

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 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).

(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 (hereinafter "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 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  $\text{mg m}^{-3}$  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 non-carcinogenic 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, "*Hyaella Azteca* Solid Phase Toxicity Testing Procedure," September, 1994.
- (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) "Sub-chronic exposure period" means a duration intermediate between a shorter-term exposure period and a chronic exposure period. For the purposes of this rule, a sub-chronic exposure is of a duration between two weeks and seven

years.

(31) "Suter et al., 1993" means Suter, G.W., II, M.E. Will, and C. Evans, "Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Terrestrial Plants," ES/ER/TM-85, September, 1993

(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. EPA/540/1-88/001. 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 OSWER 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, 1992c" means U.S. EPA, "Supplemental Guidance to RAGS: Calculating the Concentration Term," U.S. EPA, Office of Solid Waste and Emergency Response. OSWER directive 9285.7-08B. 1992.

(42) "U.S.EPA, 1992d" means U.S.EPA, framework for ecological risk assessment", EPA/630/R-92/001. February, 1992.

(43) "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.

(44) "U.S. EPA, 1995b" means U.S. EPA, User's Guide for the Industrial Source Complex (ISC3) Dispersion Models. Office of Air Quality Planning and Standards. Research Triangle Park, North Carolina. EPA-454/B-96/018.

(45) "U.S. EPA, 1995c" means U.S. EPA, Compilation of Air Pollutant Emission Factors, fifth edition. Office of Air Quality Planning and Standards. Research Triangle Park, North Carolina.

(46) "U.S. EPA, 1996a" means U.S. EPA, "Ecological Significance and Selection of Candidate Assessment Endpoints," January, 1996.

(47) "U.S. EPA, 1996b" means U.S. EPA, "Ecotox Thresholds," ECO Update 3(2), Office of Solid Waste and Emergency Response. Publication 9345.0-12F51, EPA/540/F-95/038. 1996.

(48) "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, voluntary action program staff 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, the Voluntary Action Program fee rule.]

(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 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, the generic standards rule;
- (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, the generic standards rule;
- (c) The chemical(s) of concern are not included in paragraph (B)(3) of rule 3745-300-09 of the Administrative Code, the “Generic Standards rule.” if only some of the chemical(s) 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, the generic standards rule, a volunteer may use the applicable generic direct contact soil standards, and, for the

chemical(s) 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 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, the generic standards rule, to meet the human health risk based levels described in paragraph (B)(2)(a) of rule 3745-300-08 of the Administrative Code, the generic standards rule;

(d) ENGINEERING CONTROLS OR INSTITUTIONAL CONTROLS ARE USED TO MEET APPLICABLE STANDARDS, OTHER THAN INDUSTRIAL AND COMMERCIAL LAND USE RESTRICTIONS CONTAINED IN PARAGRAPH (B)(2)(c) OF RULE 3745-300-08 OF THE ADMINISTRATIVE CODE, THE GENERIC STANDARDS RULE;

(e) It is determined, as a result of a "Phase II Property Assessment" conducted in accordance with rule 3745-300-07 of the Administrative Code, the "Phase II rule" that important ecological resources or sediments are impacted by hazardous substances or petroleum; or

(f) It is determined, as a result of a "Phase II Property Assessment" that includes the assessments required by paragraph (D)(2) of rule 3745-300-07 of the Administrative Code, the "Phase II rule", that hazardous substances or petroleum are leaching or will leach to ground water and leaching of hazardous substances or petroleum to ground water underlying or emanating from the property is required to be controlled in accordance with the groundwater classification rule.

(3) If it is determined, as a result of a "Phase II Property Assessment" conducted in accordance with paragraph (D)(3) of rule 3745-300-06 of the Administrative Code, the "Phase II rule", that radioactive materials are identified at a property the volunteer must comply with the "Atomic Energy Act of 1954," 42 USCS Section 2011 Et. seq., as amended, and regulations adopted thereunder, and Chapter 3701. or 3747. of the Revised Code and rules adopted thereunder.

