DRAFT

SITE-SPECIFIC HUMAN HEALTH RISK ASSESSMENT PROCEDURES

Pennsylvania Department of Environmental Protection

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Preamble

This document provides general guidelines on the methodology of risk assessment and risk assessment report for human health evaluation under Act 2. Regulations regarding risk assessment are in Chapter 250, Subchapter F. This guidance document does not address issues related to ecological risk assessment. Ecological risk assessment is addressed in a separate guidance.

Any person selecting the site-specific standard established by Section 304 of Act 2 should submit a risk assessment report to the Department for review and approval unless no present or future complete exposure pathways exist as demonstrated by a fate and transport analysis. If no complete exposure pathways exist, a risk assessment report and cleanup plan are not required and no remedy is required to be proposed or completed. If complete exposure pathways exist, the fate and transport analysis, which is a part of the exposure assessment, should be documented in the risk assessment report.

Under Act 2, a risk assessment report may include the following:

a) a baseline risk assessment report that describes the potential adverse effects under both current and planned future conditions caused by the presence of regulated substances in the absence of any further control, remediation or mitigation measures;

b) a risk assessment report that documents which exposure pathways will be eliminated by a pathway elimination measure so that any substantial present or probable future risk to human health or the environment is eliminated;

c) a risk assessment to develop site-specific standard report that describes the methods used to develop a concentration levels at which human health and the environment are protected; and

d) the comments obtained as a result of a public involvement plan, if any, and the responses to those public comments.

A baseline risk assessment report is not required if the Department, in its remedial investigation report or cleanup plan approval, determines that a specific remediation measure that eliminates all pathways, other than a no-action remedial alternative, can be implemented to attain the site-specific standard. [Section 250.405(c) of the regulations]. All current or probable future exposure pathways as identified in the fate and transport analysis should be addressed in the risk assessment to develop site-specific standards report.

1. Introduction

To determine if a site-specific risk assessment for human health evaluation is necessary, a site conceptual model should be developed that defines potential exposure scenarios and pathways. The exposure scenario (*e.g.*, residential, industrial, recreational), which will define the exposure pathways, must be based on site-specific land use considerations. The pathways, which describe the mechanism by which receptors may be exposed to a source, are also site-specific. Detailed guidance on land use determination and identifications of exposure scenarios and exposure pathways are addressed in Section 2.b)(i) (relating to Exposure Scenarios and Exposure Pathways) of this document (*Site-Specific Human Health Risk Assessment Procedures***)** and references cited therein. A risk assessment only needs to be performed if complete exposure pathways for human receptors exist under current or future planned conditions. If engineering or institutional controls that are to be implemented will eliminate all exposure pathways, the risk assessment report does not need to include information regarding quantification of exposure, toxicity assessment, risk algorithm and risk calculation as identified in Section II.C.7.b of this manual.

However, before getting into the mechanics of performing the assessment, it is important to clearly define the problem that is to be addressed, the objectives of the study and how the results will be used to meet these objectives. This initial step is critical to ensure a successful outcome (accurate, protective, timely, cost-effective evaluation) and that the level of effort is commensurate with the scope of the problem.

Risk assessment procedures have been well-defined in various US Environmental Protection Agency (USEPA) guidance documents. The process will not be reiterated in this document. Instead certain key issues pertinent to site-specific evaluations under Act 2 are discussed subsequently.

For risk assessment issues not directly addressed in this document, a person may consult the most recent U.S. EPA and ASTM guidelines, such as those listed on Table 1, for additional guidance. For petroleum release sites, the risk assessment methodology in ASTM E 1739 (Standard Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites) may be consulted for further guidance.

A suggested outline for the risk assessment report is provided in Section II.C.7.b of the manual. The outline is intended to provided guidance on minimum requirements for the report.

2. Risk Assessment for Human Health [Section 250.602(c) of the Regulations]

A risk assessment for human exposure from contaminated sites consists of the following four steps:

(1) site characterization;

(2) exposure assessment;

(3) toxicity assessment; and

(4) risk characterization that evaluates if the risks meet the human health protection goals specified in subsections 304(b) and (c) of Act 2.

The following discussions address key issues pertinent to these four steps of risk assessment for human exposure:

a) Site Characterization [Section 250.602(c)(1)of the Regulations]

i) Chemicals of Concern

The initial steps of the site characterization are to review the analytical data and to select the chemicals of concern that are identified in distinct areas of contamination at the site. Under Act 2 there are two possible situations in determining the chemicals of concern in a baseline risk assessment under the site-specific standard: (1) strictly using the site-specific standard, or (2) a combination of standards using site-specific and Statewide health, site-specific and background, or all three standards. These situations are discussed separately below.

In the first situation of using only the site-specific standard, the chemicals of concern can be screened using the EPA Region III Risk-Based Concentration (RBC) screening procedures [http://www.epa.gov/reg3hwmd/risk/riskmenu.htm]. The purpose of this screening procedure is only for potential reduction of the number of chemicals carried through the risk assessment. Those chemicals on the site whose maximum concentration exceeds the RBC values for carcinogenic effects or $1/10^{th}$ of the RBC values (HQ=0.1) for noncarcinogenic effects should be retained in the risk assessment. Chemicals on the site at maximum concentration below the RBC values for carcinogenic effects or $1/10^{th}$ of the RBC values for noncarcinogenic effects may be dropped from the risk assessment unless other contaminant-specific or site-specific considerations suggest that the inclusion of these constituents in the risk assessment is more appropriate to determine the total risk of the site. Chemicals that are not retained in the risk assessment may be considered having minimal influence on total risk.

In the second situation of using combination of standards, the list of chemicals of concern in the site-specific risk assessment should include those on-site chemicals that comply with neither the Statewide Health standard nor the Background standard. The chemicals of concern may be further screened or re-included using the same RBC screening procedures mentioned above.

Chemical concentrations should also be compared to blank concentrations. If the blank samples contain detectable levels of common laboratory contaminants, then the sample results should be considered as positive results only if the concentrations in the sample exceed ten times the maximum amount detected in the sample. If the concentration is less than ten times the blank contaminant level, it is concluded that the chemical was not detected in the sample and consider the blank-related chemical concentration to be the quantitation limit for the chemical in that sample. If all samples contain levels of a common laboratory contaminant that are less than ten times the level of contamination noted in the blank, then completely eliminate that chemical from the set of sample results. Common laboratory contaminants include acetone, 2-butanone (methyl ethyl ketone), methylene chloride, toluene, and phthalate esters.

