Chapter 6 Problem Formulation: Inhalation Risk Assessment

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6.1 Introduction

This chapter discusses the problem formulation step, which takes the results of the planning and scoping process and translates them into two critical products:

- A **conceptual model** that explicitly identifies the sources, receptors, exposure pathways, and potential adverse human health effects that the risk assessment will evaluate (described in Section 6.2); and

- An **analysis plan** that outlines the analytical approaches that will be used in the risk assessment (described in Section 6.3).

An additional section on data quality (Section 6.4) is also included as a reference for those portions of the risk assessment that involve data collection (e.g., emissions inventories, monitoring). EPA's *Framework for Cumulative Risk Assessment*[1] provides a more detailed discussion of the problem formulation process.

6.2 Developing the Conceptual Model

The general concern and approach articulated in the problem statement usually receives more detail in a **study-specific conceptual model**. This model explicitly identifies the sources, receptors, exposure pathways, and potential adverse human health effects that the risk assessment is going to evaluate. The study-specific conceptual model comprises both a picture and written description that illustrate: the current understanding of what sources are releasing air toxics in a particular place; how the chemicals may be transported from the point of release to the point where people can breathe them; and the types of health effects that may result. Risk assessors commonly include both a pictorial illustration (such as a technical drawing) and a narrative description of each of the above elements in the conceptual model.

The conceptual model establishes the physical boundaries of the assessment area and focuses the risk assessment on several key elements, including sources, chemicals released, fate and transport mechanisms, potentially exposed populations, potential exposure pathways and routes of exposure (e.g., breathing, ingesting), and potential adverse effects. Although participants may revise or refine the conceptual model during the risk assessment, it is important to develop an initial conceptual model early on.

Critical elements to be included in the conceptual model include:

- **The sources of air toxics**. The identity, location (latitude/longitude), and physical nature of the sources being evaluated (which may include factories, small businesses, cars/trucks, forest fires, etc.), including general emissions characteristics (e.g., stack locations, heights, other stack parameters, control device efficiency, operating schedules).

- **Stressors**. The specific air toxics that will be evaluated. Information on air toxics may come from emissions inventories, previous monitoring or modeling studies, permits, or estimates based on the principal processes or activities occurring at the source or site. Many risk assessments begin with a relatively large number of stressors that are of potential concern

(**chemicals of potential concern**, or COPC) and narrow these to the subset that contributes most to exposure and risk.

- **The exposure pathways/media of concern**. The environmental compartments into which the air toxics move after they are released and through which human exposure can occur. Once released from the sources, air toxics begin to disperse by the wind away from the point of release and may remain airborne; convert into a different substance; and/or deposit out of the air onto soils, water, or plants. People may be exposed to air toxics by breathing contaminated outdoor and/or indoor air (inhalation); ingestion (for the small number of air toxics that can accumulate in soils, sediments, and foods – a process called bioaccumulation); and skin (dermal) contact with deposited air toxics. Air toxics risk assessments always evaluate the inhalation exposure pathway. However, when sources release chemicals that persist and which also may bioaccumulate, analysis of non-inhalation pathways may also be necessary (see Parts III and IV for information on inhalation pathways).

Chemicals of Potential Concern (COPC)

Chemicals of potential concern (COPC) are those air toxics that are evaluated in the risk assessment because they have the potential to affect the risk management decision. The corresponding term for ecological risk assessment are chemicals of potential ecological concern (COPEC). The risk assessment often finds that most of the risk is associated with a subset of the COPC. The subset, which drives the risk management decisions, is referred to as chemicals of concern (COC).

- **Routes of exposure**. Potential routes of exposure include inhalation, ingestion, and dermal absorption.

- **Subpopulations**. The human populations potentially receiving exposure to the air toxics, including information about demographics (race, ethnicity, economic status, etc.) and potentially sensitive subgroups (e.g., elderly, children). Depending on the goals of the risk assessment, the conceptual model may need to consider populations currently living in a given area as well as those that might move into the area in the future.