(4) If the generic direct contact soil standards listed in paragraph (B)(3) of rule 3745-300-08 of the Administrative Code, the generic standards rule, 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 chemical(s)

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 ( $1 \times 10^{-5}$ ); and

(b) A cumulative human health risk, which is attributable to the chemical(s) of concern on, underlying or emanating from a property which have non-carcinogenic 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 stated above, 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:

(1) Carcinogenic risk.

For chemical(s) 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 ( $1 \times 10^{-5}$ );

(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 chemical(s) 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 chemical(s) of concern, is less than an excess upper bound lifetime cancer risk to an individual of one in 100,000 ( $1 \times 10^{-5}$ ) 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 chemical(s) of concern, of one in 100,000 ( $1 \times 10^{-5}$ ).

(2) Non-carcinogenic risk.

For chemical(s) of concern identified on, underlying or emanating from a property which have non-carcinogenic effects, the cumulative human health risk, which is attributable to the chemical(s) of concern, must not exceed a hazard index of 1;

(3) Carcinogenic and non-carcinogenic risk.

For chemical(s) of concern on, underlying and emanating from a property which have both carcinogenic and non-carcinogenic effects, the concentration of the chemical(s) 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 pathway to any important ecological resource has been determined in accordance with paragraph (D)(2) of rule 3745-30-07 of the Administrative Code, the chemical(s) of concern on, underlying or emanating from a 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 property-specific human health risk assessments.

(1) Whenever a "Phase II Property Assessment", conducted in accordance with rule 3745-300-07 of the Administrative Code the "PHASE II rule" which includes the assessments performed in accordance with paragraph (D)(2) of the phase II rule, identifies any pathway to human receptors, a human health property-specific risk assessment conducted in accordance with this rule which is used to support a no further action letter must demonstrate that the concentrations of chemical(s) 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 the requirements contained in the groundwater classification rule;
- (b) The implementation of remedial activities other than institutional or engineering controls, that address the chemical(s) of concern and are consistent with the requirements contained in the remediation rule;
- (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) Either controls established by a deed restriction, a limitation imposed on human receptors that mitigates or eliminates risk, or governmental controls established by local, state or federal law or regulation; 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 landscaping. Engineering controls must be:
  - (i) Effective at eliminating or mitigating exposures to all receptor populations sufficient to meet the risk goals and 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 the remedy rule in order to ensure that the control remains effective.

(e) The physical and chemical properties of the chemical(s) of concern at the property, identified under rules 3745-300-06 and 3745-300-07 of the Administrative Code, the “Phase I and Phase II rules”, 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 chemical(s) 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 “Phase II rule”. The physical distribution information must include the relative concentrations of the chemical(s) of concern in identified areas on the property.

(3) The property-specific risk assessment is comprised of five parts, which are contained in paragraphs (D)(3)(a) to (D)(3)(e) of this rule. These five parts are: the selection of chemicals of concern, the exposure assessment, the toxicity assessment, the characterization of risk and the uncertainty analysis.

(a) Selection of chemicals of concern.

hazardous substances or petroleum identified at the property which do not meet the applicable standards established for background in paragraph (I) of rule 3745-300-07 of the Administrative Code, the “Phase II rule”, or do not constitute de minimis contamination in paragraph (G) of rule 3745-300-06 of the Administrative Code, the “Phase I rule”, must be considered chemical(s) of concern and its 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 chemical(s) 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 chemical(s) of concern are detected in five per cent or fewer samples, when a minimum of twenty samples are collected from any single identified area and the certified professional makes the determination that the detection is spurious. This subparagraph does not apply if the hazardous substance or petroleum is classified as a Class A, Class B or known carcinogen as specified in the integrated risk information system.