If the blank samples contain constituents other than common laboratory contaminants, then the sample results should be considered as positive results only if the concentrations in the sample exceed five times the maximum amount detected in a any blank. As with the common laboratory contaminants, if the concentration is less than five times the blank constituent level, it is concluded that the constituent was not detected in the sample and consider the blank-related chemical concentration to be the quantitation limit for the chemical in that sample. Again, if all samples contain levels of a constituent other than common laboratory contaminant that are less than five times the level of contamination noted in the blank, then completely eliminate that chemical from the set of sample results.

Three other factors should be considered when deciding to retain constituents for the risk assessment. Specifically, these factors include the constituent's toxicity, mobility and persistence. Toxicity is obviously a driving force when determining if exposure to a site poses any adverse impact to human health or the environment. Some constituents may be frequently detected at a site, but may be considered relatively innocuous or toxicologically inert. These constituents should not be retained for the risk assessment. In contrast, some constituents may be infrequently detected, but may be relatively more toxic than most constituents. Regardless of the constituent's frequency of detection, its presence (assuming it is not anomalous) may deem it necessary to be retained as a constituent of concern.

The mobility of a constituent dictates what receptors on and off site may be potentially affected and consequently whether the constituent should be retained in the assessment. Physical and chemical properties of a compound control its transport and fate in the environment. For example, these attributes determine whether a constituent will readily volatilize into the air or be transported via advection or diffusion through the soil, groundwater and surface water. These characteristics also describe a chemical s tendency to absorb onto soil / sediment particles, in turn reducing its mobility through the environment.

Finally, the persistence of a chemical in the environment determines whether further receptors would be impacted. The persistence of a chemical in the environment depends on factors such as microbial content of soil and water and the ability of these organisms to degrade the chemical. In addition, chemical and photochemical degradation may contribute to the elimination of a particular compound. Although the parent compound may be eliminated, the byproducts of the degradation of that compound must also be considered and evaluated. These chemical-specific factors will also be used to determine whether a constituent and its byproducts are retained for the risk assessment.

To document attainment in order to obtain liability protection under Act 2, frequency of detection should not be used as a means for determining whether a constituent is retained for the risk assessment. However, infrequently detected constituents that are anomalies due to sampling, analytical or other problems would not be retained in the risk assessment.

In general, the liability protection is not afforded under the site-specific standard for those chemicals that are not identified as contamination at a site and for which attainment has not been demonstrated.

ii) Site Conceptual Model

Development of a site conceptual model is an important step in identifying additional data needs in site characterization and in defining exposure. A site conceptual model identifies all potential or suspected sources of contamination, types and concentrations of contaminants detected a the site, potentially contaminated media, potential exposure pathways and receptors. Many components of exposure (such as the source, receptors, migration pathways and routes of exposure) are determined on a site-specific basis. The site conceptual model provides a systematic way to identify and summarize this information to ensure that potential exposures at the site are accounted for accurately.

The conceptual model may be graphical, tabular or narrative but should provide an accurate understanding of complete exposure pathways for the site. Examples of site conceptual models may be found in EPA or ASTM guidance documents, including Section 4.2 of RAGS Part A (USEPA, 1989a) and the ASTM RBCA Tier 2 guidance manual (ASTM, 1995). It is suggested that the development of the site conceptual model be coordinated with the regulatory risk manager to ensure that potential pathways are adequately and appropriately addressed prior to performing the assessment.

b) Exposure Assessment [Sections 250.603 and 250.604 of the Regulations]

The exposure assessment determines or estimates (qualitatively or quantitatively) the magnitude, frequency, duration and routes of exposure. The assessment is typically performed in three steps:

(1) Characterization of the exposure setting including:

- the physical setting
- potential exposed populations

(2) Identification of complete exposure pathways which includes:

- sources and receiving media
- fate and transport in the release media
- exposure points and exposure routes

The information on sources, fate and transport (including biodegradation), exposure points and exposure routes are then integrated to determine the potential exposure pathways. Complete pathways exist when all components are present. Information for complete pathways should be summarized.

(3) Quantification of exposure of the receptor including:

- environmental concentration
- intake

The exposure assessment process is well defined in various EPA guidance documents (including primarily USEPA 1989a, 1991a,b and 1992b but see also the attached list of select references) and is not reiterated here. This section discusses some key issues pertaining to performing the site-specific exposure assessments.

i) Exposure Scenarios and Exposure Pathways

Exposure Pathways: The exposure pathway describes the mechanism by which receptors (individuals or populations) may be exposed to the source. Pathways consist of a source, receptor, route of exposure and a transport mechanism, if the exposure point is not the same as the source. The analysis of the fate and transport of the chemical can help to predict future exposures, to link sources with currently contaminated media and to identify exposure pathways. The intent of the fate and transport analysis at this stage is to identify media that are receiving or may receive site-related chemicals. The USEPA provides guidance (*e.g.*, USEPA, 1989a) on fate and transport analysis.

As discussed above, the site conceptual model is useful in defining potential exposure pathways. However, only complete pathways should be advanced through the assessment process. The effects of engineering or institutional controls that are to be implemented, which will eliminate exposure pathways, must be considered for the conceptual model development. The USEPA provides guidance (*e.g.*, USEPA, 1989a, 1991a,b, 1996a) on potential pathways for given land use scenarios.

