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

[Comment: For dates of non-regulatory government publications, publications of recognized organizations and associations, federal rules, and federal statutory provisions referenced in this rule, see paragraph (B) of rule 3745-300-01 of the Administrative Code titled "Incorporation by reference."]

(A) Applicability.

The property-specific risk assessment procedures set forth in this rule may be used to demonstrate that conditions on the property and off the property, when contamination emanates from the property, ensure protection of public health and safety and the environment on the property and off the property.

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

(2) If polychlorinated biphenyls are identified at a property, the property may be subject to cleanup levels or other provisions of the Toxic Substances Control Act and the regulations adopted thereunder. Polychlorinated biphenyls shall be addressed within the voluntary action as a hazardous substance and meet either generic numerical standards in accordance with rule 3745-300-08 of the Administrative Code or property-specific standards in accordance with this rule.

(3) Elective application.

If a volunteer elects not to apply one or more of the generic numerical standards established under rule 3745-300-08 of the Administrative Code to a chemical of concern, a property-specific risk assessment must be used to develop an applicable standard for that chemical of concern.

(4) Mandatory application.

A property-specific risk assessment must be conducted in accordance with the procedures established in this rule to determine applicable standards instead of or in addition to using the generic numerical standards in accordance with rule 3745-300-08 of the Administrative Code, if any of the following apply to the property:

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(a) The complete exposure pathways as identified in accordance with paragraph (F)(1) of rule 3745-300-07 of the Administrative Code, include exposure pathways that are not considered in the development of standards listed in rule 3745-300-08 of the Administrative Code. Such exposure pathways include, but are not limited to, volatilization of contaminants to indoor air or non-potable use of ground water;

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

(c) The chemicals of concern on the property consist of hazardous substances or petroleum that do not have generic numerical standards included in rule 3745-300-08 of the Administrative Code. If only some of the chemicals of concern identified have a generic numerical standard listed in rule 3745-300-08 of the Administrative Code, a volunteer may use the applicable generic numerical standards for the chemicals of concern having listed standards and conduct a property-specific risk assessment in accordance with this rule. When using a combination of generic numerical 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 to meet the human health risk and hazard levels described in paragraph (B) of this rule;

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

(e) Complete exposure pathways to important ecological resources other than sediment or surface water exist; or

(f) It is determined that chemicals of concern on or emanating from the property are persistent, bioaccumulative, and toxic in animal tissue and the development of the generic standards, other than Ohio-specific sediment reference values contained in attachment H of Ohio EPA's "Guidance for Conducting Ecological Risk Assessments", do not consider bioaccumulative effects.

(B) Applicable risk and hazard levels for human receptors.

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The applicable standards for human receptors developed from a property-specific risk assessment must be determined in accordance with the following risk and hazard levels:

(1) Carcinogenic risk.

For chemicals of concern which have carcinogenic effects, the cumulative human health carcinogenic risk must not exceed the following risk levels 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 one hundred thousand (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 ten thousand (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 one hundred thousand (1×10^{-5}); or

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

(2) Noncarcinogenic hazard.

For chemicals of concern which have noncarcinogenic effects, the cumulative human health hazard, which is attributable to the chemicals of concern, must not exceed a hazard index of one.

(3) Carcinogenic risk and noncarcinogenic hazard.

For chemicals of concern which have both carcinogenic and noncarcinogenic effects, the concentration of the chemicals of concern must not exceed the risk and hazard levels established in paragraphs (B)(1) and (B)(2) of this rule. If more than one complete exposure pathway exists to each receptor population, the incremental cancer risk and hazard indices determined for each exposure pathway must be summed to calculate a cumulative cancer risk

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and hazard index to each receptor population. All final cumulative human health carcinogenic risk and non-carcinogenic hazard levels are based on one significant figure.

(C) Petroleum standards.

(1) Chemicals of concern that must be evaluated are dependent on the petroleum fraction of the released product. It may be appropriate to evaluate additional petroleum constituents or typical impurities to ensure applicable standards are met. At a minimum, the indicator compounds that must be assessed and evaluated for each petroleum fraction include:

(a) For light petroleum fractions, such as natural gasoline, gasohol or naphtha solvents, environmental media on the property must be analyzed for benzene, toluene, ethylbenzene, methyl tert-butyl ether and total xylenes.