(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 chemical(s) 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 chemical(s) 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 exposure pathways in accordance with paragraph (D)(2) of rule 3745-300-07 of the Administrative Code for exposure periods (chronic, sub-chronic and shorter-term exposures). A description of the efficacy of any institutional or engineering controls used to eliminate or mitigate any complete exposure pathways must be included in the written justification. Those institutional or engineering controls described must be implemented in accordance with the requirements contained in rules 3745-300-13 and 3745-300-15 of the Administrative Code, respectively. 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; 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 chemical(s) 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; "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 paragraph (D)(3)(b)(iii) of this rule must be determined either as the product of point values or as the output value from a Monte Carlo simulation of five thousand or more iterations which solve for the chemical-specific intake equation. The Monte Carlo 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, the generic standards rule. For all other pathways, the exposure factor values must be obtained using one of the following methods:

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

For exposure factors represented by a point value, these values must be the standard default values for reasonable maximum exposure (RME) obtained in accordance with (U.S. EPA 1991a; “Support Document for Generic Standards”) for the pathway which contributes most substantially to risk, and for any other pathways for which RME-type exposures are deemed likely. For all other pathways, exposure factor point values must be the values representative of central tendency or upper bound exposures as defined in the “Support Document for Generic Standards.” When exposure factor values are represented by probability distributions as input for a Monte Carlo 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.

(2) Exposure factor values determined from property-specific information.

For the pathway which contributes most substantially to risk, and for any other pathways for which RME-type exposures are deemed likely, the property-specific exposure factor value must reasonably represent the upper bound value from a distribution of property-specific data for any exposure factor for which the recommended standard default reasonable maximum exposure

(RME) is an upper bound value contained in (U.S. EPA, U.S. EPA 1989a; Support Document for Generic Standards); or, the property-specific exposure factor value must reasonably represent the central tendency value from a distribution of property-specific data for any exposure factor for which the recommended standard default reasonable maximum exposure (RME) is a central tendency value contained in (U.S. EPA, 1989a; Support Document for Generic Standards). for all other 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 be representative of the concentration of chemical(s) of concern from each of the identified areas on the property. this representation of exposure point concentration must be consistent with concentrations of the chemical(s) of concern determined in accordance with paragraph (D)(5) of rule 3745-300-07 of the Administrative Code, the “Phase II rule” 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 chemical(s) 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 pathway determined to be complete in accordance with paragraph (D)(2) of rule 3745-300-07 of the Administrative Code as follows:

(1) 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)(5)(c)(i) of rule 3745-300-07 of the Administrative Code and ground water media (Ohio EPA, 1995) and any other 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 chemical(s) 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-site sampling in the media and laboratory analysis of these samples as required in the phase ii rule and the certified laboratory rule, respectively; or

(2) 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 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 chemical(s) of concern have special sampling considerations as described in paragraph (D)(3)(b)(iii)(b)(i) of this rule.]

The 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 this paragraph. appropriate models for some fate and transport pathways include the following: vapors in air from chemical(s) of concern in potable water (Andelman, 1990.); particulate emissions from soil to air (Cowherd et al., 1985; other models as described in U.S. EPA, 1995c); volatile emissions from soil to air from chemical(s) of concern in soil (Jury et al., 1990, U.S. EPA 1991b); movement of chemical(s) 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 chemical(s) 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 chemical(s) 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 chemical(s) 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 chemical(s) 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). All models and guidance must be used consistently with the conditions and limitations described in the references cited and calibrated to field conditions. The 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. Other models in addition to those contained in this subparagraph may be used, provided that the model meets the requirements contained in paragraph (G) of rule 3745-300-07 of the Administrative Code.

If no studies or information exist to document whether a fate and transport model meets the requirements contained in paragraph (G) of rule 3745-300-07 of the Administrative Code, the model may still be used for fate and transport pathways provided the following criteria are met: no other documented field-validated or verified models are available or appropriate for the application being modeled; the model is appropriate for the media and application being modeled; the model is generally accepted within the scientific community as being reliably peer-reviewed; and the model is reasonably consistent with the conditions throughout the modeled area.

The demonstration of these requirements must be explained in a written justification which must be contained in the risk assessment report.

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

Property-specific data which are 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, the “Phase II rule.”

(b) Property-specific information which is 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 or engineering control that meets the requirements of rule 3745-300-15 of the Administrative Code, the remediation rule.