Realistic current and future land use scenarios (*e.g.*, residential, industrial, agricultural, etc.) provide the basis for selecting the controlling exposure scenarios / pathways. Guidance on land use considerations can be found in the USEPA OSWER Directive: *Land Use in The CERCLA Remedy Selection Process* (1995) as well as earlier EPA guidance on exposure assessments as referenced above. Sources and types of information that may aid in determining the reasonably anticipated future land use include, but are not limited to:

- Current land use
- Zoning laws
- Zoning maps
- Comprehensive community master plans
- Local land use authorities
- Local officials
- Population growth patterns and Bureau of Census projections
- Accessibility of site to existing infrastructure (such as transportation and public utilities)
- Institutional controls currently in place
- Site location in relation to urban, residential, commercial, industrial, agricultural and recreational areas
- Federal / State land use designation (such as state parks)
- Historical or recent development patterns
- Cultural factors (such as historical sites)
- Natural resources information
- Stakeholder input - allows for all affected parties to define land use

- Location of on-site or nearby wetlands
- Proximity of site to a floodplain
- Proximity of site to critical habitats of endangered or threatened species
- Geographic and geologic information
- Location of Wellhead Protection areas, recharge areas, and other areas identified in the State's Comprehensive Ground-water Protection Program.

These types of information should be considered when developing the assumptions about future land use.

Some direct pathways, such as direct ingestion of soil or groundwater and direct inhalation of volatiles and/or particulates from soil, are fairly well-established and can be used routinely where they have been identified as complete pathways. At issue would be defining appropriate exposure factors (such as intake rate for the given population) since these factors exhibit a range of possible values. Typically, the choice of factors (high-end exposure vs. average exposure) is defined by the level of conservatism desired.

Dermal contact (with soil or groundwater), on the other hand, is less well-defined particularly in terms of estimating intake (the mass of substance in contact with the body per unit body weight per unit time) and more importantly absorbed dose (intake multiplied by an absorption factor to account for mass actually in the body). This pathway is best addressed at a site-specific level when identified as relevant. Although there is some guidance (USEPA, 1991c) professional judgment may play a significant role in estimating dermal exposure. The rationale behind these judgments (and indeed professional judgments wherever they are used) and, as far as possible, documented evidence in support of these judgments should be clearly provided.

Some indirect pathways (*e.g.*, inhalation of vapors via intrusion into enclosed spaces), are also best addressed on a site-specific basis because of the inherent uncertainty associated with the defining the transport from the source to the receptor. In the case of vapor intrusion into enclosed spaces, for example, actual data from direct measurements, *i.e.*, a monitoring approach, would be preferred to the use of models which have been shown to be imprecise (USEPA, 1996a; PA RA Subcommittee, 1996). Other indirect pathways (*e.g.*, soil leaching to groundwater and subsequent ingestion of groundwater) can be addressed by simple analytical models. Although site-specific data inputs to these models are typically favored as producing a more realistic estimate of exposure, site-specific data may not also be accessible. The use of a combination of default and site-specific parameters may be used provided the rationale for the choice of values is included.

Receptors and Human Exposure Factors: Receptors should be defined on a site-specific basis taking into account future land use considerations. Guidance on potential receptors for given land use are provided in EPA guidances (USEPA 1989a, 1991a,b). Care should be taken to identify potential sensitive subpopulations (*e.g.*, children) as appropriate for site-specific conditions.

Section 250.603 of the regulations specifies requirements to select exposure factors. A risk assessment may use site-specific exposure factors in accordance with U.S. EPA's Final Guidelines for Exposure Assessment, 1992 (57 FR 22888-22938) or exposure factors used in the development of the Statewide health standards identified in Subchapter C of the regulations. Site-specific exposure factors shall be clearly justified by supporting data.

Human exposure factors may be divided into receptor physiologic parameters (*e.g.*, body weight, skin surface area); contact rate (*e.g.*, consumption of water, soil ingestion rate); and time activity patterns (*e.g.*, time spent indoors/outdoors, time spent at work). Some of these variables, particularly the physiologic parameters, have been well-characterized but others such as time-activity patterns are less well documented. All parameters are subject to variability (true heterogeneity) and/or uncertainty (ignorance about a measurement). Thus, a range of values may be available for any given parameter. The choice will depend to some extent on the problem and the level of conservatism desired. Typical sources for these parameters are the USEPA Exposure Factors Handbook (1996d) which is in the process of being updated and the American Industrial Health Council (AIHC) Exposure Factors Sourcebook (AIHC, 1994) also being updated.

Fate and Transport Parameters and Models: Constituents of concern can both migrate (via leaching, advection, dispersion) and transform (via biodegradation, hydrolysis, photolysis) in the environment. These migration and transform processes must be considered when determining environmental concentration under indirect exposure. A range of fate and transport models (from simple analytical to complex numerical) are available to account for these processes. However, the level of site-specific data needed to make proper use of the models also increases with the level of sophistication of the model (*i.e.*, the increase of model technical capabilities). A tiered approach, based on level of model complexity, is best, *i.e.*, using the least resource intensive method to achieve the objective of the evaluation. The selected model must adequately represent the physical setting (*e.g.*, the geometric configuration of hydrogeological systems, soil profiles, river widths and depths, etc.) and migration and transformation processes that affect the problem. Input parameter values should be representative of field conditions. The choice of model and input parameters will need to be justified as appropriate for given site-specific conditions. Justifications should include why a model is appropriate when limitations of the selected model are considered. In addition, some measure of model validation will be required. This may be as simple as corroborating the conservative assumptions to field measurements.

For the application of a groundwater model, the following quality assurance and quality control procedures as described in Chapter 6 (relating to Models and Computers in Ground-Water Investigation) of U.S. EPA's Ground Water Handbook (USEPA, 1991d) should be considered:

- Verification of the mathematical basis of a model by comparing its output with known analytical solutions to specific problems.

- Validation of the applicability of a model to various problem categories by successful simulation of observed field data.

    i) Calibrating the model using one set of historical records: the aquifer coefficients and other model parameters are adjusted to achieve the best match between model outputs and known data.

    ii) Attempting to predict a subsequent set of historical records: No adjustments are made except for actual changes. A mismatch means that the model either is not correctly formulated or does not treat all of the important phenomena affecting the actual field situation.

- Benchmarking the efficiency of a model in solving problems by comparison with the performance of other models.

- Critical review of the problem conceptualization to ensure that the modeling effort considers all physical, chemical, and biological processes that may affect the problem.

- Evaluation of the specifics of the model's application, *e.g.*, appropriateness of the boundary conditions, grid design, time steps, etc. Calibration and sensitivity analysis to determine if the model outputs vary greatly with changes in input parameters are important aspects of this process.

