

3745-300-09 Property-Specific Risk Assessment Procedures.

(A) Definitions. As used in this rule:

- (1) "Andelman, 1990" means Andelman, J. B., "Total Exposure to Volatile Organic Chemicals in Potable Water," N.M. Ram, R.F. Christman, K.P. Cantor (eds.). Lewis publishers, Andelman, 1990.
- (2) "Aquatic life field assessment" means an evaluation which includes, as appropriate, a macrobenthic community evaluation, a fish community evaluation and bioassays.
- (3) "Biocriteria Manual" means collectively, unless specified otherwise, Ohio EPA, "Biological Criteria for the Protection of Aquatic Life: Volume II: User's Manual for Biological Field Assessment of Ohio Surface Waters," October 30, 1987 (updated January 1, 1988, amended September 30, 1989), and Ohio EPA, "Biological Criteria for the Protection of Aquatic Life: Volume III: Standardized Biological Field Sampling and Laboratory Methods for Assessing Fish and Macroinvertebrate Communities," September 30, 1989.
- (4) "Central tendency value" means a parameter value from a probability distribution of parameter values which is an estimation of the median of that distribution.
- (5) "Chemical-specific intake" means the measure of exposure of a receptor to chemical(s) of concern and is equivalent to the administered dose. Chemical specific intake is equal to the mass of a substance in contact with the exchange boundary of a receptor per unit body mass per unit time. For the purposes of this rule, chemical specific intake is expressed in units of milligrams per kilogram (mg/kg) per day.
- (6) "Chronic exposure period" means a duration which equals or exceeds ten per cent of the anticipated life span of a receptor, or seven years for a human receptor, during which direct contact between a receptor and a chemical(s) of concern is reasonably anticipated.
- (7) "Contact rate" means the amount of medium exposed to the receptor population(s) per unit of time or per event.
- (8) "Cowherd, et al., 1985" means Cowherd, C., Muleski, G. Engelhart, P., and Gillete, D., "Rapid Assessment of Exposure to Particulate Emissions From Surface Contamination," 1985. Prepared for U. S. EPA office of health and environmental assessment. EPA/600/8-85/002.
- (9) "Exposure factor point value" means a single numeric value selected from a distribution of numeric values of the exposure factor, selected on the basis of its representativeness of a central tendency or upper-bound value.

- (10) "Exposure point" means a location where the receptor populations are reasonably expected to contact the chemical(s) of concern in a medium through dermal contact, inhalation or ingestion.
- (11) "Exposure point concentration" means the mass of a chemical of concern per unit quantity of medium which is available for uptake by a receptor. For the purposes of this rule, exposure point concentrations are expressed in units of mg/kg for the soil medium, units of $\mu\text{g/L}$ for the ground water medium and units of mg/m^{-3} for the air medium.
- (12) "Exposure route" means the locus at which chemicals are exchanged between the environmental medium and the receptor.
- (13) "Fate and transport" means the behavior and movement of a chemical through environmental media.
- (14) "Hazard quotient" means the value which quantifies noncarcinogenic risk for one chemical for one receptor population over a specified exposure period. The hazard quotient is equal to the ratio of a chemical-specific intake to the reference dose.
- (15) "Johnson and Ettinger, 1991" means Johnson, P. C. and R.A. Ettinger, "Heuristic Model for Predicting the Intrusion Rate of Contaminant Vapors Into Buildings," *Environmental Science and Technologies*, 25(8): 1445-1452, 1991.
- (16) "Jury, et al., 1990" means Jury, W. A., D. Russo, G. Streile, and H. E. Ada, "Evaluation of Volatization by Organic Chemicals Residing Below the Soil Surface," 1990. *Water Resources Research*, 26(1): 13-20.
- (17) "McDonald and Harbaugh, 1988" means McDonald, Michael G., and Arlen W. Harbaugh, "Chapter A1: A Modular Three-Dimensional Finite-Difference Ground-Water Flow Model. U.S. geological survey. Open file report 83-87, 1988.
- (18) "Monte Carlo simulation" means a mathematical technique that produces a distribution of values for a calculated term by solving for that term in successive iterations. Each successive iteration requires the selection of a single input value from defined distribution(s) for each of the terms used to derive the calculated term.
- (19) "MT3D" means MT3D version 1.11, January 1992. Available through U.S. EPA, Kerr laboratory, center for subsurface modeling support.
- (20) "Ohio EPA, 1995" means Ohio EPA, "Technical Guidance Manual for Hydrogeologic Investigations and Ground Water Monitoring," 1995.

- (21) "Ohio EPA Sediment Toxicity Test" means Ohio EPA, "*Hyaletta Azteca* Solid Phase Toxicity Testing Procedure," May, 1998.
- (22) "Quality Assurance Manual" means "Manual of Ohio EPA Surveillance Methods and Quality Assurance Practices," October 1, 1988 (revised December, 1991).
- (23) "Reference dose (RFD)" means a value representative of a daily exposure level for the human population, including sensitive subpopulations, that is not likely to cause adverse non-cancer health effects during a lifetime.
- (24) "Ravi and Johnson, N.D.G." means Ravi, Varadhan and Jeffrey A. Johnson, "VLEACH - A One-Dimensional Finite Difference Vadose Zone Leaching Model," version 2.2. Dynamac Corporation. Developed for U.S. EPA office of research and development, Robert S. Kerr environmental research laboratory. Ada, Oklahoma.
- (25) "RISKPRO's AT123D for Windows©, July, 1995" means "RISKPRO's AT123D for Windows©," general sciences corporation. Laurel, MD. July, 1995.
- (26) "RISKPRO's SESOIL for Windows©, July, 1995" means "RISKPRO's SESOIL for Windows©," general science corporation. Laurel, MD. July, 1995.
- (27) "Shorter-term exposure period" means an exposure period of a duration less than two weeks for humans and which may be the result of one or several exposure events.
- (28) "Single-medium pathway" means an exposure pathway in which the source medium for a chemical of concern is the medium from which contact is made between the receptor and the chemical. Examples of single-medium pathways include, but are not limited to, ingestion of soil-borne chemicals, and dermal contact with chemicals dissolved in ground water.
- (29) "Slope factor" means a value from which an upper-bound estimate of excess cancer risk posed by the exposure of a human to a chemical-specific intake can be calculated.
- (30) "Subchronic exposure period" means a duration intermediate between a shorter-term exposure period and a chronic exposure period. For the purposes of this rule, a subchronic exposure is of a duration between two weeks and seven years for the use in the evaluation of human receptors.
- (31) "Support document for generic standards" means the "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures," February, 2002.

