1. INTRODUCTION

The Environmental Protection Agency's (EPA's) Superfund Program has updated its approach for determining risk from inhaled chemicals to be consistent with the inhalation dosimetry methodology described in *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (USEPA, 1994; hereafter, the *Inhalation Dosimetry Methodology*).[1] This document provides Superfund site risk assessors with guidance that should help more consistently address the *Inhalation Dosimetry Methodology*.

This document outlines recommended processes consisting of a series of steps as well as recommended equations for EPA Regions to consider when estimating inhalation exposure and risk at Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) sites. This guidance is intended to provide a recommended methodology for consistently addressing the inhalation pathway in risk assessments for Superfund sites.

Some of the statutory provisions described in this document contain legally binding requirements. However, this document does not substitute for those provisions or regulations, nor is it a regulation itself. Thus, it cannot impose legally binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances. Any decisions regarding a particular remedy selection decision will be made based on the statute and regulations, and EPA decisionmakers retain the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. EPA may change this guidance in the future.

1.1 Background

EPA's *Risk Assessment Guidance for Superfund (RAGS), Part A* (USEPA, 1989; hereafter, *RAGS, Part A*) outlined a previously recommended approach for conducting site-specific baseline risk assessments for inhaled contaminants.[2] According to the original RAGS approach, the inhalation exposure estimate was typically derived in terms of a chronic, daily "air intake" (mg/kg-day) using the following general approach. The intake of the chemical was estimated as a function of the concentration of the chemical in air (CA), inhalation rate (IR), body weight (BW), and the exposure scenario. Age-specific values for BW and IR were used when evaluating childhood exposures. Table 1 presents the *RAGS, Part A* equation for calculating intake for inhalation exposure. Inhalation toxicity values were "converted" into similar units for the risk quantification step. Cancer risk was estimated by multiplying the chronic daily intake of the chemical from the air by the "inhalation cancer slope factor" (CSF_i); the Hazard Quotient (HQ) for non-cancer effects was estimated by dividing the intake of the chemical by an "inhalation reference dose" (RfD_i).[3]

The approach outlined in *RAGS, Part A* was developed before EPA issued the *Inhalation Dosimetry Methodology*, which describes the Agency's refined recommended approach for interpreting

[1] The *Inhalation Dosimetry Methodology* can be found at the following web address: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=71993.

[2] See sections 6.6.3, 7.2.3, 7.3.3, and 8.2 of *RAGS, Part A*.

[3] EPA defines an HQ in *RAGS, Part A* as: "The ratio of a single substance exposure level over a specified time period (e.g., subchronic) to a reference dose (RfD) for that substance derived from a similar exposure period" (USEPA, 1989).

inhalation toxicity studies in laboratory animals or studies of occupational exposures of humans to airborne chemicals. Under the *Inhalation Dosimetry Methodology*, the experimental exposures are typically extrapolated to a Human Equivalent Concentration (HEC), and a reference concentration (RfC) is typically calculated by dividing the HEC by uncertainty factors (UFs). As described in the Agency's *Guidelines for Cancer Risk Assessment* (USEPA, 2005a), the HEC developed in accordance with the *Inhalation Dosimetry Methodology* typically is also used in developing an inhalation unit risk (IUR) for cancer risk assessment (which may also be called an inhalation cancer slope factor).[4] The procedure that was used to calculate the published RfC or IUR is described in the Integrated Risk Information System (IRIS) profile or other toxicological reference document for a chemical.

TABLE 1
RAGS, PART A EQUATION DESCRIBING THE ESTIMATION OF INHALATION EXPOSURE

Equation	Location in RAGS, Part A
Intake (mg/kg-d) = CA x (IR/BW) x (ET x EF x ED)/AT	Exhibit 6-16, Page 6-44
Key: CA (mg/m^3) = contaminant concentration in air; IR (m^3/hr) = inhalation rate; BW (kg) = body weight; ET (hours/day) = exposure time; EF (days/year) = exposure frequency; ED (years) = exposure duration; and AT (days) = averaging time (period over which exposure is averaged).	

The Superfund Program has updated its inhalation risk paradigm to be compatible with the *Inhalation Dosimetry Methodology*, which represents the Agency's current methodology for inhalation dosimetry and derivation of inhalation toxicity values.[5] This document recommends that when estimating risk via inhalation, risk assessors should use the concentration of the chemical in air as the exposure metric (e.g., mg/m^3), rather than inhalation intake of a contaminant in air based on IR and BW (e.g., mg/kg-day).