For selection of groundwater models, some important technical capabilities for groundwater models are identified in Table 2. Additional guidance on the selection and use of fate and transport models can be found in the USEPA and ASTM documents listed in Table 3 of this document.

The use of monitoring methods may also be appropriate for defining environmental fate as in the case of natural attenuation. All supporting data should be provided to support such an evaluation. The ASTM is in the process of developing a guide for addressing natural attenuation.

<u>Generic vs. Site-Specific Considerations:</u>

In general, risk assessments should be based upon realistic exposure scenarios using current or planned future land use, incorporating any changes from early response

actions known or planned. Site-specific information on exposure pathways, receptors and exposure factors, including actual data, should be used to the maximum extent possible.

However, not all exposure parameters need to be site-specific. Certain generic human physical parameters (*e.g.*, body weight and air intake) that do not vary significantly in the general human population and, thus, from site to site are such exceptions. Default values, from single point estimates to distributions for these parameters, are available from such sources as the USEPA Exposure Factors Handbook (USEPA, 1989b) and the AIHC Exposure Factors Sourcebook (AIHC, 1994). Both of these data sources are in the process of being updated. A draft update (USEPA, 1996d) of the USEPA Exposure Factors Handbook, 1989 version (USEPA, 1989b) is undergoing final revisions. Default values of single point estimates for these parameters are also available from Subchapter C of the regulations.

Factors affecting the choice of exposure scenario (land use), complete exposure pathways, the distribution of contaminants in the media, the characteristics of the media, and the activity patterns and demographics of the surrounding populations should be considered, whenever possible, as site-specific. For example, if the planned future land use is industrial, the appropriate population would be adults and default physiological information may be obtained from the above named sources. However, if the concern is for a residential land use, children may be the population of concern. Default physiological information is still available from the above sources but the actual values would be different because the site-specific considerations dictate a different land use and receptor population.

It is possible that for a given situation, a sensitive subpopulation may be of concern (*e.g.*, pregnant women, subsistence fishermen). Some data for these populations may be available from national, regional surveys incorporated in the above sources but in some instances the data may need to be generated. The choice of data must be supported in the peer review literature and proved to be appropriately applied. For information generated on a site-specific basis, proper QA / QC measures should be exercised and the data should be generated with the understanding of the regulatory agency as to how the information will be used.

ii) Exposure Characterization

Exposure characterization is the quantification step in the process. In the forward calculation of risk, both the environmental concentration and the intake must be determined. In the reverse calculation of site-specific standards, an acceptable concentration is derived based on intake and a predetermined level of risk.

Environmental Concentration: This is the concentration expected to be contacted over the exposure period. Since typically, risk assessments are performed for a chronic

exposure scenario, *i.e.*, the contact period is long (typically 30 - 70 years), an average concentration (or an upper confidence limit on the arithmetic average) is used. It is important, therefore, to assess the potential fate of the material in the environment to provide the best estimate of this environmental concentration over time. In some instances, short-term exposure is to be evaluated, in which case some other metric (*e.g.*, maximum) concentration may be more appropriate. USEPA OSWER Directive 9285.7-081 provides guidance on the concentration term.

Intake: Three types of variables are associated with defining intake: chemical related variables, *i.e.*, the concentration term and its associated fate and transport parameters; variables that describe the exposed population such as physiologic parameters, contact rate and time / activity patterns; and an assessment-determined variable, *i.e.*, the period over which the exposure is averaged.

Since most exposure factors exhibit both variability and uncertainty, recent EPA guidance encourages the development of a range of exposure (and risk) descriptors (Habicht memo, USEPA, 1992a; Browner, USEPA, 1995b; Science Policy Council, USEPA, 1995d). The use of probabilistic analysis (such as Monte Carlo simulations) is one way to account for variability and uncertainty. However, these evaluations are resource intensive and so may be inappropriate for simple sites. Deterministic evaluation, *i.e.*, point estimates, are a useful alternative. If single point estimates are developed, however, it is recommended that a most likely exposure (MLE) be quantified in addition to the typical high-end exposure (comparable to the reasonable maximum exposure or RME used in the generation of the Statewide health standards). In this way, a range of exposures can thus be provided as context for risk management decisions. Thus, even within the site-specific evaluation, a tiered approach may be useful (*i.e.*, from point estimates to ranges) depending on the level of sophistication required to address the problem at hand.

iii) Good Exposure Assessment Practices

As a fundamental practice, the methods and data used in the exposure assessment should clearly support the conclusions within the known and stated bounds of uncertainty. Documentation is a core principle of a good exposure assessment. Hawkins, Jayjock and Lynch (1992) provided eight general practices that make for good exposure assessments. Burmaster and Anderson (1994) further defined “good practice” as it relates to probabilistic assessments. It is suggested that exposure assessments be consistent with these practices as appropriate.

c) Toxicity Assessment [Section 250.605 of the Regulations]

The purpose of toxicity assessment is to collect and weigh the available evidence regarding the potential for particular contaminants to cause adverse effects in exposed individuals and to provide an estimate of the relationship between the extent of

exposure to a contaminant and the increase likelihood and / or severity of adverse effects.

The carcinogenic and noncarcinogenic (systemic) effects of each chemical of concern at the site should be evaluated.

For toxicity assessment, the person should use appropriate reference doses and cancer slope factors from one of the following sources, in the order indicated:

a) Integrated Risk Information System (IRIS);

b) Health Effects Assessment Summary Tables (HEAST);

c) United States Environmental Protection Agency, National Center for Environmental Assessment (NCEA) provisional values;

d) Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles;

e) California EPA, California Cancer Potency Factors; and

f) United States Environmental Protection Agency criteria documents, including drinking water criteria documents, drinking water health advisory summaries, ambient water quality criteria documents, and air quality criteria documents.