- (32) "Transport-mediated pathway" means an exposure pathway in which contact occurs between a receptor and a chemical of concern in a medium distinct from the source medium of that chemical of concern. Examples of transport-mediated pathways include, but are not limited to, ingestion of ground water into which soil-borne chemicals have leached, and inhalation of vapors which have volatilized from soil-borne chemicals.
- (33) "U.S. EPA, 1988" means U.S. EPA, "Superfund Exposure Assessment Manual," U.S. EPA, office of remedial response. EPA540/1-88/001. April 1988.
- (34) "U.S. EPA, 1989a" means U.S. EPA, "Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual (Part A)," U.S. EPA, office of remedial response. EPA/540/1-89/002. December, 1989.
- (35) "U.S. EPA, 1989b" means U.S. EPA, "Exposure Factors Handbook," U.S. EPA, office of health and environmental assessment. EPA/600/8-89/043. 1989.
- (36) "U.S. EPA, 1989c" means U.S. EPA, "Risk Assessment Guidance for Superfund, Volume II: Environmental Evaluation Manual," EPA/540/1-89-001. 1989.
- (37) "U.S. EPA, 1991a" means U.S. EPA, "Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors," U.S. EPA, Office of Remedial Response. U.S. EPA office of solid waste and emergency response directive 9285.6-03. 1991.
- (38) "U.S. EPA, 1991b" means U.S. EPA, "Risk Assessment Guidance for Superfund, Volume I Human Health Evaluation Manual (Part B, Development of Risk-Based Preliminary Remediation Goals.)" U.S. EPA, office of research and development. EPA/540/R-92/003. December, 1991.
- (39) "U.S. EPA, 1992a" means U.S. EPA, "Dermal Exposure Assessment: Principles and Applications," U.S. EPA, office of health and environmental assessment. EPA/600/8-91/011B. 1992.
- (40) "U.S. EPA, 1992b" means U.S. EPA, "Guidelines for Exposure Assessment," 52 FR 22888. Washington, D.C. 1992.
- (41) "U.S. EPA 1997" means: U.S. EPA "Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments, Interim Final", EPA/540/R-97/006, June 1997.

- (42) "U.S. EPA 1998" means: U.S. EPA, "Guidelines for Ecological Risk Assessment," EPA/630/R-95/002F, April 1998.
- (43) "U.S. EPA, 1992c" means U.S. EPA, "Supplemental Guidance to RAGS: Calculating the Concentration Term," U.S. EPA, Office of Solid Waste and Emergency Response. U. S. EPA office of solid waste and emergency response directive 9285.7-08B. 1992.
- (44) "U.S. EPA, 1992d" means U.S. EPA, Framework for Ecological Risk Assessment", EPA/630/r-92/001. February, 1992.
- (45) "U.S. EPA, 1995a" means U.S. EPA, "Health Effects Assessment Summary Tables: FY-1995 Annual," U.S. EPA, office of solid waste and emergency response. EPA/54015-95/036. May, 1995.
- (46) "U.S. EPA, 1995b" means U.S. EPA, Users Guide for the Industrial Source Complex (ISC3) Dispersion Models. U. S. EPA office of air quality planning and standards. Research Triangle Park, North Carolina. EPA-454/b-96/018.
- (47) "U.S. EPA, 1995c" means U.S. EPA, Compilation of Air Pollutant Emission Factors, fifth edition. U. S. EPA office of air quality planning and standards. Research Triangle Park, North Carolina.
- (48) "U.S. EPA, 1996a" means U.S. EPA, "Ecological Significance and Selection of Candidate Assessment Endpoints," January, 1996.
- (49) "U.S. EPA Sediment Toxicity Test" means U.S. EPA, "Methods for Measuring the Toxicity and Bioaccumulation of Sediment-Associated Contaminants with Freshwater Invertebrates," EPA/600/R-94/024. June, 1994.

(B) Applicability.

If a property-specific risk assessment is being used to demonstrate that a property meets the applicable standards and the risk goals set forth in paragraphs (C), (E), (F) and (H) of this rule, then the property-specific risk assessment must be conducted according to the procedures outlined in paragraphs (D), (E) and (F) of this rule.

[Comment: Technical assistance from Ohio EPA division of emergency and remedial response is available upon request. Technical assistance may include review of documents and study results relating to the entire voluntary action or any portion thereof. Volunteers will be charged for technical assistance provided by Ohio EPA in accordance with rule 3745-300-03 of the Administrative Code.]

(1) Elective application.

The property-specific risk assessment procedures set forth in this rule may be used at a property to demonstrate that the remedy evaluated in the property-specific risk assessment or the condition of the property is protective of public health and safety and the environment on the property and off the property when contamination emanates from the property. 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, a property-specific risk assessment must be used to develop an applicable standard for that chemical of concern.

[Comment: A volunteer may perform a property-specific risk assessment instead of applying the generic standards for the direct contact soils. Use of a property-specific risk assessment to determine applicable standards for direct contact soils does not preclude a volunteer from applying the generic standards for the ground water on the property. Likewise, a volunteer may perform a property-specific risk assessment instead of using any of the applicable generic standards contained in rule 3745-300-08 of the Administrative Code.]

(2) Mandatory application.

A property-specific risk assessment must be conducted following the procedures established in this rule to determine applicable standards in place of or in addition to using the generic direct contact soil standards, if any of the following apply to the property:

- (a) The exposure pathways for the intended land use, as identified in paragraph (D) of rule 3745-300-07 of the Administrative Code, include pathways that are not listed in the support document for generic standards or in paragraph (B)(2)(c) of rule 3745-300-08 of the Administrative Code;
- (b) The exposure factors for the intended land use include exposure factor values not listed in the support document for generic standards or receptor populations that are not listed in the support document for generic standards, or paragraph (B)(2)(c) of rule 3745-300-08 of the Administrative Code;
- (c) The chemicals of concern are not included in paragraph (B)(3) of rule 3745-300-09 of the Administrative Code. If only some of the chemicals of concern identified have a generic direct contact soil standard value listed in paragraph (B)(3) of rule 3745-300-08 of the Administrative Code, a volunteer may use the applicable generic direct contact soil standards, and, for the chemicals of concern which do not have generic direct contact soil standards, determine an applicable standard following the procedures required by this rule. When using a combination of generic direct contact soil standards and applicable

standards, determined by a property-specific risk assessment conducted in accordance with this rule, the volunteer must adjust the concentrations of the applicable standards, using the procedures contained in paragraph (B)(2)(b) of rule 3745-300-08 of the Administrative Code, to meet the human health risk based levels described in paragraph (B)(2)(a) of rule 3745-300-08 of the Administrative Code;

- (d) It is determined, as a result of a “Phase II Property Assessment” conducted in accordance with rule 3745-300-07 of the Administrative Code, that important ecological resources or sediments are impacted by hazardous substances or petroleum;
- (3) If radioactive materials are identified at a property, the property may be subject to the Atomic Energy Act of 1954, 68 Stat. 919, 42 U.S.C.A. 2011, as amended, and regulations adopted thereunder and Chapters 3701. and 3747. of the Revised Code and rules adopted thereunder.

[Comment: Radioactive materials separate or mixed with hazardous substances or petroleum are not encompassed by this chapter or Chapter 3746, of the Revised Code.]

- (4) If polychlorinated biphenyls (PCBs) are identified at a property, the property may be subject to cleanup levels or other provisions of the Toxic Substances Control Act, 90 Stat. 2003 (1976), 15 U.S.C.A. 2601, as amended, and the regulations adopted thereunder.

[Comment: Federal regulations contained in 40 C.F.R. part 761 (effective Aug. 28, 1998) authorize alternate PCB cleanup levels at a property contingent on implementation of institutional controls, or engineering controls or other remedy subject to operation and maintenance. Compliance with the federal cleanup levels and related provisions may serve to comply in part with applicable provisions of this chapter. For example, use of a compacted soil cap pursuant to 40 C.F.R. part 761 to cover PCBs exceeding one part per million (ppm) in soils may comprise part of a minimum two foot point of compliance for commercial or industrial land use, or an engineering control subject to operation and maintenance under this chapter.]