1.2 Purpose and Scope

The intake equation described above (*RAGS, Part A*, Exhibit 6-16) is not consistent with the principles of EPA's *Inhalation Dosimetry Methodology* because the amount of the chemical that reaches the target site is not a simple function of IR and BW. Instead, the interaction of the inhaled contaminant with the respiratory tract is affected by factors such as species-specific relationships of exposure concentrations (ECs) to deposited/delivered doses and physiochemical characteristics of the inhaled contaminant. The *Inhalation Dosimetry Methodology* also considers the target site where the toxic effect occurs (e.g., the respiratory tract or a location in the body remote from the portal-of-entry) when applying dosimetric adjustments to experimental concentrations (USEPA, 1994). Therefore, this *RAGS, Part A* equation is not recommended for estimating exposures to inhaled contaminants.

[4] The phrase "inhalation cancer slope factor," as used in this guidance, refers generally to the risk per a measure of inhalation exposure. Inhalation exposure in cancer bioassays or occupational studies from which slope factors may be derived is most commonly expressed as an exposure concentration (e.g., µg agent/m^3 air). Please note that this differs from past use of the phrase "inhalation cancer slope factor" or "CSF_i" by the Superfund program to refer to a cancer slope expressed as an "inhalation intake" (e.g., *RAGS, Part A* (USEPA, 1989)).

[5] For additional information about the Superfund program's adoption of the *Inhalation Dosimetry Methodology*, please refer to the summary of a 2003 Superfund workshop on inhalation risk assessment: http://www.epa.gov/oswer/riskassessment/pdf/finalinhalationriskworkshop.pdf.

The purpose of this document is to provide a recommended approach for developing the information necessary to assist risk assessment and risk management decision-making at waste sites involving potential risks from inhalation exposures.[6, 7] This includes providing equations that may be used in conducting baseline risk assessments and in calculating risk-based concentrations (RBCs). It is intended that *RAGS, Part F* will replace those portions of *RAGS, Part A*, which addressed inhalation risk.

1.3 Effects on Other Office of Superfund Remediation and Technology Innovation Guidance

EPA recommends that the intake equation presented in *RAGS, Part A* (USEPA, 1989, Exhibit 6-16) should no longer be used when evaluating risk from the inhalation pathway. Implementation of a risk assessment approach consistent with the *Inhalation Dosimetry Methodology* will also affect the following guidance documents: *RAGS, Part B*, Section 3.3: Volatilization and Particulate Emission Factors (USEPA, 1991); and the Office of Solid Waste and Emergency Response's (OSWER's) *Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils* (USEPA, 2002a; hereafter the *Vapor Intrusion Guidance*). EPA no longer recommends using the equations in Section 3.3 of *RAGS, Part B* nor the inhalation toxicity values generated using simple route-to-route extrapolation, such as those presented in the 2002 draft *Vapor Intrusion Guidance* and related documents.[8]

This guidance does not affect the equations pertaining to risk from inhaled chemicals in the *Soil Screening Guidance* (USEPA, 1996), Section 2.4, or the *Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites* (USEPA, 2002b), Sections 4.2.3, 5.3.2 and Appendix B, other than to clarify that the IURs and RfCs used in the equations are based on continuous exposure (24 hours per day). If the exposure scenario of interest is less than 24 hours per day, the scenario-specific exposure time (ET) in hours per day should be used in the equations and the averaging time should be in units of hours (see Equations 6 and 8 in this document). *RAGS, Part D* (USEPA, 2001) is also not affected by *RAGS, Part F*, as it includes sufficient flexibility to accommodate the revisions described in this guidance. In addition, the screening values presented on the "Regional Screening Levels for Chemical Contaminants at Superfund Sites" screening level/preliminary remediation goal table are consistent with *RAGS, Part F* (USEPA, 2008a).[9] Readers can contact EPA headquarters with questions about the compatibility of specific Superfund documents with *RAGS, Part F*.

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[6] Note that the assessment of risk from inhaled nanoparticles is outside the scope of this document.

[7] If a site contains asbestos contamination, risk assessors should contact EPA's Technical Review Workgroup for Metals and Asbestos for assistance.

[8] Related documents include the *Johnson and Ettinger (1991) Model for Subsurface Vapor Intrusion into Buildings* spreadsheet models (http://www.epa.gov/oswer/riskassessment/airmodel/johnson_ettinger.htm) and the accompanying *User's Guide for Evaluating Subsurface Vapor Intrusion into Buildings* (USEPA, 2004a).

[9] This table can be found on EPA Regions 3, 6, and 9 websites (http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/index.htm; http://www.epa.gov/earth1r6/6pd/rcra_c/pd-n/screen.htm; and http://www.epa.gov/region09/waste/sfund/prg/index.html).