If no toxicity values are available from sources identified above, the person may develop, for the Department's review in the risk assessment report, toxicity values from appropriately justified surrogates or chemical-specific toxicity values with consideration of the following:

a) Available data should first be evaluated to determine the likelihood that the agent is a carcinogen. If the chemical is determined that it is likely or possibly a human carcinogen then a toxicity value (slope factor) should be calculated based on most recent and available information from peer reviewed journals. EPA has developed its most recent approach for defining carcinogens and developing slope factors in the Proposed Guidelines for Carcinogen Risk Assessment (USEPA, 1996b). This approach should be applied when determining whether a chemical is a carcinogen and determining its slope factors.

b) A toxicity factor should also be developed for the potential noncarcinogenic effects based on most recent and available information from peer reviewed journals. A reference dose is the toxicity value used most often in evaluating noncarcinogenic effects. EPA's Risk Assessment Guidance for Superfund describes the protocol for developing reference doses. Depending on the

exposure duration anticipated at the site, a chronic reference dose would be developed for exposure expected to last 7 to 70 years, a subchronic reference dose would be calculated for exposure less than 7 years (USEPA, 1989a).

c) The toxicity value must be based on peer reviewed literature that includes all relevant sources of data and must be a balanced description of both positive and negative findings on the toxicity of the chemical, the weight of evidence supporting the toxicity value, and the main sources of uncertainty of the toxicity value documented in the risk assessment report's uncertainty section.

The toxicity of lead is not easily defined by the above approach. EPA has developed the Integrated Exposure Uptake Biokinetic (IEUBK) Model to determine cleanup numbers for children exposed to lead in soil under a residential exposure scenario. For adult exposure in either the residential or nonresidential scenario, the IEUBK model does not apply and other models, such as the Bower model(Bowers et al., 1994), or the physiologically-based pharmacokinetic model (O'Flaherty 1995; 1997) developed to determine the effects of lead on adults, may be used to determine site-specific cleanup numbers.

d) Risk Characterization

The risk characterization section summarizes the toxicity and exposure assessments into either a quantitative estimate of risk or the development of cleanup concentrations for each of chemicals of concern at the site. The objectives of the risk assessment that were described in the introduction paragraphs of this document should again be defined and a description of how the results of the report meet those objectives should be provided. The report should exemplify the values of clarity, transparency, reasonableness and consistency as stated in the Policy for Risk Characterization at the U.S. Environmental Protection Agency (USEPA, 1995b).

The conceptual model for the site should be described and for each completed pathway, the total cancer risk and non cancer hazard quotient should be defined or a cleanup concentration for that pathway. In developing cleanup numbers for the site, cumulative excess risk to exposed populations, including sensitive subgroups, shall not be greater than 1 in 10,000 for known or suspected carcinogens. The risks associated with carcinogens should be cumulative if the same individuals exposed to these carcinogens consistently. For noncarcinogens (systemic toxicants) cleanup standards shall represent the level to which human exposed population could be exposed on a daily basis without appreciable risk of deleterious effect. Where several systemic toxicants affect the same target organ or act by the same method of toxicity, the hazard index shall not exceed one. The risks associated with systemic toxicants also should be cumulative in the toxicity assessment if these toxicants affect the same target organ or act by the same method of toxicity.

To evaluate the short-term and long-term effectiveness of a selected remedy, the potential risk associated with implementation of the remedy and the risk associated with exposure to the remediated media must be evaluated. The algorithms that were defined in the exposure assessment should be used to characterize these potential risks.

The risk characterization associated with short-term effectiveness considers the exposure of workers at the site and the exposure of receptors in the vicinity surrounding the site to migrating media during the implementation of the selected remedy. A comparison of a focused list of remedial alternatives may help predict the risks associated with the implementation of the selected remedy or whether the implementation of alternatives may have any significant impact to human health and the environment.

The risk characterization associated with long-term effectiveness demonstrates whether the selected remedy attains the remedial objectives (site-specific cleanup standards) and whether post-remedial risks achieve the acceptable levels of risk. There may be times when a specific cleanup level for one constituent may not be attained, but the overall post-remedial risk may be within acceptable levels. Evaluation of the post-remedial risk is based on a prediction of what the post-remedial exposure concentrations would be. For example, a cap would eliminate exposure to surface soils, thus, rendering the risk to surface soils to be negligible. If bioremediation is considered, the remedial objective would be the concentration that provides the basis for characterization of the post-remedial risk. If the calculated post-remedial risk is within the acceptable range, the selected remedy would be considered a viable solution.

e) Uncertainty Analysis

An often forgotten component of the risk assessment process is the characterization of uncertainty. Uncertainty represents ignorance (or lack of perfect knowledge) about poorly-characterized phenomena or models (Burmaster and Anderson, 1994). The concept is important and indeed implicit in the risk-based approach but is often ignored in practice. For example, the Statewide health standards are acknowledged to be conservative and one of the rationales for being conservative is to account for the uncertainty inherent in developing the standards. In the site-specific evaluation, it is recommended that a tiered approach to addressing uncertainty be used. In applying the tiered approach, the level of effort should be commensurate with the magnitude of the decision to be made.

At an initial level, point estimates of exposure and risk (or site-specific standards) may be developed that describe both the high-end individual (RME) and a mid-range individual (MLE). If the level of risk is below the level of regulatory concern, the analysis need go no further. A qualitative evaluation of the uncertainty should be

included at a minimum indicating what the most uncertain and most sensitive parameters are and their likely impact on the results. It is important to put in perspective uncertainties inherent in the toxicity assessment as well as the exposure assessment.

At some middle level of effort, statistical estimates (experimental estimates, population variability, estimation error) should be listed and the impact of these on the results discussed. A more formal sensitivity analysis may be performed to rank the input parameters on the basis of their contribution to the uncertainty.

At the highest levels, methods to quantitatively address variability and uncertainty (including but not limited to probabilistic analysis) should be used to carefully determine the overall precision of the risk estimates as they relate to scenarios, models and inputs.

Probabilistic Analysis: Typically, risk assessments have used a deterministic (single point) approach to estimating risk. However, risk is defined as a probability of injury or damage. Further, exposure-related variables are generally recognized as having a range of possible values. Thus, probabilistic analysis is a useful tool for estimating risk since it can account for both variability and uncertainty.

However, probabilistic analysis is resource intensive and is maybe, inappropriate for simple evaluations. Although the use of probabilistic analysis for risk assessments associated with site remediation has advanced significantly in the last five years, there are still data gaps which also limit its utility on a routine basis. Recent advances include methods for backcalculating soil cleanup levels (Burmaster et al., 1995 and Burmaster and Thompson, 1995); EPA's guiding principles for Monte Carlo analysis (USEPA, 1997) as a result of an EPA sponsored workshop on the issue in May 1996 (USEPA, 1996c). Both Regions III and VIII have also recently provided guidance (USEPA, 1994, 1995c).