- (5) If the generic direct contact soil standards listed in paragraph (B)(3) of rule 3745-300-08 of the Administrative Code are applied to one or more identified areas of the property and applicable standards are applied to one or more other areas of the property as determined following this rule, then the volunteer must ensure that the following risk goals are met:

- (a) A cumulative carcinogenic risk, which is attributable to the chemicals of concern on, underlying or emanating from a property, that does not exceed an excess upper bound lifetime cancer risk to an individual of one in 100,000 (1×10^{-5}); and
- (b) A cumulative human health hazard, which is attributable to the chemicals of concern on, underlying or emanating from a property which have noncarcinogenic effects, that does not exceed a hazard index of 1.

[Comment: For example, if a volunteer applies the generic numeric standards to one identified area of an industrial property and applies applicable standards, determined following the procedures contained in this rule, to another identified area on the property, then the volunteer must ensure that the risk goals, contained in this paragraph and not those risk goals for industrial properties contained in paragraph (C)(1)(b) of this rule, are met for the entire property.]

(C) Applicable risk goals.

The applicable standards developed from a property-specific risk assessment must be determined in accordance with the following risk goals. For the purposes of this rule the term “risk goals” means both carcinogenic risk and non-carcinogenic hazard:

(1) Carcinogenic risk.

For chemicals of concern on, underlying or emanating from the property which have carcinogenic effects, the cumulative human health carcinogenic risk must not exceed the following risk goals based on the reasonably anticipated use of the property:

- (a) For residential and commercial property land use, the cumulative carcinogenic risk, which is attributable to the chemicals of concern, must not exceed an excess upper bound lifetime cancer risk to an individual of one in 100,000 (1×10^{-5});
- (b) For industrial property land use, the cumulative carcinogenic risk must not exceed the following:
 - (i) An excess upper bound lifetime cancer risk to an individual, which is attributable to the chemicals of concern, of one in 10,000 (10^{-4}) provided that a demonstration that the cumulative cancer risk to off-property receptors, which is attributable to chemicals of concern, is less than an excess upper bound lifetime cancer risk to an individual of one in 100,000 (1×10^{-5}) unless the conditions contained in paragraph (B)(4) of this rule apply to the property; or

- (ii) An excess upper bound lifetime cancer risk to an individual, which is attributable to the chemicals of concern, of one in 100,000 (1×10^{-5}).

(2) Noncarcinogenic hazard.

For chemicals of concern identified on, underlying or emanating from a property which have noncarcinogenic effects, the cumulative human health hazard, which is attributable to the chemicals of concern, must not exceed a hazard index of 1;

(3) Carcinogenic risk and noncarcinogenic hazard.

For chemicals of concern on, underlying and emanating from a property which have both carcinogenic and noncarcinogenic effects, the concentration of the chemicals of concern must not exceed the risk goals established in paragraphs (C)(1) and (C)(2) of this rule; and

(4) Risk to important ecological resources.

Whenever a complete exposure pathway to an important ecological resource has been determined in accordance with paragraph (D)(2) of rule 3745-300-07 of the Administrative Code, the chemicals of concern on, underlying or emanating from the property must not exceed concentrations that cause adverse environmental impacts to important ecological resources that are present or are reasonably expected to be present. For purposes of this rule and this chapter, an important ecological resource is reasonably expected to be present if the existing habitat could support such an important ecological resource were it not for the presence of the chemicals of concern on, underlying or emanating from the property. Adverse environmental impacts include, but are not limited to, reproductive impairment, developmental impairment, death or impairments which result from bioaccumulation.

(D) Procedures for human health risk assessments.

- (1) Whenever a “Phase II Property Assessment”, conducted in accordance with rule 3745-300-07 of the Administrative Code identifies any pathway to human receptors, a human health property-specific risk assessment conducted in accordance with this rule used to support a no further action letter must demonstrate that the concentrations of chemicals of concern on, underlying or emanating from a property meet the applicable risk goals under paragraph (C) of this rule.

(2) Voluntary action activities affecting the property-specific risk assessment.

The property-specific risk assessment must 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 chemicals of concern and are consistent with the requirements contained in rule 3745-300-15 of the Administrative Code;
- (c) The use of institutional controls including, without limitation, land and water use restrictions contained in the property deed. Institutional controls must be:
 - (i) Effective at eliminating or mitigating exposures to all receptor populations sufficient to meet the risk goals contained in paragraph (C) of this rule;
 - (ii) 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) Controls established by a deed restriction, as a limitation imposed on human receptors that mitigates or eliminates risk; and
 - (iv) 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 must be:
 - (i) Effective at eliminating or mitigating exposures to all receptor populations sufficient to meet the risk goals or applicable standards in paragraph (C), (E), (F) or (H) of this rule;
 - (ii) Effective and reliable for the climatic conditions and activities at the property to which the control will be applied;
 - (iii) Reliable during the period of time which the control is used to achieve and maintain applicable standards; and
 - (iv) Capable of being monitored and maintained as required by an operation and maintenance plan or agreement developed in

accordance with rule 3745-300-15 of the Administrative Code in order to ensure that the control remains effective.

- (e) The physical and chemical characteristics of the chemicals of concern 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; and
- (f) Relevant exposure pathway information for a property. Property-specific information includes:
 - (i) The physical characteristics of the property and adjacent properties, identified following the procedures under rules 3745-300-06 and 3745-300-07 of the Administrative Code that describe and define complete exposure pathway(s) determined in accordance with paragraph (D)(2) of rule 3745-300-07 of the Administrative Code. Physical characteristics must include, at a minimum: topography; climate; native soils and fill materials; 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; and
 - (ii) The spatial distribution of the chemicals of concern in identified areas on the property, which are determined in accordance with the procedures under rule 3745-300-07 of the Administrative Code. The physical distribution information must include the relative concentrations of the chemicals of concern in identified areas on the property.
- (3) The property-specific risk assessment is comprised of four parts, which are contained in paragraphs (D)(3)(a) to (D)(3)(d) of this rule. These four parts are: the selection of chemicals of concern, the exposure assessment, the toxicity assessment, and the characterization of risk.
 - (a) Selection of chemicals of concern.

Hazardous substances or petroleum identified at the property which do not meet the applicable standards established for background pursuant to paragraph (H) of rule 3745-300-07 of the Administrative Code, or do not constitute de minimis contamination in paragraph (G) of rule 3745-300-06 of the Administrative Code, or cannot be removed from the list of chemicals of concern pursuant to paragraph (D)(5) of 3745-300-07 of the Administrative

Code, must be considered chemicals of concern and their risk must be evaluated pursuant to all the appropriate risk assessment calculations and methods referenced in paragraph (D)(3) of this rule, unless one of the following applies:

- (i) The chemicals of concern are essential human nutrients that are present on, underlying or emanating from the property in concentrations near naturally occurring levels, and may be toxic only at very high concentrations. These chemicals include iron, magnesium, calcium, potassium and sodium.
- (ii) The chemicals of concern are determined to contribute to less than one percent of the estimated risk and or hazard attributed to a pathway-receptor combination in accordance with the procedures contained in U.S. EPA, 1989a.

(b) Exposure assessment

The exposure assessment must determine the reasonably anticipated magnitude, frequency, duration and routes of exposure on the property and on areas adjacent to the property. The exposure assessment must consider the information obtained or activities performed under paragraph (D)(2) of this rule for the intended land use.

- (i) Identification of receptor populations.

The exposure assessment must evaluate the hazard potential to all receptor populations that are reasonably anticipated to be exposed to chemicals of concern on the property. Populations that must be evaluated for the magnitude and frequency of exposure for each relevant exposure period, including chronic, subchronic and shorter-term exposure, to chemicals of concern are the populations identified as receptors in accordance with paragraph (D)(1)(g) of rule 3745-300-07 of the Administrative Code.