(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 (hereinafter “IRIS”).toxicity information must be obtained through the most current update of IRIS for chemicals of concern being evaluated in the property-specific risk assessment. If the toxicity information, required to be used in the property-specific risk assessment, is not contained in IRIS, then the volunteer must use the toxicity information contained in the “Health Effects and Assessment Summary Tables”;

(B) “Health Effects and Assessment Summary Tables” (hereinafter “HEAST”). Toxicity information must be obtained from the most current update of HEAST. If the toxicity information, required to be used in the property-specific risk assessment is not contained in HEAST, then the volunteer must use the provisional values from the “National Center for Environmental Assessment”;

(C)“National Center for Environmental Assessment” (hereinafter “NCEA”) provisional values. An Ohio EPA

Division of Emergency and Remedial Response representative must be consulted if NCEA provisional values are proposed for use in a property-specific risk assessment. If the toxicity information required to be used in the property-specific risk assessment is not contained in the provisional values from the NCEA, the volunteer must use the toxicological profiles from the “Agency for Toxic Substances and Disease Registry”;

(D) “Agency for Toxic Substances and Disease Registry” (Hereinafter “ATSDR”) Toxicology profiles. An Ohio EPA Division of Emergency and Remedial Response representative must be consulted if values derived from toxicological profiles are proposed for use in a property-specific risk assessment. If the toxicity information, required to be used in the property-specific assessment, is not contained in the toxicological profiles from ATSDR, then the volunteer must use the toxicity information contained in the U.S. EPA criteria documents;

(E) 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. An Ohio EPA Division of Emergency and Remedial Response representative must be consulted if these values are proposed for use in a property-specific risk assessment. If the toxicity information, required to be used in the property-specific risk assessment is not contained in the U.S. EPA criteria documents then the volunteer must use Ohio EPA toxicity information; or

(F) Ohio EPA toxicity information. If the toxicity information required to be used in a property-specific risk assessment is not contained in the U.S. EPA criteria documents then the volunteer must consult with an Ohio EPA division of emergency and remedial response representative to determine the appropriate toxicity information for use in the property-specific risk assessment.

[comment: for example, when lead, total petroleum hydrocarbons (TPH), 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 the requirements in paragraph (D)(3)(d) of this rule, then the volunteer must 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 chemical(s) 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, 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, U.S. EPA 1992a).

[Comment: for example, a toxicity value calculated from an absorbed dose critical study for non-carcinogenic 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 non-carcinogenic 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; U.S. EPA, 1995a).

(d) Characterization of risk.

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

(i) Cancer risk characterization.

Cancer risks must be estimated as the incremental probability of an individual member of a receptor population developing cancer over a lifetime as a result of exposure to all carcinogenic chemical(s) of concern at the property; this estimation of cancer risk will hereafter be referred to as incremental cancer risk. The incremental cancer risk must be calculated separately for each receptor population identified in accordance with the procedures described in paragraph (D)(3)(b)(i) of this rule. The incremental cancer risk for each receptor population must not exceed the applicable carcinogenic risk goal contained in paragraph (C)(1) of this rule. The 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(s) of concern and for each exposure pathway identified in accordance with paragraphs (D)(3)(a) and (D)(3)(b)(ii) of this rule respectively; and

(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 chemical(s) of concern must be calculated separately for each 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 exposure pathway as described in paragraph (D)(3)(d)(i)(b) of this rule, the cumulative incremental cancer risk posed by the chemical(s) of concern across these multiple 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 risk characterization.

A hazard index value is calculated to determine the exposure which will be not likely to cause non-cancer adverse health effects

posed by chemical(s) of concern to each receptor population at a property for the duration of that exposure in accordance with the applicable non-cancer risk goals described in paragraph (C)(2) of this rule. the hazard index must be calculated separately for each receptor population over a specified exposure period 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 non-cancer effects described by a reference dose or reference concentration for each 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 non-cancer risk 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 non-cancer risk posed by these chemical(s) of concern must be calculated as a hazard index value for each exposure pathway in accordance with the procedures described in U.S. EPA, 1989a. one or more non-carcinogenic chemicals of concern may be excluded from a hazard index calculation based on the consideration of all major non-carcinogenic toxic endpoints and mechanisms of action which must include, at a minimum, those toxic endpoints and mechanisms of action identified with the critical effect upon which the Reference Dose or Reference Concentration (used in conjunction with paragraph (D)(3)(d)(ii)(a) of this rule) is based, for each non-carcinogenic chemical of concern. A written justification for such an exclusion must be submitted in the risk assessment report; and