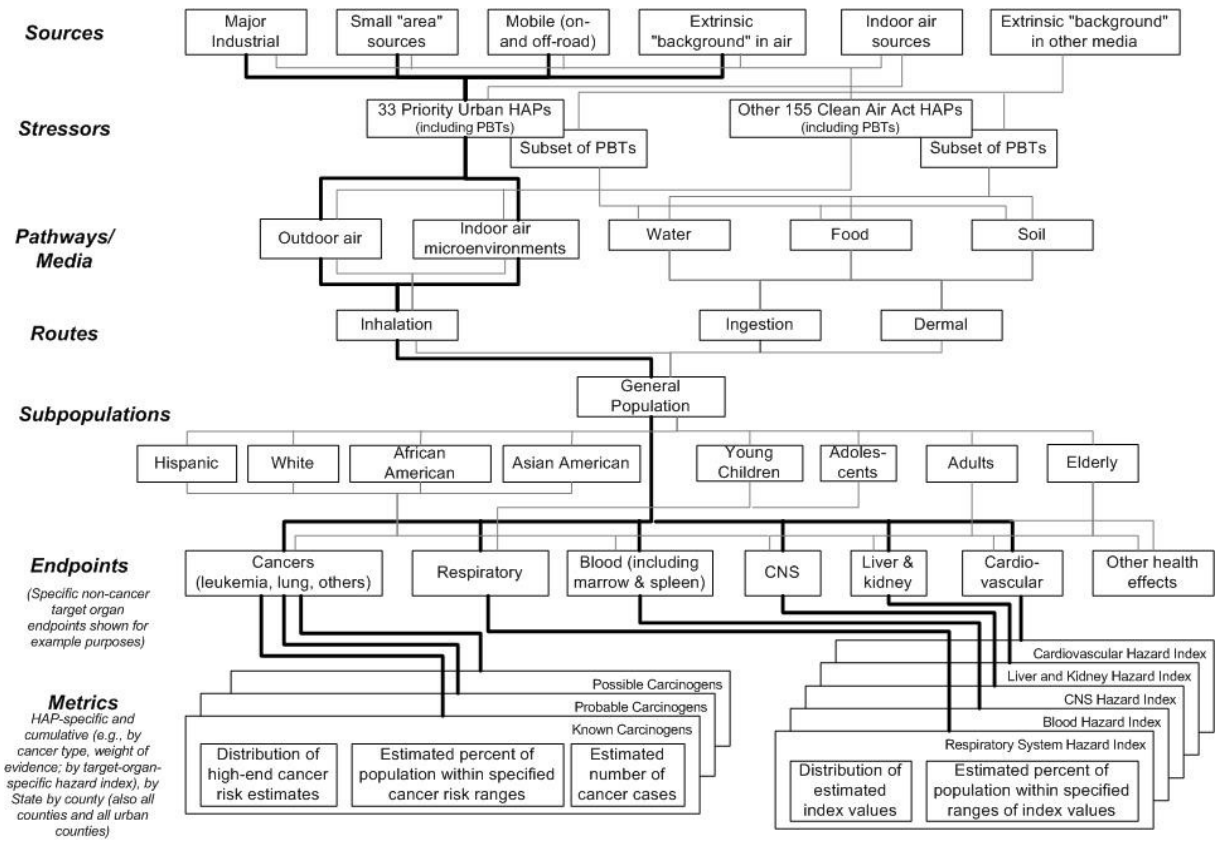
- **Endpoints**. The harmful effects that may result from exposure to air toxics, including cancer, respiratory effects, birth defects, and reproductive and neurological disorders. Air toxics can damage the organs at the initial point of contact or enter the body and move via the bloodstream to other target organs or tissues. Choice of endpoints generally depends on the toxic effects exhibited by the specific air toxics being assessed. Risk assessors generally represent potential adverse health effects to humans from exposure to air toxics through the inhalation pathway as cancer and noncancer outcomes (see Exhibit 5-3). Unless risk assessors study a specific chemical that is linked to a specific health outcome (which is not usually the case), a general statement that "risk of cancer and noncancer hazard will be evaluated" is usually sufficient.

- **Metrics**. It should be determined how cancer risk and noncancer hazard will be estimated and reported.