- (ii) Evaluation of exposure pathways.

The property-specific exposure assessment must evaluate all exposure pathways which are determined to be complete in accordance with paragraph (D)(2) of rule 3745-300-07 of the Administrative Code for exposure periods (chronic, subchronic and shorter-term exposures). A description of the efficacy of each institutional control or engineering control used to eliminate or mitigate any complete

exposure pathways must be included in the written justification. Those institutional controls or engineering controls described must be implemented in accordance with rules 3745-300-13 and 3745-300-15 of the Administrative Code. Exposure pathways determined to be complete in accordance with paragraph (D)(2) of rule 3745-300-07 of the Administrative Code must be evaluated in accordance with the procedures contained in U.S. EPA, 1989a, U.S. EPA, 1992a, and U.S. EPA, 1992b.

(iii) Quantification of chemical-specific intake.

Chemical-specific intakes must be calculated to quantify the exposure of each receptor population as identified in accordance with paragraph (D)(1)(g) of rule 3745-300-07 of the Administrative Code, to chemicals of concern on 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. The volunteer must calculate the chemical-specific intakes using the formulae as identified in U.S. EPA, 1989a, U.S. EPA, 1991b, and support document for generic standards. The numerical values for the exposure factor terms in formulae must be determined in accordance with the requirements in paragraphs (D)(3)(b)(iii)(a) and (D)(3)(b)(iii)(b) of this rule.

(a) Exposure factors.

The exposure factor values must be determined either as the product of point values or as the output value from a probabilistic simulation of five thousand or more iterations which solve for the chemical-specific intake equation. A probabilistic simulation output value for the intake must be the ninetieth percentile or greater value.

For risk-derived unrestricted potable use ground water, the exposure factor values must be obtained using the reasonable maximum exposure (RME) point values or distributions contained in the "Support Document for Generic Standards", which are the basis for the development of the generic unrestricted potable use standards listed in paragraph (C)(3) of rule 3745-300-08 of the Administrative Code. For all other pathways, the exposure factor values must be obtained using one of the following methods:

(i) Exposure factor values not determined from property-specific information.

For exposure factors represented by a point value, these values must be upper bound or central tendency values with an estimate of upper-bound exposures obtained in accordance with U.S. EPA, 1991a, and the support document for generic standards 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 must be the values representative of central tendency, upper bound or other appropriate exposures as defined in the support document for generic standards. When exposure factor values are represented by probability distributions as input for a probabilistic simulation, the probability distributions must be those used for the derivation of the generic numerical standards listed in the support document for generic standards for all exposure factor terms for which such distributions are described.

- (ii) 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 must reasonably represent the upper bound value or central tendency value from a distribution of property-specific data, as appropriate, consistent with an estimate of upper-bound exposures as described in, U.S. EPA, 1989a, and the support document for generic standards. For all other complete exposure pathways, the property-specific exposure factor values must 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 them, must meet

the criteria for property-specific data as described in paragraph (D)(3)(b)(iv) of this rule.

(b) Exposure point concentration.

Exposure point concentrations must represent the concentration of chemicals of concern from each of the identified areas on the property. This representation of exposure point concentration must be consistent with concentrations of the chemicals of concern determined in accordance with paragraph (D)(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)(a) of this rule.

[Comment: There must be consistency between the exposure point concentration and the exposure factor terms when defining those exposure factor values which describe the extent and spatial distribution of the chemicals of concern on the property. These concerns are of particular relevance when the entire property is determined to be a single identified area.]

Exposure point concentrations must be determined for each complete exposure pathway determined to be complete in accordance with paragraph (D)(2) of rule 3745-300-07 of the Administrative Code as follows:

(i) On-property single-medium pathways.

When the exposure point concentration is determined for single-medium pathways identified for on-property receptor population(s), the exposure point concentration must be derived from direct measurement data in accordance with paragraph (D)(6) of rule 3745-300-07 of the Administrative Code, as appropriate, and ground water media consistent with, Ohio EPA, 1995, and any other environmental media identified in a "Phase II Property Assessment", unless sampling to obtain direct measurement data is determined to likely exacerbate the risk to human health or the environment posed by chemicals of concern in that medium.

[Comment: For example, due to the behavior of dense non-aqueous phase liquids (DNAPL), obtaining samples in the ground water media may facilitate migration of the DNAPL.]

Direct measurement data must be determined from on-property sampling of the environmental media and laboratory analysis of the samples as required by rule 3745-300-07 of the Administrative Code; or

- (ii) Off-property single-medium pathways, on-property single-medium pathways with special sampling considerations, on-property transport-mediated pathways, or off-property transport-mediated pathways.

When the exposure point concentration is determined for single-medium pathways for off-property receptor populations, or when exposure point concentration is determined for transport-mediated pathways identified for on-property or off-property receptor populations, exposure point concentration must be derived from direct measurement data as described in paragraph (D)(3)(b)(iii)(b)(i) of this rule. If direct measurement data are not used either on the property or off the property, the exposure point concentration must be derived from fate and transport models approved for the environmental medium or media concerned.

[Comment: The decision to use direct measurement data or values derived from a fate and transport model should address concerns regarding exposure to an on-property receptor which occurs through a single-medium pathway in which the single-medium chemicals of concern have special sampling considerations as described in paragraph (D)(3)(b)(iii)(b)(i) of this rule.]

The property-specific risk assessment must include a justification for the selection of a modeled value over a directly measured value. If fate and transport models are used, they must be selected in accordance

with paragraph (F) of rule 3745-300-07 of the Administrative Code. All models and guidance must be used consistently with the conditions and limitations described in the references cited and calibrated to field conditions. The property-specific risk assessment must include a written justification for all models selected. Property-specific data used as fate and transport model inputs must meet the criteria for property-specific data as described in paragraph (D)(3)(b)(iv) of this rule.-

[Comment: Appropriate models for some fate and transport pathways include the following: (1) vapors in air from chemical(s) of concern in potable water (Andelman, 1990.);(2) particulate emissions from soil to air (Cowherd et al.,1985; other models as described in U.S. EPA, 1995c); (3)volatile emissions from soil to air from chemicals of concern in soil (Jury et al., 1990, U.S. EPA, 1991b); (4) movement of chemicals of concern through the vadose zone into ground water (“VLEACH” from U.S. EPA Kerr laboratory center for subsurface modeling support, as described in Ravi and Johnson, N.D.G.) or, in lieu of using the above-mentioned models to predict movement of the chemicals of concern through the vadose zone into ground water, a volunteer may use the leach-based soil values derived by Ohio EPA using “SESOIL” which prevent the leaching of chemicals of concern through the vadose zone and into the ground water at concentrations exceeding the generic potable ground water standards and are contained in the document, ”Ohio EPA Derived Leach-Based Values Using SESOIL,” October, 1996; movement of chemicals of concern through ground water (“MT3D” in conjunction with modflow from U.S. EPA Kerr laboratory center for subsurface modeling support, as described in Zheng, C., “A Modular Three-Dimensional Transport Model for Simulation of Advection, Dispersion, and Chemical Reaction of Contaminants on Groundwater Systems.” S.S. Papadopoulos & Associates, Inc. Rockville, Maryland. Developed for U.S. EPA, office of research and development. Robert S. Kerr Environmental Research Laboratory. Ada, Oklahoma. 1990, and McDonald and Harbaugh, 1988, respectively); and movement of vapors from chemicals of concern in soil into buildings (Johnson and Ettinger, 1991); and dispersion in air from soil emissions, (Industrial Source Complex, Short term Model Version, U.S. EPA, 1995b).]