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

(c) For heavy petroleum fractions, such as hydraulic oil, lube oil, or residual fuel oils, environmental media on the property must be analyzed for acenaphthene, anthracene, chrysene, benzo[a]pyrene, benzo[a]anthracene, benzo[b]fluoranthene, benzo[k]fluoranthene, dibenzo[a,h]anthracene, fluoranthene, fluorene, indeno[1,2,3-cd]pyrene, naphthalene, and pyrene. In addition, where the heavy petroleum is used motor oil, used cutting oil, or hydraulic oil, additional chemicals of concern that may be typical impurities of the used heavy petroleum fractions product must also be identified and included in the analysis, as appropriate.

(d) For petroleum from an unknown source, environmental media must be analyzed for benzene, ethylbenzene, toluene, total xylenes, methyl tert-butyl ether, acenaphthene, anthracene, chrysene, benzo[a]anthracene, benzo[a]pyrene, benzo[b]fluoranthene, benzo[k]fluoranthene, dibenzo[a,h]anthracene, fluoranthene, fluorene, indeno[1,2,3-cd]pyrene, naphthalene, and pyrene. In addition, additional chemicals of concern that may be typical impurities of used petroleum fractions must also be identified and included in the analysis,

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as appropriate.

(2) Evaluating compliance with applicable standards. The concentrations of chemicals of concern evaluated in accordance with paragraph (D)(3)(a) of this rule on the property must meet applicable standards for the media and exposure pathways evaluated. As appropriate, applicable standards for petroleum and its constituents or impurities must be evaluated in the following manner:

(a) A human health property-specific risk assessment must be conducted that includes derivation of applicable standards in accordance with paragraph (D) of this rule or use of generic numerical standards contained in rule 3745-300-08 of the Administrative Code. Generic numerical standards may be used for the exposure pathways included in rule 3745-300-08 of the Administrative Code. Other exposure pathways, such as volatilization of chemicals into indoor air, must be evaluated in accordance with paragraph (D) of this rule. Evaluation of cumulative risks in accordance with paragraphs (B) and (D)(3)(d) of this rule must be conducted.

(b) Soil saturation concentrations of total petroleum hydrocarbons must be determined for the property by determining the vertical hydraulic conductivity of the unsaturated soil or otherwise demonstrate the soil type most representative of the soils impacted by petroleum. The corresponding petroleum fraction identified at the property must meet the residual saturation concentration contained in table I of this rule.

Table I: total petroleum hydrocarbon soil saturation concentration (values are in mg/kg).

	Residual Saturation Concentrations for:	Residual Saturation Concentrations for:	Residual Saturation Concentrations for:
	Sand and Gravel; Unknown Soil Type	Silty/Clayey Sand	Glacial Till and Silty Clay
Petroleum Fraction	KV: 10^{-3} - 10^{-4} cm/s	KV: 10^{-4} - 10^{-5} cm/s	KV: < 10^{-5} cm/s
Light (C_6 -C_{12})	1,000	5,000	8,000
Middle (C_{10} -C_{20})	2,000	10,000	20,000
Heavy (C_{20}-C_{34}	5,000	20,000	40,000
Where: mg/kg means milligrams per kilogram, K_v means vertical hydraulic conductivity			

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of the unsaturated soil, cm/s means centimeters per second, and C_x means carbon chain length.

(c) Properties with free product exceed applicable standards for unrestricted potable use of ground water. Ground water at properties with free product must meet the appropriate ground water response requirements in accordance with rule 3745-300-10 of the Administrative Code.

(d) Evaluation of sediment, surface water, and ecological exposure pathways must be determined in accordance with requirements in this rule and rule 3745-300-08 of the Administrative Code as appropriate.

(D) Procedures for human health risk assessments.

(1) A human health property-specific risk assessment conducted in accordance with this rule must demonstrate that the concentrations of chemicals of concern on, underlying or emanating from a property meet the applicable risk and hazard levels under paragraph (B) of this rule.