Exhibit 6-1 provides an example of a generalized conceptual model for air toxics risk assessments with examples of possible linkages. The example shown is a graphical illustration;

it would also be possible to develop a pictorial illustration. The conceptual model for a specific risk assessment will likely include only part of this general model. For example, pathways involving soil, water, and food will only be included if PB-HAP compounds are COPC. In the conceptual model, the sources, pathways, and expected health outcomes are drawn to illustrate what the assessors think may be happening in the study when sources are releasing air toxics to the environment. For a specific study, risk assessors would augment the illustration with the actual names/locations of sources, the COPC they release, the populations of concern and their location, and the specific health outcomes of concern (the generic endpoints of cancer and noncancer health outcomes, as drawn here, are usually sufficient for this stage of the assessment). The accompanying narrative will describe each of the elements of the illustration in detail and will provide sufficient information to clarify the critical elements of each piece of the picture.

Exhibit 6-1. Generalized Conceptual Model for Air Toxics Risk Assessments



This figure illustrates a general conceptual model for air toxics risk assessments with examples of potential linkages. The conceptual model for a specific risk assessment will likely include only part of this general model. In this figure, the heavy lines represent the conceptual model used for the initial National-scale Air Toxics Assessment (*Draft for EPA Science Advisory Board Review*, available online at http://www.epa.gov/ttn/atw/sab/sabrev.html). This assessment focused on 33 air toxics and was limited to inhalation exposures. Cancer and noncancer endpoints were assessed using distributions, estimated percentages of the population within specified risk or hazard index ranges, and estimated incidence (only for cancer cases).

If PB-HAP compounds identified in Exhibit 4-2 (or other air toxics that persist and may bioaccumulate and/or bioconcentrate) are present in emissions, both the conceptual model and the analysis plan may need to consider pathways other than inhalation (e.g., deposition to soil and surface waters, uptake by biota, and ingestion of these media and biota) for human and ecological receptors. For purposes of this Reference Manual, we discuss the elements/considerations for the conceptual model and analysis plan that are particular to multipathway human health risk assessment in Part III and ecological risk assessment in Part IV. However, the planning, scoping, and problem formulation process specific to multipathway analyses is generally integrated with the process for the inhalation analysis as early as feasible.

6.3 Developing the Analysis Plan

Risk assessors use the study-specific conceptual model as a guide to help determine what types, amount, and quality of data are needed for the study to answer the questions the risk assessment has set out to evaluate. Specifically, the analysis plan matches each element of the conceptual model with the analytical approach that the assessors will use to develop data about that element (Exhibit 6-2).

Most often, the analysis plan details the link between each element of the conceptual model and the specific analytical approach. The participants would then describe each of the analytical approaches in sufficient detail to provide the risk assessors with sufficient direction to allow them to produce the desired high quality data. For example, when determining exposure concentrations of COPC at the point of exposure to humans, the analysis plan will describe the exact sampling/analytical lab methods and/or models that risk assessors will use to generate this data, who will perform the analyses, when the analyses will be done, quality assurance/quality control requirements (including data validation procedures), roles/responsibilities of analysts, and documentation requirements. This section of the analysis plan would also provide a discussion of how data gaps should be identified and documented and how assessors will address uncertainties.

The analysis plan may also include a comparison between the level of confidence needed for the management decision and the actual level of confidence it expects from alternative analytical approaches; this will determine which alternative best meets the management goals, within the constraints of time and resources. In addition, the analytical approach may include a phased or tiered risk assessment approach to facilitate management decisions (see Section 6.4 below).

The analysis plan is most helpful when it contains explicit statements of how participants selected the various analytical approaches, what piece of the conceptual model they intended the approach to evaluate, how the approach integrates with other analytical elements, and specific milestones for completing the risk assessment. Assessors generally include uncertainties associated with analyses, and approaches for addressing these uncertainties, in the analysis plan when possible.