(c) If the hazard index values representing non-cancer risk for one receptor population over a specified exposure period have been determined for more than one exposure pathway as described in paragraph (D)(3)(d)(ii)(b) of this rule, the cumulative non-cancer risk posed by these chemical(s) of concern must be calculated 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. exclusion of one or more non-carcinogenic chemicals of concern from the hazard index calculations performed in accordance with paragraph (D)(3)(d)(ii)(b) of this rule must be reconsidered with respect to the toxic endpoints and mechanisms of action identified for the non-carcinogenic chemical(s) of concern associated with all exposure pathways considered in accordance with this paragraph.

(e) Uncertainty analysis.

(i) The risk assessment must evaluate the uncertainty associated with the property- specific risk assessment. The uncertainty analysis must include a qualitative description of uncertainty associated with each of the following:

(A) The initial selection of the chemical(s) of concern used to characterize exposures and risk on the basis of the property-specific sampling or modeled data;

(B) Toxicity values, and their uncertainty and modifying factors, low-level dose extrapolations and els associated with their derivation;

(C) The identification of existing and future exposure pathways including but not limited to land use assumptions, exposure parameter values and distributions, contaminant derived from fate and transport assumptions, applicability of exposure models, and the impact of engineering controls on altering exposure pathways; and

(D) The additive or antagonistic effects of exposure to multiple concern through multiple pathways.

(ii) In addition to a qualitative discussion of uncertainty, the volunteer may also provide a quantitative uncertainty analysis utilizing Monte Carlo simulation. Inclusion of graphic output and descriptive text arising from this approach will communicate the risk ranges within the modeled exposed population and how these values differ from those derived from the use of single point exposure parameters as described in paragraph (D)(3)(b)(iii) of this rule. Quantitative uncertainty analysis may only be applied to exposure variables. Quantitative uncertainty analysis must not be performed on toxicity values.

(E) Procedures for ecological risk assessment.

(1) A property-specific ecological 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, identified in accordance with paragraph (D)(2) of rule 3745-300-07 of the Administrative Code, to important ecological resources exist, an ecological 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 risk assessment must be conducted. A qualitative ecological 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 risk assessment is not appropriate for the property, a quantitative ecological risk assessment must be conducted in accordance with (Suter et al., 1993, U.S.EPA, 1989C, U.S. EPA 1992d, U.S.EPA 1996a, U.S.EPA, 1996b) using appropriate end-point species and toxicological benchmarks. Data collection to assess ecological risk for both qualitative and quantitative ecological risk assessments must be performed in accordance with the procedures described in rule 3745-300-07 of the Administrative Code, the "Phase II rule."

[Comment: An Ohio EPA Emergency and Remedial Response representative may be contacted if a volunteer needs assistance in determining whether a qualitative or quantitative risk assessment is appropriate for a property.]

## (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 pathways to sediments are identified in accordance with paragraph (D)(2) of rule 3745-300-07 of the Administrative Code, the “Phase II rule”.

[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) If pathways to humans have been 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,” July, 1996, to determine the concentrations and physical distribution of the hazardous substances or petroleum; and

(ii) Conduct a property-specific human health risk assessment for the sediment exposure pathways following the methodology outlined in paragraph (D) of this rule.

[ Comment: for purposes of this rule, the pathway to humans should be considered if the surface water which contains the sediments can produce a consistent supply of edible-sized fish (edible-sized fish are generally considered to be fish five to six inches or larger unless a situation exists where humans are consuming small whole body fish, such as smelt. ) and chemical(s) of concern that have the potential to bioaccumulate in fish tissue are present in the sediment or the surface water. those chemicals which bioaccumulate in fish tissue include, but are not limited to, chlordane; 4,4'-DDT; P,P'-DDE; P,P'-DDT; dieldrin; hexachlorobenzene; hexachlorobutadiene; hexachlorohexane; alpha- hexachlorohexane; beta-hexachlorohexane; delta-hexachlorohexane; gamma- hexachlorohexane; lead; mercury; mirex; nonachlor; octachlorostyrene; polychlorinated biphenyls; pentachlorobenzene; photomirex; chlorinated dioxins and

dibenzofurans; terachlorobenzenes; toxaphene; and the phthalate esters; or if the surface water which contains the sediments is reasonably anticipated to support recreational activities such as wading, fishing, swimming, and boating.]