(iv) Criteria for use of property-specific data.

Property-specific data used in the identification of receptor population(s) as 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, must meet the following criteria:

- (a) Property-specific physical data must be collected in accordance with paragraph (D) 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 population(s) must be representative of the reasonably anticipated land use category and the actual property characteristics, and must be included in an institutional control or engineering control that meets the requirements of rule 3745-300-15 of the Administrative Code; and
- (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 must be demonstrated to be consistent with property-specific conditions.

(c) Toxicity assessment.

(i) Information hierarchy.

The toxicity information, used in a property-specific risk assessment, must be obtained from the following hierarchy:

- (a) Integrated risk information system, established and updated by U.S. EPA (IRIS). The most current toxicity information must be obtained from IRIS for chemicals of concern 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 contained in IRIS;
 - (i) “National Center for Environmental Assessment” (NCEA) provisional values or “Health Effects and Assessment Summary Tables” (HEAST) toxicity information. If the toxicity information required to be used in the property-specific risk assessment is not contained in the provisional values from the NCEA,

or HEAST the volunteer must use the toxicological profiles from the “Agency for Toxic Substances and Disease Registry” (ATSDR);

- (ii) ATSDR toxicological profiles. If the toxicity information, required to be used in the property-specific risk assessment, is not contained in the toxicological profiles from ATSDR then the volunteer must use the relevant toxicity information contained in the U.S. EPA criteria documents;
- (iii) U.S. EPA criteria documents. Criteria documents include but are not be limited to drinking water criteria documents, drinking water health advisory summaries, ambient water quality criteria documents, and air quality criteria documents.

[Comment: When IRIS does not contain toxicological information relevant to a property that is the subject of a property-specific risk assessment, and therefore the volunteer needs to reference a source given in paragraphs (D)(3)(c)(i)(b) of this rule for use with the property-specific risk assessment, the volunteer should contact a Ohio EPA division of emergency and remedial response representative to determine the most current relevant information source. For example, when lead, total petroleum hydrocarbons, or other chemicals of concern which lack toxicity criteria (i.e., slope factors and reference doses) are selected in accordance with paragraph (D)(3)(a) of this rule and toxicity criteria are required to conduct a property-specific risk assessment in accordance with this rule, the volunteer needs to contact a Ohio EPA division of emergency and remedial response representative to obtain the relevant methodology to assess toxicity and quantify risk.]

- (ii) Absorption factors and adjustment of toxicity values.

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 chemicals of concern must be evaluated in conjunction with the quantification of chemical-specific intake as described in paragraph (D)(3)(b)(iii) of this rule for each exposure pathway, in accordance with the procedures described in U.S. EPA, 1989a, and U.S. EPA, 1992a. The quantification of risk performed in accordance with the procedures described in paragraph (D)(3)(d) of this rule,

characterization of risk, must be performed so that chemical-specific intake and toxicity values are both expressed as the absorbed dose or both expressed as the administered dose. Default and chemical-specific absorption factor values must be obtained in accordance with U.S. EPA, 1989a, and U.S. EPA, 1992a.

[Comment: For example, a toxicity value calculated from an absorbed dose critical study for noncarcinogenic effects is considered an absorbed reference dose, and a toxicity value extrapolated from data in carcinogenic effects studies using administered doses is considered an administered dose slope factor. Chemical-specific intake equations which do not account for absorption via the exposure route are considered to be administered dose intake equations, whereas those chemical-specific intake equations which include an exposure factor term (the absorption factor) accounting for absorption of the chemical through the barrier at the exposure route point of entry are considered to be absorbed dose intakes. Risk calculations performed with an absorbed dose toxicity value must be evaluated in conjunction with an absorbed dose intake, calculated as an administered dose intake value multiplied by an absorption factor appropriate for the specific route of exposure being evaluated. Chemical-specific absorbed dose intakes must be evaluated in conjunction with an absorbed dose toxicity value, or with an administered dose toxicity value modified by the absorption factor appropriate for the exposure route the toxicity value was measured from or extrapolated to represent.]

[Comment: The dermal pathway exposures as described in paragraph (D)(3)(b)(iii) of this rule are calculated as absorbed dose intakes, and any toxicity value not derived from absorbed dose data must be appropriately adjusted by an absorption factor. Thus, for example, an oral reference dose derived from an administered dose critical study must be multiplied by a chemical-specific or default oral absorption factor so that the reference dose value adjusted for absorption is considered in conjunction with the absorbed dose intake value. Another example is an oral slope factor derived from administered dose data, which must be divided by a chemical-specific or default oral absorption factor so that the slope factor value adjusted for absorption is considered in conjunction with the absorbed dose intake value.]

- (iii) Adjustment of toxicity data for risk characterization.

Certain toxicity values obtained from the sources identified in paragraph (D)(3)(c)(i) of this rule are expressed in units other than those required for the quantification of risk described in paragraph (D)(3)(d) of this rule. For the characterization of noncarcinogenic risk, the units which define the dimensions of the chemical-specific intakes must be the same as the units which define the dimensions of the toxicity value. For the characterization of carcinogenic risk, the units which define the dimensions of the chemical-specific intakes must be the inverse of the units which define the dimensions of the toxicity value. The units which define the dimensions of both the toxicity values and chemical-specific intakes must be consistent for all pathways for which the risk must be cumulatively characterized as described in paragraph (D)(3)(d) of this rule, the conversion of toxicity values must be performed in accordance with the procedures described in U.S. EPA, 1989a, and U.S. EPA, 1995a.

(d) Risk characterization.

Risk characterization must integrate the exposure and toxicity assessments in order to quantitatively determine the risk or hazard posed by the chemicals of concern at the property. The risk characterization must evaluate carcinogenic risks and noncarcinogenic hazard separately and evaluate uncertainty based on the criteria listed in paragraphs (D)(3)(d)(i) through (D)(3)(d)(ii) of this rule.

(i) Cancer risk characterization.

Cancer risks must be estimated as an incremental probability of an individual member of a receptor population developing cancer over a lifetime as a result of exposure to carcinogenic chemicals of concern at the property; this estimation of cancer risk will hereafter be referred to as incremental cancer risk. An incremental cancer risk must be calculated separately, 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 must not exceed the applicable carcinogenic risk goal contained in paragraph (C)(1) of this rule. An estimate of incremental cancer risk is calculated as follows:

- (a) Determination of incremental cancer risk must be performed in accordance with the procedures described in paragraphs (D)(3)(c)(ii) and (D)(3)(c)(iii) of this rule and in U.S. EPA, 1989a, for each carcinogenic chemical of concern 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 chemical of concern as described in paragraph (D)(3)(d)(i)(a) of this rule, the cumulative incremental cancer risk posed by these multiple chemicals of concern must be calculated separately, as appropriate, for each complete exposure pathway in accordance with the procedures described in U.S. EPA, 1989a; and
- (c) If incremental cancer risk is determined for a receptor population for more than one complete exposure pathway as described in paragraph (D)(3)(d)(i)(b) of this rule, the cumulative incremental cancer risk posed by an estimate based on the complete exposure pathways at the property must be calculated in accordance with the procedures described in paragraph (D)(3)(c)(iii) of this rule and in U.S. EPA, 1989a.

(ii) Non-cancer hazard characterization.