Exhibit 6-2. Important Elements to be Included in an Analysis Plan	
Sources	How will information on the sources in the analysis (e.g., source location, important release parameters) be obtained and analyzed?
Pollutants	How will chemicals of potential concern (COPC) be confirmed and their emissions values be estimated?
Exposure pathways	How will the identified exposure pathways be assessed? How will ambient concentrations be estimated?
Exposed population(s)	How will exposures to populations of interest be characterized? How will their exposure concentrations be estimated? What will be the temporal resolution? What sensitive subpopulations may be affected?
Endpoints	How will information on the toxicity of the COPC be obtained (what are the data sources)? What risk metrics will be derived for the risk characterization?

In addressing the above aspects of the analysis, the plan should also clearly describe the following:

- How will *quality* be ensured in each step (e.g., what will be included in the quality assurance/quality control plans)?
- How will *uncertainty and variability* in the results be assessed?
- How will all stages of the assessment be *documented*?
- Who are the *participants* and what are their *roles and responsibilities* in the various activities?
- What is the *schedule* for each step (including milestones)?
- What are the *resources* (e.g., time, money, personnel) being allocated for each step?

The analysis plan may not result in just one document, but rather in a combination of multiple work plans that, taken together, constitute "the analysis plan." For example, for a study where assessors will perform both air dispersion modeling and air monitoring, participants may develop a separate work plan for both modeling and monitoring. However, assessors usually develop a master plan that describes all the different pieces and their relationship to one other.

The remainder of this subsection describes the important elements of the analysis plan, including:

- Identification of sources;
- Identification of chemicals of potential concern;
- Identification of exposure pathways/routes;
- Identification of exposed populations; and
- Identification of endpoints and metrics.

6.3.1 Identification of the Sources

As noted in Part I, EPA classifies sources of air toxics into a variety of categories for regulatory purposes, including stationary sources, mobile sources, and indoor sources (see Chapter 4). In addition, risk assessors also commonly group substances by their chemical and physical properties to both better estimate the fate and transport of chemicals in the environment and to

make inferences about the types of exposure pathways likely to be important in the exposure assessment.

This part of the analysis plan specifies the approach to be used to identify the specific sources that will form the initial focus of the analysis. Depending on the goals of the risk assessment, these sources may be limited to a single source or multiple sources at a facility (i.e., facility-specific risk assessments discussed in Volume II of this reference library) or may cover a wider variety of sources, including mobile sources, stationary sources, and possibly other sources such as indoor and natural sources (e.g., community-based risk assessments discussed in Volume III of this reference library). Identifying sources may be relatively straightforward (e.g., for facility-specific risk assessments) or may involve considerable research, particularly when dealing with a large number of smaller sources. In such an analysis, the initial tier of evaluation generally focuses on all identifiable sources within the assessment area. In subsequent tiers, it may be possible to remove some of these sources from the exposure assessment if one can determine that they contribute a very small fraction to the total risk estimate. Chapter 12 contains the techniques for conducting this type of screening.

6.3.2 Identification of the Chemicals of Potential Concern

This part of the analysis plan specifies the approach to be used to identify the most important air toxics that sources release (i.e., the chemicals of potential concern, or COPC). The COPCs will be the primary focus of the exposure and risk assessment. The initial tier of analysis often includes all of the air toxics released from the identified important sources. Depending on the specific air toxics of concern, the risk assessment also may need to consider secondary compounds that are formed from the reaction in the atmosphere.

Two techniques are available to focus the risk assessment on the most important air toxics:

- During problem formulation, a simple toxicity-emissions weighted screening approach can be conducted (discussed in Section 6.3.2.1).

- Once an initial risk characterization has been performed, subsequent tiers of analysis may remove specific chemicals from the COPC list if they are determined to contribute only a very small fraction to the total risk estimate (discussed in Section 6.3.2.2).

(Note that some assessors may wish to simply carry through the analysis all of the chemicals emitted to the assessment area. This is appropriate; however, it may require sufficient resources and result in little useful information.)

6.3.2.1 Toxicity-Weighted Screening Analysis

To determine which air toxics to include in the Tier 1 inhalation risk assessment, a relative risk evaluation called a **toxicity-weighted screening analysis (TWSA)** may be calculated based on the emissions data for all air toxics released from the facility/source being assessed. A TWSA is particularly useful if there are a large number of air toxics in the facility/source emissions and there is a desire to focus the risk analysis on a smaller subset of air toxics that contribute the most to risk. A TWSA can be performed as described below.