(b) If complete pathways to important ecological resources are 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," July, 1996, to determine the concentrations and spatial distribution of the hazardous substances or petroleum and may compare the ninety-five per cent upper confidence limit or maximum concentrations, as determined in accordance with paragraph (D)(5) of RULE 3745-300-07 of the Administrative Code, the "Phase II rule", to the ecotoxicologically-based benchmarks from the following guidance using the following hierarchy:

(i) "Ecotox Thresholds," U.S. EPA , January, 1996 publication 9345.0-12 FSI EPA 540/F-95/038; PB95-963324; or

(ii) The lowest effect level (LEL) values contained in "Guidelines for the Protection and Management of Aquatic Sediment Quality in Ontario," August, 1993; or

(iii) Benthic aquatic life chronic toxicity values for the non-polar organics and the lowest effect level (LEL) values for metals from the "State of New York, Technical Guidance for Screening Contaminated Sediments," July 1994.

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, the "Phase II rule", 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, the "Phase II rule", 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 which 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 ( $MI_{WB}$ ) 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 which 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 to conduct a quantitative macroinvertebrate study. if the water body does not have sufficient depth to conduct a quantitative macroinvertebrate study, a qualitative macroinvertebrate study must be conducted following the "Biocriteria Manual" and the instruction provided by the Ohio EPA biocriteria training course. 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.]

(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 the surface water containing the potentially impacted sediments is 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 located in the identified areas for the sediments, determined in accordance with rules 3745-300-06 and 3745-300-07 of the Administrative Code, the “Phase I and Phase II rules”.

[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.]

[Comment: when a voluntary property contains any wetland areas, a volunteer may need to obtain a permit under the Clean Water Act, 33 USCS @ 1344. The volunteer should contact the permit authority for the U.S. Army Corps of Engineers at the U.S. Army Corps of Engineers Office in the area where the property is located.]

(3) Sediments on a property must meet applicable standards. Applicable standards for sediments 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 biological criteria listed under rule 3745-1-07, table 7-17 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 determine 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. In many cases, elimination or containment of the source in the soils combined with passive remediation is the most appropriate remedy, as active remediation of the sediments may release contaminants into the water column. 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 or agreement as outlined in rule 3745-300-15 of the Administrative Code, the remediation rule, is necessary.].

(G) Surface water assessment

Applicable standards for surface waters on the property must be determined in accordance with paragraph (D) of rule 3745-300-08 OF THE ADMINISTRATIVE Code, the generic numerical standards rule.

(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 in this rule, applicable standards from a property-specific risk assessment are one or more of the following:

(a) Concentrations of chemical(s) 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 chemical(s) 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 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 under 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) The source for all chemical-specific values for the above equation must be obtained from one the following sources:

U.S. EPA, "Soil Screening Guidance: Technical Background Document." Publication 9355.4-17a, May, 1996;

"Support Document for Generic Standards";

U.S. EPA, "Supplemental Technical Support Document for the Hazardous Waste Identification Rule: Risk Assessment for Human and Ecological Receptors Volumes 1 and 2," RTI, November, 1995;

U.S. EPA, "Technical Support Document for the Hazardous Waste Identification Program: Risk Assessment for Human and Ecological Receptors, Volumes 1 and 2," RTI, August, 1995; or

If chemical-specific values for the above equation are not available in the sources listed above, an Ohio EPA Division of Emergency and Remedial Response representative; and

(ii) Physical values must be obtained from one of the following sources:

U.S. EPA, "Technical Background Document for Soil Screening Guidance, Review Draft," Office of Solid Waste and Emergency Response. EPA/540/R-94/106, December, 1994; or

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 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 the generic numeric standards rule or may determine that the chemicals of concern are below background levels following the background determination procedures contained in the phase ii property assessment rule.]