A hazard index value is calculated to determine the exposure which will be not likely to cause noncancer adverse health effects posed by chemicals of concern to each receptor population at a property for the duration of that exposure in accordance with the applicable noncancer hazard goals described in paragraph (C)(2) of this rule. A hazard index must be calculated separately for each receptor population over a specified exposure period (i.e., chronic, sub-chronic or short-term exposure) identified in accordance with the procedures described in paragraph (D)(3)(b)(ii) of this rule, as follows:

- (a) A hazard quotient must be calculated for each chemical of concern (identified in accordance with the procedures described in paragraph (D)(3)(a) of this rule) with noncancer effects described by a reference dose or reference concentration for each complete exposure pathway (identified in accordance with the procedures described in paragraph (D)(3)(b)(ii) of this rule), in accordance with the procedures described in paragraphs (D)(3)(c)(ii) and (D)(3)(c)(iii) of this rule and in U.S. EPA, 1989a; and

- (b) If hazard quotient values representing noncancer hazards for one receptor population over a specified exposure period have been determined for more than one chemical of concern as described in paragraph (D)(3)(d)(ii)(a) of this rule, the cumulative noncancer hazards posed by these chemicals of concern must be calculated, as appropriate, as a hazard index value for each complete exposure pathway in accordance with the procedures described in U.S. EPA, 1989a. One or more noncarcinogenic chemicals of concern may be excluded from a hazard index calculation based on the consideration of major noncarcinogenic toxic endpoints, (included, as available, target organ, mode of action or mechanism of action) which must include, at a minimum, those toxic endpoints identified with the critical effect upon which the reference dose or reference concentration is based, for each noncarcinogenic chemical of concern. A written justification for such an exclusion must be submitted in the property-specific risk assessment report; and
 - (c) If the hazard index values representing noncancer hazard for one receptor population over a specified exposure period have been determined for more than one complete exposure pathway as described in paragraph (D)(3)(d)(ii)(b) of this rule, the cumulative noncancer hazard posed by one or more complete exposure pathways must be calculated, as appropriate, as a hazard index value in accordance with the procedures described in paragraph (D)(3)(c)(iii) of this rule and in U.S. EPA, 1989a. Additionally, exclusion of one or more noncarcinogenic chemicals of concern 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 noncarcinogenic chemical(s) of concern associated with each complete exposure pathway considered in accordance with this paragraph.
- (iii) Uncertainty analysis.
 - (a) Uncertainty associated with the property-specific risk assessment must be evaluated. The uncertainty analysis may include a qualitative

description or quantitative evaluation of uncertainty associated with each of the following:

- (i) The initial selection of the chemicals of concern and the determination of the exposure point concentration for each chemical of concern, including sampling, analysis, and fate and transport modeling;
- (ii) The estimation of the chemical-specific intake factor, including the quantification of point values or distributions for each exposure factor;
- (iii) The identification of existing and reasonably anticipated complete exposure pathways, including but not limited to land use assumptions, exposure factor point values or distributions, contaminant concentrations derived from fate and transport assumptions, applicability of exposure models, and the impact of institutional controls or engineering controls on the elimination or alteration of complete exposure pathways;
- (iv) Toxicity criteria for the evaluation of non-cancer effects, including any uncertainty factor or modifying factor, and low-level dose extrapolation, and the confidence level associated with the derivation of each criterion;
- (v) Toxicity criteria for the evaluation of cancer effects, including the weight-of-evidence classification, low-level dose extrapolation, and confidence level associated with the derivation of each criterion;
- (vi) The additive or antagonistic effects of exposure to multiple chemicals of concern through one or more complete exposure pathways;
- (vii) An evaluation of site-specific studies, or any other epidemiological or health studies, using accepted scientific protocol and methods, which may be available and are relevant to the exposure scenarios and chemicals of concern at the property.

- (b) In addition to a qualitative discussion of uncertainty, the volunteer may also provide a quantitative uncertainty analysis utilizing the following methodologies:

 - (i) Multiple deterministic estimates of risk or hazard, for each receptor population, based on central tendency, upper-bound or other estimates of exposure, and an evaluation of the factors listed in paragraphs (D)(3)(d)(iii)(a)(i) through (D)(3)(d)(iii)(a)(vii); or
 - (ii) A probabilistic evaluation of multiple quantified chemical-specific intakes, or multiple quantified estimates of incremental cancer risk or non-cancer hazard, using a Monte Carlo simulation or other appropriate probabilistic analysis.
- (E) Procedures for ecological risk assessment.

 - (1) An ecological, property-specific risk assessment must be conducted to demonstrate that the remedy selected or chemical(s) of concern remaining on the property is protective of important ecological resources. If complete exposure pathways, determined in accordance with paragraph (D)(2) of rule 3745-300-07 of the Administrative Code, to important ecological resources exist, an ecological property-specific risk assessment must be conducted to demonstrate compliance with the risk goals contained in paragraph (C)(4) of this rule.
 - (2) Unless the exposure pathways originate from the sediments on the property, a qualitative or quantitative ecological property-specific risk assessment must be conducted. A qualitative ecological property-specific risk assessment may be appropriate and may be conducted in order to demonstrate that chemicals of concern are not on, underlying or emanating from a property at concentrations that could be harmful to important ecological resources in cases where toxicity is likely to be low based on the concentrations of chemicals of concern, the land use, the habitat quality and the areal extent of the habitat. If a qualitative ecological property-specific risk assessment is not appropriate for the property, a quantitative ecological property-specific risk assessment must be conducted in accordance with (U.S. EPA, 1998, U.S. EPA, 1997, U.S. EPA, 1989c, U. S. EPA 1992d, and U.S. EPA 1996a.) using appropriate end-point species and toxicological benchmarks. Data collection to assess ecological risk for both qualitative and quantitative ecological property-specific risk assessments must be performed in accordance with the procedures described in rule 3745-300-07 of the Administrative Code.

[Comment: Ecological receptors are quantitatively assessed using food-web models or direct contact evaluations. Food-web models quantify the transfer of chemicals of concern from one medium to another including substances that may be transferred from abiotic media such as soil or surface water to, and through, other abiotic or biotic media such as tissues (*e.g.*, plants, animals). Direct contact evaluations estimate adverse effects to organisms from exposure to chemicals of concern contained within a specific medium without identifying specific routes of exposure.

Only the ingestion exposure route is quantitatively assessed for terrestrial mammals and birds. Plants, soil invertebrates and microorganisms, are assessed using direct contact evaluations. A direct contact evaluation generally consists of a simple comparison of a medium concentration with an appropriate toxicologically-based criterion derived using the same medium that is being assessed. Additional evaluations of fish and aquatic invertebrates may include biological criteria in accordance with Chapter 3745-1 of the Administrative Code when appropriate, or biological surveys or assays.

An Ohio EPA emergency and remedial response representative may be contacted if a volunteer needs assistance in determining whether qualitative or quantitative ecological property-specific risk assessment is appropriate for a property.

A screening step may be used in the quantitative ecological property-specific risk assessment to identify which chemicals of concern are the major contributors to ecological harm. A screening step may also be used to demonstrate whether the chemicals of concern in media are below levels which are reasonably anticipated to adversely impact ecological receptors. Appropriate screening values for soil and sediment can be obtained from an Ohio EPA division of emergency and remedial response representative.]

- (F) Procedures for assessment and remediation of sediments.
- (1) An evaluation of the sediments on the property, following the procedures contained in paragraphs (F)(2) to (F)(4) of this rule, must be conducted whenever any complete exposure pathways involving the sediments are identified in accordance with paragraph (D)(2) of rule 3745-300-07 of the Administrative Code.