The TWSA is intended to be entirely emissions- and toxicity-based, without considering dispersion, fate, receptor locations, and other exposure parameters. It essentially compares the emissions rates of each air toxic to a hypothetical substance with an inhalation unit risk value of 1 per $\mu g/m^3$ (for carcinogenic effects) and/or a reference concentration (RfC) of 1 mg/m^3 (for noncancer effects). It requires emissions (release) information as well as the applicable dose-response values (see Chapter 12). However, is also can be used even with a single emission point and many air toxics. The steps for emissions-based toxicity-emissions weighted screening are presented below.

1. Identify all the inhalation unit risks (IURs) and RfCs for the air toxics in the facility/source emissions.
2. Determine the emission rate (e.g., tons/year) of each air toxic.
3. Multiply the emission rate of each air toxic by its IUR to obtain a toxicity-emissions product.
4. Rank-order the toxicity-emissions products and obtain the sum of all products.
5. Starting with the highest ranking product, proceed down the list until the cumulative sum of the products reaches a high proportion (e.g., 99 percent) of the total of the products for all the air toxics. Include in the assessment all the air toxics that contributed that proportion (e.g., 99 percent) of the total (see Exhibit 6-3 for an example calculation).
6. Repeat steps 3-5, but instead divide the emissions rate by the RfCs to obtain "noncancer equivalent tons"/year (see Exhibit 6-4 for an example calculation).

Chemicals with no toxicity data will necessarily not be included in the initial list of COPCs identified by the TWSA screening process. However, this does not necessarily mean that they are not potential risk drivers. Chemicals with no toxicity data are to be evaluated as part of the overall uncertainty analysis for the risk assessment. If there is sufficient evidence to support the hypothesis that an omitted chemical is a potential risk driver, the risk assessment team may opt to develop a toxicity value for the chemical (see Chapter 12 for more information on identifying toxicity values for chemicals). Also, if evidence suggests that a chemical that is screened out (e.g., is below the 99^{th} percentile in the TWSA) would nevertheless have an individual HQ or cancer risk greater than the selected screening level, the assessor may consider keeping the chemical in the list of COPCs.

6.3.2.2 Risk-Based Screening Analysis

In subsequent tiers of analysis, a **risk-based screening analysis** can be used to further focus the assessment on the significant air toxics of concern. This approach would be similar to the TWSA except that estimated individual cancer risk and noncancer hazard estimates would be used instead of toxicity-weighted emissions (an example risk-based screening analysis is presented in Chapter 13). A risk-based screening analysis might include the following steps:

1. Using applicable input data, run a simple dispersion and/or exposure model and calculate cancer risk at a selected point (e.g., maximum exposed individual location).
2. Rank-order the individual risk estimates for each emitted air toxic and obtain the sum of the cancer risk.
3. Starting with the highest ranking cancer risk, proceed down the list until the individual air toxics contributing a large proportion (e.g., 99 percent) of the total risk are included. Include those air toxics in subsequent tiers of analysis.
4. Repeat steps 1-3 for noncancer hazard.