It is suggested that probabilistic analysis be used as part of a tiered approach to risk assessment in the site remediation process.

If an uncertainty analysis includes Monte Carlo simulations, the person should consider the following guidelines as described in EPA's guiding principles for Monte Carlo analysis (USEPA, 1997) to ensure high quality science:

- The purpose and scope of the assessment should be clearly articulated in a "problem formulation" section that includes a full discussion of any highly exposed or highly susceptible subpopulations evaluated (*e.g.*, children, the elderly, etc.). The questions the assessment attempts to answer are to be discussed and the assessment endpoints are to be well defined.

- The methods used for the analysis (including all models used, all data upon which the assessment is based, and all assumptions that have a significant impact upon the results) are to be documented and easily located in the report. This documentation is to include a discussion of the degree to which the data used are representative of the population under study. Also, this documentation is to include the names of the models and software used to generate the analysis. Sufficient information is to be provided to allow the results of the analysis to be independently reproduced.

- The results of sensitivity analyses are to be presented and discussed in the report. Probabilistic techniques should be applied to the compounds, pathways, and factors of importance to the assessment, as determined by sensitivity analyses or other basic requirements of the assessment.

- The presence or absence of moderate to strong correlations or dependencies between the input variables is to be discussed and accounted for in the analysis, along with the effects these have on the output distribution.

- Information for each input and output distribution is to be provided in the report. This includes tabular and graphical representations of the distributions (*e.g.*, probability density function and cumulative distribution function plots) that indicate the location of any point estimates of interest (*e.g.*, mean, median, 95 percentile). The selection of distributions is to be explained and justified. For both the input and output distributions, variability and uncertainty are to be differentiated where possible.

- The numerical stability of the central tendency and the higher end (*i.e.*, tail) of the output distributions are to be presented and discussed.

- Calculations of exposures and risks using deterministic (*e.g.*, point estimate) methods are to be reported if possible. Providing these values will allow comparisons between the probabilistic analysis and past or screening level risk assessments. Further, deterministic estimates may be used to answer scenario specific questions and to facilitate risk communication. When comparisons are made, it is important to explain the similarities and differences in the underlying data, assumptions, and models.

- Since fixed exposure assumptions (*e.g.*, exposure duration, body weight) are sometimes embedded in the toxicity metrics (*e.g.*, Reference Doses, Reference Concentrations, unit cancer risk factors), the exposure estimates from the probabilistic output distribution are to be aligned with the toxicity metric.

f) References for Human Health Risk Assessment

American Industrial Health Council, 1994 Exposure Factors Sourcebook,.

American Society for Testing and Materials, Standard Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites, E-1739, Philadelphia, PA, Tier 2 Guidance Manual.

Bowers, T., B. D. Beck, H.S. Karam, 1994. Assessing the Relations Between Environmental Lead Concentrations and Adult Blood Lead Levels, Risk Analysis, Volume 14 p.183-189.

Burmaster, D. E., and P.D. Anderson, 1994. Principles of Good Practice for the Use of Monte Carlo Techniques in Human Health and Ecological Risk Assessments, Risk Analysis, Volume 14, Number 4, pp. 477 - 481.

Burmaster, D. E., K.J. Lloyd and K.M. Thompson, 1995. The Need for New Methods to Backcalculate Soil cleanup Targets in Interval and Probabilistic Cancer Risk Assessments. Human and Ecological Risk Assessment, Vol 1, No 1, pp. 89 - 100.

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O'Flaherty, E.,1995. Physiologically-based models for bone-seeking elements. V: Lead absorption and disposition in childhood. Toxicol. Appl. Pharmacol. 131:297-308.

O'Flaherty, E., 1997. PBKM Model Manual. Physiologically-based Model of Human Lead Kinetics. University of Cincinnati, Cincinnati, Ohio.

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US EPA, 1989a. Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual (Part A). Interim Final, Office of Emergency and Remedial Response, Washington, DC. EPA / 540 / 1-89 / 002.

US EPA, 1989b. Exposure Factors Handbook. Exposure Assessment Group, Office of Health and Environmental Assessment. EPA / 600 / 8-89 / 043.

US EPA, 1991a. Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals). Interim. EPA/540/R-92/003.

US EPA, 1991b. Human Health Evaluation manual, Supplemental Guidance: Standard Default Exposure Factors. Office of Solid Waste and Emergency Response Directive 9285.6-03, March 25.

US EPA, 1991c. Dermal Exposure Assessment: Principles and Applications (Interim Report). Office of Research and Development. EPA/600/8-91/011B. NTIS PB92205665.

US EPA, 1991d. Handbook, Ground Water, Volume II: Methodology, EPA/625/6-90/016b.

US EPA, 1992a. Guidance on risk characterization for risk managers, and risk assessors. Washington, D.C.: USEPA Memorandum from F. Henry Habicht II, Deputy Administrator, Feb 26, p. 6 with p. 34 attachment entitled Guidance for Risk Assessment.

US EPA, 1992b. Guidelines for exposure assessment; Notice. Fed Reg., Washington, D.C., May 29. p. 22888-22938.

US EPA, 1992c. Supplemental guidance to RAGS: Calculating the concentration term. Washington, D.C.: Office of Solid Waste and Emergency Response. Publication 9285.7-081. May.

USEPA, 1994. Use of Monte Carlo Simulations in Risk Assessments, EPA 903-F-94-001, Region III, Philadelphia, PA, February.

US EPA, 1995a. Land Use in the CERCLA Remedy Selection Process. OSWER Directive 9355.7-04. March.

USEPA, 1995b. Policy for Risk Characterization at the US Environmental Protection Agency. Carol Browner, March. (Available at Internet: http://www.epa.gov/ORD/spc/rcpolicy.htm)

USEPA, 1995c. The Use of Monte Carlo Simulation in Risk Assessment. Region VIII Superfund Technical Guidance, RA-10, Denver, CO, September.