[Comment: If contaminated sediments are not located on a property and contamination from the sediments on a property is not emanating or has not emanated to sediments located on an adjacent property, then a sediment assessment is not required.]
 - (2) Evaluation of sediments identified in paragraph (F)(1) of this rule must include the following:

- (a) For each complete exposure pathway to human receptors identified in accordance with paragraph (D)(2) of rule 3745-300-07 of the Administrative Code, the volunteer must:
- (i) Sample the sediments in the identified areas in accordance with the procedures contained in the Ohio EPA, "Sediment Sampling Guide and Methodologies," 2nd edition, November, 2001, to determine the concentrations and physical distribution of the hazardous substances or petroleum; and
 - (ii) Conduct a human health property-specific risk assessment for the exposure pathways following the methodology outlined in paragraph (D) of this rule.

[Comment: For purposes of this rule and rule 3745-300-07 of the Administrative Code, an exposure pathway to humans is considered to exist if the surface water which contains the sediments produces or can produce a consistent supply of edible-sized fish (generally, fish five to six inches or larger unless a situation exists where humans are consuming small whole body fish, such as smelt) and chemicals of concern that are persistent, bioaccumulative and toxic are present in the sediment or the surface water. Those chemicals which are persistent, bioaccumulative and toxic and bioaccumulate in fish tissue include, but are not limited to, chlordane; the following substances; aldrin/dieldrin, chlordane, 1,1'-(2,2,2-trichloroethylidene) bis[4-chlorobenzene] (DDT) and metabolites (DDD+DDE), hexachlorobenzene, hexachlorobutadiene (hexachloro-1,3-butadiene); hexachlorocyclohexanes (BHCs, alpha-BHC, beta-BHC, delta-BHC); lindane (gamma-hexachlorocyclohexane); alky-lead, mercury and its compounds, mirex, photomirex, phthalate esters octachlorostyrene, polychlorinated biphenyls (PCBs), 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD); dioxin; PCDF (furans), 1,2,3,4-tetrachlorobenzene, 1,2,4,5-tetrachlorobenzene; toxaphene; and other chemicals that may reasonably be anticipated to bioaccumulate in animal tissues; or if the surface water which contains the sediments is reasonably anticipated to support recreational activities such as wading, fishing, swimming, and boating.]

- (b) For each complete exposure pathways to important ecological resources identified in accordance with paragraph (D)(2) of rule 3745-300-07 of the Administrative Code, the volunteer must sample the sediments in the identified areas in accordance with the procedures in contained in the Ohio EPA, "Sediment Sampling Guide and Methodologies," 2nd edition, November, 2001. Such sampling must determine the concentrations and

spatial distribution of the hazardous substances or petroleum in the sediments. The volunteer may compare the ninety-five per cent upper confidence limit or maximum concentrations, as determined in accordance with paragraph (D)(6) of rule 3745-300-07 of the Administrative Code, to property-specific background levels for naturally occurring chemicals of concern determined in accordance with rule 3745-300-07 of the Administrative Code or the ecotoxicologically-based benchmarks from the following guidance using the following hierarchy:

- (i) Consensus-based threshold effects concentration (TEC) values contained in the “Development and Evaluation of Consensus-based Sediment Quality Guidelines for Freshwater Ecosystems”, D.D. MacDonald, C.G. Ingersoll, and T.A. Berger, Arch. Environ. Contam. Toxicol. 39, 20-31 (2000); or
- (ii) Ecological data quality levels contained in U.S. EPA, Region 5, “Final Technical Approach for Developing Ecological Data Quality Levels for RCRA Appendix IX Constituents and Other Significant Contaminants of Ecological Concern,” April 1998.

[Comment: Persistent, bioaccumulative and toxic chemicals of concern should not be screened from soil or sediment unless the method used to derive the screening value considered exposure to higher trophic level organism(s) in the development of the screening value. Persistent bioaccumulative and toxic chemicals must be evaluated using a food-web model that contains one top predator that feeds predominantly on mammals or fish associated with the affected media. If persistent, bioaccumulative and toxic chemicals are present in sediments, then a piscivorous predator such as a mink or belted kingfisher should be used. In contrast, if persistent, bioaccumulative and toxic chemicals are present in soil, then a carnivorous receptor such as a red-tailed hawk or red fox should be chosen to represent the top predator]

If the ninety-five per cent upper confidence limit or maximum concentration, as determined in accordance with paragraph (D)(5) of rule 3745-300-07 of the Administrative Code, does not exceed the appropriate benchmark listed in this paragraph, then applicable standards have been met for that hazardous substance or petroleum. If the ninety-five per cent upper confidence limit or maximum concentration, as determined in accordance with paragraph (D)(5) of rule 3745-300-07 of the Administrative Code, exceeds the appropriate benchmark listed in this paragraph for any hazardous substances or petroleum or the sediment samples were not compared to the appropriate benchmarks

listed in this subparagraph, the volunteer must evaluate the sediments on the property in accordance with the methodology contained in paragraph (F)(2)(c) of this rule.

[Comment: Exceedance of any of the benchmark values above does not imply that sediment remediation is required. An exceedance of a benchmark means that further sediment assessment, as detailed below, is necessary.]

- (c) If the applicable standards contained in paragraph (F)(2)(b) of this rule have not been met for the sediments on the property or sediment samples were not compared to the appropriate benchmarks in accordance with paragraph (F)(2)(d) of this rule, sediment toxicity must be evaluated according to the following methodology:
 - (i) For all surface waters containing sediments identified under paragraph (F)(1) of this rule, that have an aquatic life use designation of warm water habitat, exceptional warm water habitat (excluding lakes and reservoirs), modified warm water habitat, limited warm water habitat or cold water habitat assigned under Chapter 3745-1 of the Administrative Code, a biological survey must be conducted. The biological survey must include:
 - (a) A fish and physical habitat survey must be used to calculate the qualitative habitat evaluation index (QHEI), the index of biotic integrity (IBI) and, where applicable, a modified index of well-being (MIWB) for the surface water on the property following the procedures contained in the biocriteria manual and the quality assurance manual. The sampling locations for the fish and physical habitat survey must be the same locations established in paragraph (F)(2)(c) of this rule, if possible.
 - (b) A quantitative macroinvertebrate survey must be used to calculate the invertebrate community index (ICI) for the surface waters on the property following 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, a qualitative macroinvertebrate study must be conducted following the “Biocriteria Manual” and the instruction provided by the biocriteria training and certification obtained in accordance with rule 3745-300-05 of the Administrative Code. The

sampling locations for the quantitative macroinvertebrate survey must be the same locations established in paragraph (F)(2)(c)(i) of this rule, if possible.

[Comment: If a qualitative macroinvertebrate study is to be conducted, it is highly recommended that an Ohio EPA, division of emergency and remedial response representative be consulted regarding appropriate steps to perform the study.]

- (ii) For all surface waters, containing sediments identified under paragraph (F)(1) of this rule, with an aquatic life use designation of limited resource water, nuisance prevention or no aquatic life use designation assigned under Chapter 3745-1 of the Administrative Code, or that are a lake, reservoir, wetland or pond, sediment bioassays using sediment samples taken from the surface waters on the property must be conducted to evaluate sediment toxicity. Sediment bioassays must include the *Hyalella Azteca* bioassay conducted following the procedures contained in the Ohio EPA sediment toxicity test and the *Chironomus Tentans* bioassay conducted following the procedures in the U.S. EPA sediment toxicity test. Sediment bioassay sampling locations must be determined in accordance with this rule and rule 3745-300-07 of the Administrative Code.