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

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 3745-300-11 of the Administrative Code;

(c) The use of institutional controls including, without limitation, activity and use limitations contained in the environmental covenant. Institutional controls must be:

(i) Effective at eliminating or mitigating exposures to all receptor populations sufficient to meet the risk and hazard levels contained in paragraph (B) 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

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control is used to achieve and maintain applicable standards; and

(iii) Transferable 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 and hazard levels or applicable standards in 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 3745-300-11 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 (F)(1) 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

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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 or exposure units on the property, which are determined in accordance with the procedures under rule 3745-300-07 of the Administrative Code. The physical distribution information 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 (F) of rule 3745-300-06 of the Administrative Code, or cannot be removed from the list of chemicals of concern pursuant to paragraph (F)(4)(f) of 3745-300-07 of the Administrative Code, must be considered chemicals of concern and 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 in concentrations near naturally occurring levels, and may be toxic only at very high concentrations. These chemicals include iron, magnesium, calcium, potassium and sodium; or

(ii) The chemicals of concern are determined to contribute to less than one per cent of the estimated risk and or hazard attributed to a pathway-receptor combination in accordance with the procedures contained in U.S. EPA's "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation manual (Part A)."

(b) Exposure assessment.

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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 risk and hazard potential to all receptor populations as identified in accordance with paragraph (E)(6) of rule 3745-300-07 of the Administrative Code that are reasonably anticipated to be exposed to chemicals of concern on the property. Populations must be evaluated for the magnitude and frequency of exposure for each exposure period.

(ii) Evaluation of exposure pathways.

The property-specific exposure assessment must evaluate all complete exposure pathways in accordance with paragraph (F)(1) of rule 3745-300-07 of the Administrative Code. 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 3745-300-11 of the Administrative Code. Complete exposure pathways must be evaluated in accordance with the procedures contained in U.S. EPA's "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A);" "Exposure Factors Handbook;" "Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors;" and "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)."

(iii) Quantification of chemical-specific intake as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code.

Chemical-specific intakes must be calculated to quantify the exposure of each receptor population as identified in accordance with paragraph (E)(6) of rule 3745-300-07 of the Administrative Code, to 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

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volunteer must calculate the chemical-specific intakes using formulas identified in U.S. EPA's "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A);" "Exposure Factors Handbook;" "Human Health Evaluation Manual, Supplemental Guidance: Standarad Default Exposure Factors;" and "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)," and Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures." The numerical values for the exposure factor terms in formulas 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 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 point values or distributions contained in Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures," which are the basis for the development of the generic unrestricted potable use standards listed in paragraph (D)(3)(c) 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 as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code with an estimate of upper-bound exposures as defined in paragraph (A) of rule 3745-300-01 of the

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Administrative Code obtained in accordance with U.S. EPA's "Human Health Evaluation Manual, Supplemental Guidance: Standarad Default Exposure Factors;" and Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures" for the complete exposure pathway which contributes most substantially to risk, and for any other complete exposure pathways for which upper-bound exposures are deemed likely. For all other complete exposure pathways, exposure factor point values as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code must be the values representative of central tendency, upper bound or other appropriate exposures as defined in Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures." When exposure factor values are represented by probability distributions as input for a probabilistic simulation, the probability distributions must be those used for the derivation of the generic numerical standards listed in Ohio EPA's "Support Document for the Deveopment of Generic Numerical Standards and Risk Assessment Procedures" 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. Exposure factor values must be consistent with an estimate of upper-bound exposures as described in U.S. EPA's "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)," and Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures." For all other complete exposure pathways, the

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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 as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code.

Exposure point concentrations must be determined for each complete exposure pathway and must represent the concentration of chemicals of concern from each of the identified areas or exposure units on the property. This representation of exposure point concentration must be consistent with concentrations of the chemicals of concern determined in accordance with paragraph (F)(5) of rule 3745-300-07 of the Administrative Code, and the exposure factor values as determined in accordance with paragraph (D)(3)(b)(iiii)(a) of this rule.

(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 (E) of rule 3745-300-07 of the Administrative Code;

(b) Property-specific information used to define any parameter which requires the prediction of human use and activity patterns on a property, or the physical, physiological and behavioral characteristics of the receptor 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

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that meets the requirements of rule 3745-300-11 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. The most current toxicity information must be obtained from the integrated risk information system 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 the integrated risk information system, or is not listed in Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures," the volunteer must consult with Ohio EPA to obtain appropriate toxicity information.

(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 complete exposure pathway, in accordance with the procedures described in U.S. EPA's "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)," and "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)." Risk characterization performed in accordance with the procedures described in

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paragraph (D)(3)(d) of this rule 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's "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)," and "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)" or from Ohio EPA's "Support Document for the Development of Generic Numerical Standards and Risk Assessment Procedures."