USEPA, 1995d. Guidance for Risk Characterization. Science Policy Council, February. (Available at Internet: http://www.epa.gov/ORD/spc/rcguide.htm)

USEPA, 1996a. Technical Background Document for Soil Screening Guidance. 9355.4-17A, EPA/540/R-95/041.

USEPA, 1996b. Proposed Guidelines for Carcinogen Risk Assessment, EPA/600/P-92/003C, April.

USEPA, 1996c. Summary Report for the Workshop on Monte Carlo Analysis. EPA/630/R-96/010. September.

USEPA, 1996d. Draft Exposure Factors Handbook (3 volumes: Volume I - General Factors - EPA/600/P-95/002Ba; Volume II - Food Ingestion Factors - EPA/600-P-95/002Bb; Volume III - Activity Factors - EPA/600/P-95-002Bc). National Center for Environmental Assessment, August. (Available at internet: http://www.epa.gov/ncea/exposfac.htm)

USEPA, 1997. Guiding Principles for Monte Carlo Analysis, EPA/630/R-97/001, March.

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TABLE 1. Risk Assessment Guidelines for Human Health Evaluation

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1. Interim Final Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Part A, Baseline Risk Assessment (RAGS Volume 1 Part A). EPA / 540 / 1-89 / 002.

2. Interim Final Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Part B, Development of Risk-based Preliminary Remediation Goals (RAGS Volume 1 Part B), OSWER 9285.7-01B, U.S. EPA, Office of Solid Waste and Emergency Response, December 1991.

3. Interim Final Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Part C, Risk Evaluation of Remedial Alternatives (RAGS Volume 1 Part C). EPA / 540 / R-92 / 004.

4. Interim Final Human Health Evaluation Manual, Supplemental Guidance, `Standard Default Exposure Factors', OSWER Directive 9285.6-03.

5. Interim Final Guidance for Soil Ingestion Rates. OSWER Directive 9850.4.

6. Exposure Factors Handbook. EPA / 600 / 8-89 / 043. (This document is in a process of being updated.)

7. Interim Final Guidance for Data Usability in Risk Assessment. EPA / 540 / G-90 / 008.

8. Superfund Exposure Assessment Manual. EPA / 540 / 1-88 / 001, OSWER Directive 9285.5-1.

9. US EPA Region III Technical Guidance Manual, Risk Assessment, Chemical Concentration Data Near the Detection Limit. EPA / 903 / 8-91 / 001.

10. US EPA Region III Technical Guidance Manual, Risk Assessment, Exposure Point Concentrations in Groundwater. EPA / 903 / 8-91 / 002.

11. US EPA Region III Technical Guidance Manual, Risk Assessment, Selecting Exposure Routes and Contaminants of Concern by Risk-Based Screening. EPA / 903 / R-93-001.

12. US EPA Region III Technical Guidance Manual, Risk Assessment, Assessing Dermal Exposure from Soil. EPA / 903-K-95-003.

13. Guiding Principles for Monte Carlo Analysis. EPA/630/R-97/001.

14. Dermal Exposure Assessment: Principles and Applications (Interim Report). US EPA Office of Research and Development. EPA/600/8-91/011B. NTIS PB92205665.

15. Guidelines for exposure assessment; 57 Fed Reg., May 29, 1992, p. 22888-22938.

16. Guidelines for Developmental Toxicity Risk Assessment; 56 Fed Reg., December 5, 1991, p. 63798-63826.

17. Guidelines for Reproductive Toxicity Risk Assessment; 61 Fed Reg., October 31, 1996, p. 56274-56322.

18. Guidelines for the Health Risk Assessment of Chemical Mixtures; 52 Fed Reg., September 24, 1986, p. 34014-34025.

19. Proposed Guidelines for Neurotoxicity Risk Assessment; 60 Fed Reg., October 4, 1995, p. 52032-52056.

20. Guidelines for Mutagenicity Risk Assessment; 51 Fed Reg., September 24, 1986, p. 34006-34012.

21. Proposed Guidelines for Carcinogen Risk Assessment; 61 Fed Reg., April 23, 1996, p. 17960-18011.

22. Guidance for Risk Characterization; USEPA Science Policy Council, February 1995. (Available at Internet: http://www.epa.gov/ORD/spc/rcguide.htm).

23. ASTM E 1739, Standard Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites.

24. ASTM E 1689, Standard Guide for Developing Conceptual Site Models for Contaminated Sites.

25. ASTM E 978, Standard Practice for Evaluating Mathematical Models for the Environmental Fate of Chemicals.

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TABLE 2. Technical Capability Criteria for Groundwater Models

- Ability to estimate a mixing zone in the upmost aquifer under a site and model the contaminants in this mixing zone.
- Ability to account for contaminant sorption with the aquifer solids including the ability to account for mass transfer or kinetic limitations in contaminant sorption and desorption.
- Ability to account for soil and bedrock heterogeneity.
- Ability to account for the gas phase transport.
- Ability to account for dispersive and advective transport in flowing groundwater.
- Ability to account for special rules described in Act 2, such as 15' direct contact depth.
- Ability to be implemented on a PC hardware/software platform.
- Ease of use/availability of program/level of documentation.
- Ability to account for volatilization.
- Ability to simulate varying recharge conditions (infiltration rates) and varying background groundwater flows.
- Ability to handle degradation.

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TABLE 3. Guidances and Resources of Fate and Transport Models and Methodologies

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A person planning to use fate and transport models and methods to estimate exposure concentrations and to develop site-specific standards should give consideration to the following models, methods, and guidances.

Equations for Soil-to-Air Volatilization Factor and Particulate Emission Factor:

These can be found in U.S. EPA's "Soil Screening Guidance: User's Guide, Second Edition" Publication 9355.4-23, July 1996, Office of Solid Waste and Emergency Response, Washington, DC 20460.

Groundwater Models:

Various groundwater models have been identified in the following documents:

1. U.S. EPA 1988 Superfund Exposure Assessment Manual, EPA/540/1-88/001, OSWER Directive 9285.5-1, Section 3.5.

2. U.S. EPA, 1988 Selection Criteria for Mathematical Models Used in Exposure Assessments: Ground-Water Models, 600/8-88/075.

3. U.S. EPA, 1989 Groundwater Modeling: An Overview and Status Report, EPA/600/2-89/028 (NTIS PB89-229497). (Also available from International Ground Water Modeling Center, Institute for Ground-Water Research and Education, Colorado School of Mines, Golden, Colorado 80401.)