(e) The applicable standards for surface waters under paragraph (G) of this rule.

(2) Reporting limits.

The volunteer should contact the certified laboratory that is conducting analyses in support of the voluntary action to determine if the applicable standards calculated in accordance with this rule are within the laboratory's 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 chemical(s) of concern on the property at or below the applicable standards.

(3) Point of compliance for soils and ground water.

(a) Point of compliance for soils.

(i) Applicable soil standards based on direct contact with surficial soils.

A volunteer, or owner if different from the volunteer, must meet and maintain compliance with the direct contact soil standards to a depth where it is reasonably anticipated that surficial soils will be made available for direct contact through excavation, grading, drilling or other circumstances. The following minimum surface soil depths to which the direct contact soil standards apply are as follows:

(A) For properties for which no institutional controls have been implemented, the point of compliance for applicable standards based on direct contact of chemical(s) of concern in soil is a minimum depth of ten feet. The volunteer must comply with applicable direct contact soil standards at depths below ten feet when it is reasonably anticipated that soils will be made available for direct contact through excavation, grading, drilling or other circumstances.

(B) For non-residential properties for which institutional controls have been implemented as part of a remedy in accordance with the requirements contained in paragraphs (B) and (E)(13) of rule 3745-300-13 and rule 3745-300-15 of the Administrative Code, the point of compliance for applicable standards based on direct contact of chemical(s) of concern in soil is a minimum depth of two feet. The volunteer must comply with applicable direct contact soil standards at depths below two feet when it is reasonably anticipated that soils will be made available for direct

contact through excavation, grading, drilling or other circumstances.

[Comment: the two paragraphs above state the different points of compliance which must be met, at a minimum, when a property-specific risk assessment is performed. the ten foot point of compliance must be met if the land use is unrestricted, that is, the land can be used for whatever the volunteer desires (e.g. homes, park, farmland, etc.). the two foot point of compliance must be met if there is a restriction (institutional control) on the land which limits how the volunteer can use the land (e.g. a restriction that states the land can only be used for industrial purposes).]

(ii) Applicable soil standards based on leaching of soil-borne chemical(s) of concern to ground water.

The point of compliance for applicable soil standards based on leaching of soil-borne chemical(s) of concern to ground water, when such leaching must be prevented in accordance with rule 3745-300-10 of the Administrative Code, is the depth to the uppermost saturated zone.

(iii) Applicable soil standards based on other identified pathways. the point of compliance for applicable soil standards developed in this rule for pathways identified in paragraph (D)(2) of rule 3745-300-07 of the Administrative Code, the “Phase II rule”, other than those identified in paragraphs (G)(3)(a)(i) and (G)(3)(a)(ii) of this rule, must be determined so that the exposure to receptors is appropriately addressed.

(b) Point of compliance for ground water.

The point of compliance for ground water underlying or emanating from a property must be in accordance with rule 3745-300-10 of the Administrative Code.

(c) Point of compliance for other media.

The point of compliance for applicable standards developed in this rule for pathways identified in paragraph (D)(2) of rule 3745-300-07 of the Administrative Code, the “Phase II rule”, for media other than those identified in paragraphs (G)(3)(a) and (G)(3)(b) of this rule, must be determined so that the exposure to receptors is appropriately addressed.

(I) Risk assessment report.

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

- (1) The circumstances under which the risk assessment was conducted with respect to paragraphs (B)(1) AND (B)(2) of this rule;
- (2) A list of the institutional 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 institutional and engineering controls.];
- (3) A list of the chemicals of concern on the property which were not considered in the property-specific risk assessment because they met 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 were 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.

3745-300-09

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Effective: \_\_\_\_\_

Certification: \_\_\_\_\_

Date: \_\_\_\_\_

Promulgated Under: RC Chapter 119.

Rule Amplified: RC Chapter 3746.

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Prior Effective Dates: None