(d) Risk characterization.

Risk characterization 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.

(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 (B)(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 this rule and in U.S. EPA's "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)" 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;

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(b) If incremental cancer risk is determined for a receptor population for more than one carcinogenic chemical of concern, 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's "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A);" and

(c) If incremental cancer risk is determined for a receptor population for more than one complete exposure pathway, 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)(d) of this rule and in U.S. EPA's "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)."

(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 (B)(2) of this rule. A hazard index must be calculated separately for each receptor population over a specified exposure period (i.e., chronic or sub-chronic exposure) identified in accordance with the procedures described in paragraph (D)(3)(b)(ii) of this rule, as follows:

(a) A hazard quotient as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code must be calculated for each chemical of concern with noncancer effects described by a reference dose or reference concentration as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code for each complete exposure pathway in accordance with the procedures described in this rule and in U.S. EPA's "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A);" and

(b) If hazard quotient values representing noncancer hazards for one receptor population over a specified exposure period

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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's "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)." Separate hazard index calculations may be performed based on the consideration of major noncarcinogenic toxic endpoints, 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 separate hazard index calculations 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 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 this rule and in U.S. EPA's "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)." 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.

Uncertainty associated with the property-specific risk assessment may be evaluated. The uncertainty analysis may include a qualitative description or quantitative evaluation of uncertainty associated with the following: selection of chemicals of concern and the exposure point concentration; estimates of chemical-specific intake factors; complete exposure pathways;

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toxicity criteria; additive or antagonistic effects of exposure to multiple chemicals of concern through one or more complete exposure pathways; or evaluation of site-specific, epidemiological, or health studies.

(E) Procedures for ecological risk assessment.

(1) For each complete exposure pathway to important ecological resources from environmental media containing chemicals of concern that are persistent, bioaccumulative and toxic, the volunteer must evaluate the environmental media using a food web model in accordance with Ohio EPA's "Guidance for Conducting Ecological Risk Assessments," unless;

(a) The concentrations of chemicals of concern in sediment do not exceed Ohio-specific sediment reference values contained in attachment H of Ohio EPA's "Guidance for Conducting Ecological Risk Assessments;" or

(b) The concentrations of chemicals of concern in sediment do not exceed the values listed in paragraph (H)(2)(b) of rule 3745-300-08 of the Administrative Code and those values consider bioaccumulative effects.

(2) A qualitative property-specific 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.

(3) A quantitative property-specific ecological risk assessment must be conducted in accordance with Ohio EPA's "Guidance for Conducting Ecological Risk Assessments" if complete exposure pathways from environmental media other than surface water or sediment on a property exist to important ecological resources and the provisions in paragraph (E)(2) of this rule do not apply.

(4) Data collection to assess ecological risk for both qualitative and quantitative ecological property-specific risk assessments must be performed in accordance with rule 3745-300-07 of the Administrative Code.

(F) Procedures for assessment and remediation of sediments.

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(1) For each complete exposure pathway from sediments on or emanating from the property to human receptors identified in accordance with paragraph (F)(1) of rule 3745-300-07 of the Administrative Code, the volunteer must determine if concentrations of chemicals of concern in sediments meet applicable standards in accordance with paragraph (G) of rule 3745-300-08 of the Administrative Code or conduct a human health property-specific risk assessment following the methodology outlined in paragraph (D) of this rule. 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 and chemicals of concern that are persistent, bioaccumulative and toxic are present in the sediment or the surface water or if the surface water which contains the sediments is reasonably anticipated to support recreational activities such as wading, fishing, swimming, and boating.

(2) For each complete exposure pathway from sediments on the property to important ecological resources where applicable standards determined in accordance with paragraph (H)(2) of rule 3745-300-08 of the Administrative Code have not been met or sediment samples were not compared to the appropriate values in accordance with paragraph (H) of rule 3745-300-08 of the Administrative Code, sediment toxicity must be evaluated according to the following methodology:

(a) For all surface waters that have an aquatic life use designation of warmwater habitat, exceptional warmwater habitat (excluding lakes and reservoirs), modified warmwater habitat, or coldwater habitat assigned under Chapter 3745-1 of the Administrative Code, a biological survey must be conducted. The biological survey must include:

(i) A fish and physical habitat survey must be used to calculate the qualitative habitat evaluation index, the index of biotic integrity and, where applicable, a modified index of well-being for the surface water on the property following the procedures contained in the biocriteria manual as defined in paragraph (A) of 3745-300-01 of the Administrative Code and Ohio EPA's "Surveillance Methods and Quality Assurance Practices." The sampling locations for the fish and physical habitat survey must include the same locations where sediment samples were collected, if possible; and

(ii) A quantitative macroinvertebrate survey must be used to calculate the invertebrate community index for the surface waters on the

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property following the biocriteria manual unless the waterbody does not have sufficient depth and flow to conduct a quantitative macroinvertebrate study. If the waterbody 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 certification and qualified data collector approval obtained in accordance with paragraph (D) of rule 3745-300-05 and paragraph (B) of rule 3745-4-03 of the Administrative Code. The sampling locations for the quantitative macroinvertebrate survey must include the same locations established where sediment samples were collected, 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.]

(b) For all surface waters with an aquatic life use designation of limited resource water assigned under Chapter 3745-1 of the Administrative Code, or that are a lake, reservoir, wetland or pond, sediment bioassays using sediment samples taken from the surface waters on the property must be conducted to evaluate sediment toxicity. Sediment bioassay sampling locations must be determined in accordance with this rule and rule 3745-300-07 of the Administrative Code. Sediment bioassays must include, at a minimum, the ten-day survival and growth test for "Hyalella Azteca" and "Chironomus tentans" following the procedures in the U.S. EPA sediment toxicity test as defined in paragraph (A) of rule 3745-300-01 of the Administrative Code. "Chironomus riparius" may be substituted for "Chironomus tentans" if needed.

(c) For all surface waters with an aquatic life use designation of limited warm water habitat, or with no aquatic life use designation assigned under Chapter 3745-1 of the Administrative Code, a volunteer must either conduct a use attainability analysis as detailed in the biocriteria manual to assign the appropriate aquatic life use designation, or apply biocriteria for warm water habitat. Consult with a Ohio EPA division of environmental response and revitalization representative for assistance in making a determination on an aquatic life use designation for an unlisted waterbody.

(3) Unless concentrations of chemicals of concern in sediments meet applicable standards in accordance with paragraph (H) of rule 3745-300-08 of the

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Administrative Code, applicable standards for sediments and surface water on a property are as follows:

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

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

(b) For surface water with an aquatic life use designation of limited resource water assigned under Chapter 3745-1 of the Administrative Code and for surface waters which are wetlands, ponds, lakes, or reservoirs, the applicable standards are the absence of toxic effects to both organism groups as defined in the U.S. EPA sediment toxicity test.

(4) The following actions must be taken when, in accordance with paragraphs (F)(3)(a) and (F)(3)(b) 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 3745-300-11 of the Administrative Code, must be implemented to meet applicable

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standards.

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

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

(G) Surface water assessment.

If concentrations of chemicals of concern in surface water exceed applicable standards in accordance with paragraph (F)(2)(a) of rule 3745-300-08 of the Administrative Code, then applicable standards for surface water are those found in paragraphs (E) and (F)(3) of this rule.

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

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

(1) Concentrations of chemicals of concern which meet the risk and hazard levels for human health in accordance with the requirements contained in paragraphs (B) and (C) of this rule and in accordance with the procedures described in paragraphs (D) and (F) of this rule;

(2) Concentrations of chemicals of concern that protect important ecological resources in accordance with the procedures contained in paragraph (E) of this rule;

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

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

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

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

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}),

(a) All chemical-specific values for the above equation must be obtained from one of the following sources:

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

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

(iii) Hazardous substances data bank;

(iv) The physical properties database;

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(v) CHEMFATE chemical search;

(vi) Risk assessment information system; or

(vii) 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.

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

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

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

(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 (A)(3) and (A)(4) 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. Pursuant to rule 3745-300-11 of the Administrative Code, the volunteer must 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;

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(5) All appropriate documentation which supports the derivation and application of exposure factors used to quantify intake as described in paragraph (D)(3)(b)(iii) of this rule and meets the criteria 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) Ecological risk report, in accordance with paragraph (E) of this rule;

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

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

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