4. National Academy of Sciences 1990. (NAS) Ground Water Models: Scientific and Regulatory Applications. National Academy Press, Washington, DC.

5. U.S. EPA, 1994 Ground Water Modeling Compendium, Second Edition EPA-500-B-94-003. 1994. Resource Management and Information Staff, Office of Solid Waste and Emergency Response, Washington, DC 20460.

6. van der Heijde, P. M. 1994 Identification and Compilation of Unsaturated/ Vadose Zone Models. EPA/600/R-94/028. 1994. R.S. Kerr Environmental Research Laboratory, Office of Research and Development, U.S. EPA, Ada, OK.

7. U.S. EPA, 1993. Compilation of Ground-Water Models. EPA/600/R-93/118. Office of Research and Development, Washington, DC 20460.

Additional information regarding groundwater models may be obtained from the following sources:

1. U.S. EPA, Center for Exposure Assessment Modeling (CEAM), 960 College Station Road, Athens, Georgia 30605-2700; telephone (706)546-3549; Internet address: ftp://ftp.epa.gov/epa_ceam/wwwhtml/ceamhome.htm

2. U.S. EPA, Robert S. Kerr Environmental Research Laboratory, Center for Subsurface Modeling Support (CSMOS), P. O. Box 1198, Ada, Oklahoma 74820; telephone (405)436-8586; Internet address: http://www.epa.gov/ada/csmos.html

3. International Ground-Water Modeling Center (IGWMC), Institute for Ground-Water Research and Education, Colorado School of Mines, Golden, Colorado 80401. Internet address: http://www.mines.edu/igwmc/

Any person planning to select and run computer models in analyzing contaminant migration should consult the following EPA or ASTM documents for guidance:

1. U.S. EPA. 1988. Selection Criteria for Mathematical Models Used in Exposure Assessments: Ground-Water Models, 600/8-88/075 1988.

2. U.S. EPA. 1994. Ground Water Modeling Compendium, Second Edition EPA-500-B-94-003. Resource Management and Information Staff, Office of Solid Waste and Emergency Response, Washington, DC.

3. U.S. EPA. 1994. Assessment Framework for Ground Water Modeling Applications, EPA-500-B-94-004. July 1994. OSWER Directive 9029.00. Office of Solid Waste and Emergency Response, Washington, DC.

4. U.S. EPA. 1992. Quality Assurance and Quality Control in the Development and Application of Ground-Water Models, EPA/600/R-93/011. Office of Research and Development, Washington, DC 20460.

5. ASTM E 978, Standard Practice for Evaluating Mathematical Models for the Environmental Fate of Chemicals.

Surface Water Models:

Useful surface water models are identified in the following documents:

1. Section 3.4 of U.S. EPA. 1988. Superfund Exposure Assessment Manual", EPA/540/1-88/001, OSWER Directive 9285.5-1.

2. U.S. EPA. 1987. Selection Criteria for Mathematical Models Used in Exposure Assessments: Surface Water Models, Office of Health and Environmental Assessment. EPA/600/8-87/042.

3. U.S. EPA. 1985. Water Quality Assessment: A Screening Procedure for Toxic and Conventional Pollutants in Surface and Ground Water-Part I, EPA/600/6-85/002a. Environmental Research Laboratory, U.S. EPA, Athens, GA 30613.

4. U.S. EPA. 1985. Water Quality Assessment: A Screening Procedure for Toxic and Conventional Pollutants in Surface and Ground Water-Part II, EPA/600/6-85/002b. Environmental Research Laboratory, U.S. EPA, Athens, GA 30613.

In addition, the Department utilizes the following computer models to develop water quality-based effluent limitations:

1. Water Quality Analysis Model (WQM6.3)

2. Lake Tropic Analysis Program

3. Pennsylvania Single discharge Wasteload Allocation Program for Toxics and Other Substances (PENTOXSD), Release 1.0.

Additional information regarding specific surface water models may be obtained from U.S. EPA, Center for Exposure Assessment Modeling (CEAM), 960 College Station Road, Athens, Georgia 30605-2700; telephone (706)546-3549; Internet address: ftp://ftp.epa.gov/epa_ceam/wwwhtml/ceamhome.htm. Specific questions regarding the Department's computer codes should be referred to Bureau of Watershed Conservation, Department of Environmental Protection, P.O. Box 8555, Harrisburg, PA 17105-8555; telephone: (717)787-9637.

Air Models:

Useful available air models are identified in the following documents:

1. Section 3.3 of U.S. EPA's "Superfund Exposure Assessment Manual", EPA/540/1-88/001, OSWER Directive 9285.5-1. April 1988.

2. "Interim Final Air/Superfund National Technical Guidance Study Series (NTGS). Volume V: Procedures for Air Dispersion Modeling at Superfund Sites." Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, NC 27711. (Available through Internet at: http://www.epa.gov/scram001/).

3. "Guideline for Air Quality Models (Revised)" (GAQM), 40 CFR Part 51, Appendix W. (Available through Internet at: http://www.epa.gov/scram001/).

Any person planning to select and run computer models in analyzing air contaminant migration should consult the following guides:

1. "Guideline for Air Quality Models (Revised)" (GAQM), 40 CFR Part 51, Appendix W. (Available through Internet at: http://www.epa.gov/scram001/).

2. "Interim Final Air/Superfund National Technical Guidance Study Series (NTGS). Volume V: Procedures for Air Dispersion Modeling at Superfund Sites." Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, NC 27711. (Available through Internet at: http://www.epa.gov/scram001/).

The models identified in GAQM may be downloaded directly from EPA SCRAM Electronic Bulletin Board at (919)541-1447 or through Internet at http://www.epa.gov/scram001/. Additional information regarding air models may be obtained from the following sources:

1. The Support Center for Regulatory Air Models (SCRAM), U.S. EPA. (919)541-5384. Internet address: http://www.epa.gov/scram001/.

2. Air Quality Modeling Section, Bureau of Air Quality Control, Department of Environmental Protection, P. O. Box 8468, Harrisburg, PA 17105-8468; telephone: (717)787-9495.

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