[Comment: For surface water that has no aquatic life use designation assigned under Chapter 3745-1 of the Administrative Code, a volunteer may conduct a use attainability analysis as detailed in the “Biocriteria Manual” to determine the appropriate aquatic life use designation. Consult with a Ohio EPA division of emergency and remedial response representative for assistance in making a determination on an aquatic life use designation for an unlisted water body.]

[Comment: When a property contains any wetland areas, or the filling of a wetland or a water body is being considered, a volunteer may need to obtain a permit under the applicable federal or state law or the regulations adopted thereunder. The volunteer needs to contact the appropriate authority to determine the applicable permitting requirements for the property. For example, for the U.S. army corps of engineers contact the U.S. army corps of engineer’s office for the area where the property is located.]

- (3) Applicable standards for sediments on a property are as follows:
- (a) For all surface waters, applicable standards are the appropriate ecotoxicologically-based benchmarks when sediment samples are collected and compared to the benchmarks in accordance with paragraph (F)(2)(b) of this rule.
 - (b) 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, limited warm water habitat or cold water habitat assigned under Chapter 3745-1 of the Administrative Code, the applicable standards are the applicable standards for surface waters in accordance with rule 3745-300-08 of the Administrative Code.
 - (c) For surface water with an aquatic life use designation of limited resource water, nuisance prevention or no aquatic life use designation assigned under Chapter 3745-1 of the Administrative Code and for surface waters which are wetlands or ponds, the applicable standards are the absence of toxic effects to either organism group as defined in the Ohio EPA sediment toxicity test and U.S. EPA sediment toxicity test manuals.
 - (d) For surface waters which are lakes or reservoirs, the applicable standards are the absence of toxic effects to either organism group as defined in the Ohio EPA sediment toxicity test and U.S. EPA sediment toxicity test manuals.
- (4) The following actions must be taken when, in accordance with paragraphs (F)(3)(a) to (F)(3)(d) of this rule, applicable standards for sediments have not been met:
- (a) The volunteer must submit a written demonstration to be contained in the risk assessment report under paragraph (I) of this rule substantiating the determination that hazardous substances or petroleum on the property are not contributing to the failure to meet the applicable standards set forth in paragraph (F)(3) of this rule. Applicable standards for sediment are met if the volunteer can demonstrate that hazardous substances or petroleum on the property are not contributing to the failure to meet the applicable standards set forth in paragraph (F)(3) of this rule; or
 - (b) A remedy, conducted in accordance with rule 3745-300-15 of the Administrative Code, must be implemented to meet applicable standards.

[Comment: Sediments can be remediated to meet the applicable standards by a combination of elimination or containment of sources in the soil media on the property and remediation. Remediation can be active or passive. When a

remedy is chosen, be it active or passive, that does not attain applicable standards at the time of the issuance of an NFA letter, an operation and maintenance plan as outlined in rule 3745-300-15 of the Administrative Code, is necessary.].

(G) Surface water assessment.

Applicable standards for surface waters at the property must be determined in accordance with paragraph (E) of rule 3745-300-08 of the Administrative Code.

(H) Compliance with applicable standards.

(1) Determination of applicable standards from a property-specific risk assessment.

If the volunteer elects 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:

- (a) Concentrations of chemicals of concern which meet the risk goals for human health in accordance with the requirements contained in paragraphs (C)(1) to (C)(3) of this rule and in accordance with the procedures described in paragraph (D) of this rule;
- (b) Concentrations of chemicals of concern which meet the risk goals for protection of important ecological resources in accordance with the requirements contained in paragraph (C)(4) of this rule and in accordance with the procedures contained in paragraph (E) of this rule;
- (c) The applicable standards for sediments under paragraphs (F)(3)(a) to (F)(3)(d) of this rule;
- (d) The applicable standards for surface water under paragraph (G) of this rule;

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

Where:

C_{sat} is the soil saturation concentration (mg/kg)

S is the water solubility (mg/L water)

ρ_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)

θ_w is the water-filled soil porosity (L_{water}/L_{soil})

H is the dimensionless Henry's Law constant

θ_a is the air-filled soil porosity (L_{pore}/L_{soil}),

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)(a) to (H)(1)(d) of this rule. The volunteer must use the equation below, along with property-specific information, to calculate a property-specific soil saturation concentration.

- (i) All chemical-specific values for the above equation must be obtained from one of the following sources:
 - (a) U.S. EPA, "Soil Screening Guidance: Technical Background Document." publication 9355.4-17a, May, 1996;
 - (b) Support document for generic standards;
 - (c) The "Hazardous Substances Data Bank" (HSDB), toxicology data network, national library of medicine. <http://toxnet.nlm.nih.gov/>; or
 - (d) If chemical-specific values for the above equation are not available in the sources listed above, contact an Ohio EPA division of emergency and remedial response representative to determine other appropriate values, if any; and
- (ii) Physical values must be obtained from one of the following sources:
 - (a) U.S. EPA, "Technical Background Document for Soil screening Guidance, Review Draft," U. S. EPA, office of

solid waste and emergency response. EPA/540/R-94/106, December, 1994; or

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

[Comment: The volunteer may elect to apply standards for the affected media on the property other than the risk derived standards contained in this rule provided that those standards are applicable to the property. For example, a volunteer may choose to apply the generic direct contact or ground water standards contained in rule 3745-300-08 of the Administrative Code or may determine that the chemicals of concern are below background levels following the background determination procedures contained in rule 3745-300-07 of the Administrative Code.]

- (2) Reporting limits.

The volunteer is responsible for determining that the certified laboratory, which performs analyses in support of the no further action letter, is capable of detecting the chemicals of concern on the property at or below the applicable standards.

- (3) Points of compliance. Applicable points of compliance for use on a property must be determined in accordance with paragraph (G) of rule 3745-300-07 of the Administrative Code.

- (I) Risk assessment report.

Upon completion of a property-specific risk assessment conducted in accordance with this rule, a risk assessment report must be prepared and must contain, at a minimum, the following information:

- (1) The circumstances under which the property-specific risk assessment was conducted with respect to paragraphs (B)(1) and (B)(2) of this rule;
- (2) A list of the institutional controls and engineering controls implemented at the property upon which the property-specific risk assessment is based.
[Comment: Pursuant to rule 3745-300-15 of the Administrative Code, the volunteer is also required to demonstrate the efficacy of those controls.];
- (3) A list of the chemicals of concern on the property which were not considered in the property-specific risk assessment because they meet the criteria under paragraphs

- (D)(3)(a)(i) and (D)(3)(a)(ii) of this rule and a written demonstration, including, 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 quantitate intake as described in paragraph (D)(3)(b)(iii) of this rule and meets the criteria contained 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) Uncertainty analysis, as described in paragraph (D)(3)(e) of this rule;
 - (9) Ecological risk report, as described in paragraph (E) of this rule;
 - (10) Sediment assessment report, as described in paragraph (F) of this rule;
 - (11) Surface water assessment report, if surface waters were required to be assessed, as described in paragraph (G) of this rule; and
 - (12) A summary of compliance with applicable standards, as described in paragraph (H) of this rule.

Effective:

Certification: _____

Date: _____

Promulgated under: RC Chapter 119.

Rule amplified: RC Chapter 3746.

Rule authorized by: RC 3746.04

Prior effective dates: December 16, 1996

ORC 119.032 review date: