{oc}) \\
K_{oc}\ is\ the\ soil\ organic\ carbon/water\ partition\ coefficient\ (l/kg) \\
f_{oc}\ is\ the\ fraction\ organic\ carbon\ of\ soil\ \ g/g \\
\theta_w\ is\ the\ water-filled\ soil\ porosioty\ \ (L_{water}/L_{soil}) \\
H'\ is\ the\ dimensionless\ Henry's\ Law\ constant \\
\theta_a\ is\ the\ air-filled\ porosity\ \ (L_{pore}/L_{soil})
\end{gathered}$$

(a) The volunteer shall obtain all chemical-specific values for the above equation from one of the following sources:

(i) Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures."

(ii) If chemical-specific values for the above equation are not available in the sources listed above, contact Ohio EPA to determine other appropriate values.

(b) The volunteer shall obtain physical values from one of the following sources:

(i) U.S. EPA's "Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites."

(ii) Property-specific data that meet the criteria in paragraph (D)(3)(b)(iv) of this rule.

(I) Risk assessment information. Upon completion of a property-specific risk assessment conducted in accordance with this rule, the volunteer shall present the information in a risk assessment report or

in a section of the phase II property assessment. The volunteer shall prepare a risk assessment and shall include, at a minimum, the following information:

(1) The circumstances under which the property-specific risk assessment was conducted with respect to paragraphs (A)(2) and (A)(3) of this rule.

(2) A list of the institutional controls and engineering controls implemented upon which the property-specific risk assessment is based. Pursuant to rule 3745-300-11 of the Administrative Code, the volunteer shall demonstrate the efficacy of those controls.

(3) A list of the COCs on or from the property which are not considered in the property-specific risk assessment because the COCs meet the criteria under paragraph (D)(3)(a) of this rule and a written demonstration, which includes supporting data, of how those criteria are met.

(4) A list of the receptor populations and exposure pathways identified under paragraphs (D)(3)(b)(i) and (D)(3)(b)(ii) of this rule, respectively, and a written justification for the selection or elimination of those receptor populations and exposure pathways.

(5) All appropriate documentation which supports the derivation and application of exposure factors used to quantify intake as described in paragraph (D)(3)(b)(iii) of this rule and meets the criteria in paragraph (D)(3)(b)(iv) of this rule.

(6) A list of all the toxicity values that are used in the property-specific risk assessment, in accordance with paragraph (D)(3)(c) of this rule, and the sources for those values.

(7) Characterization of risk, as described in paragraph (D)(3)(d) of this rule.

(8) Ecological risk report, in accordance with paragraph (E) of this rule.

(9) Sediment assessment report, in accordance with paragraph (F) of this rule.

(10) Surface water assessment report, if surface waters are required to be assessed, in accordance with paragraph (G) of this rule.

(11) A summary of compliance with applicable standards, in accordance with paragraph (H) of this rule.