Exhibit 6-3. Example TWSA Calculation for Cancer Effects					
Air Toxic	**Emissions (tons/year)**	**IUR**	**Cancer Equivalent Tons/year**	**Percent of Total**	**Cumulative Percent**
1,3-butadiene	8.2×10^{1}	3.0×10^{-5}	2.5×10^{-3}	23.8%	23.8%
carbon tetrachloride	1.5×10^{2}	1.5×10^{-5}	2.2×10^{-3}	21.3%	45.1%
beryllium compounds	8.6×10^{-1}	2.4×10^{-3}	2.1×10^{-3}	19.8%	64.9%
arsenic compounds	4.2×10^{-1}	4.3×10^{-3}	1.8×10^{-3}	17.5%	82.4%
2,3,7,8-TCDD	2.0×10^{-5}	3.3×10^{1}	6.6×10^{-4}	6.4%	88.8%
chromium (VI) compounds	3.7×10^{-2}	1.2×10^{-2}	4.4×10^{-4}	4.3%	93.1%
polycyclic organic matter[(a)]	4.3	2.1×10^{-1}	3.7×10^{-4}	3.6%	96.7%
cadmium compounds	1.0×10^{-1}	1.8×10^{-3}	1.8×10^{-4}	1.8%	98.4%
formaldehyde	8.9	1.3×10^{-5}	1.2×10^{-4}	1.1%	99.5%
1,3-dichloropropene	5.2	4.0×10^{-6}	2.1×10^{-5}	0.2%	99.7%
allyl chloride	2.8	6.0×10^{-6}	1.7×10^{-5}	0.2%	99.9%
methylene chloride	1.9×10^{1}	4.7×10^{-7}	8.7×10^{-6}	0.1%	100.0%
benzene	9.3×10^{-2}	7.8×10^{-6}	7.3×10^{-7}	0.0%	100.0%
Total			1.0×10^{-2}	100.0%	

Heavy line denotes 99% cutoff. In this example, 1,3-dichloropropene, allyl chloride, methylene chloride, and benzene could be dropped from the cancer analysis.
[(a)] Cancer equivalent tons/year and IUR are based on the assumption that benzo(a)pyrene represents 5% of emissions.

6.3.3 Identification of the Exposure Pathways/Routes

This part of the analysis plan specifies the approach to be used to identify the specific exposure pathways/routes that will be assessed. An exposure pathway/route describes the movement of air toxics from the point of release to the point where exposure may occur and generally consists of four elements:

1. A source and mechanism of release (emissions);
2. A transport medium (for inhalation, air);
3. A point of potential human contact with the contaminated medium (the **exposure point**); and
4. An exposure route at the contact point (e.g., inhalation).

Exhibit 6-4. Example TWSA Calculation for Noncancer Effects					
Air Toxic	**Emissions (tons/year)**	**RfC**	**Noncancer Equivalent Tons/year**	**Percent of Total**	**Cumulative Percent**
beryllium compounds	8.6×10^{-1}	2.0×10^{-5}	4.3×10^{4}	38.3%	38.3%
1,3 butadiene	8.2×10^{1}	2.0×10^{-3}	4.1×10^{4}	36.7%	75.0%
arsenic compounds	4.2×10^{-1}	3.0×10^{-5}	1.4×10^{4}	12.6%	87.6%
cadmium compounds	1.0×10^{-1}	2.0×10^{-5}	5.1×10^{3}	4.6%	92.1%
carbon tetrachloride	1.5×10^{2}	4.0×10^{-2}	3.7×10^{3}	3.3%	95.4%
allyl chloride	2.8	1.0×10^{-3}	2.8×10^{3}	2.5%	97.9%
formaldehyde	8.9	9.8×10^{-3}	9.1×10^{2}	0.8%	98.7%
2,3,7,8-TCDD	2.0×10^{-5}	4.0×10^{-8}	5.0×10^{2}	0.4%	99.1%
chromium (VI) compounds	3.7×10^{-2}	1.0×10^{-4}	3.7×10^{2}	0.3%	99.5%
toluene	1.3×10^{2}	4.0×10^{-1}	3.2×10^{2}	0.3%	99.8%
1,3-dichloropropene	5.2	2.0×10^{-2}	2.6×10^{2}	0.2%	100.0%
methylene chloride	1.9×10^{1}	1.0	1.9×10^{1}	0.0%	100.0%
benzene	9.3×10^{-2}	6.0×10^{-2}	1.6	0.0%	100.0%
		Total	1.1×10^{5}	100.0%	
Heavy line denotes 99% cutoff. In this example, chromium (VI) compounds, toluene, 1,3-dichloropropene, methylene chloride, and benzene could be dropped from the noncancer analysis.					

A critical determination in the exposure assessment is whether the potential exposure pathways identified during scoping are **complete** (i.e., there is a plausible mechanism by which the air toxic emitted from the source can reach the exposure point and a plausible mechanism by which the human receptor can come into contact with the chemical at the exposure point). Exposure cannot occur without a complete exposure pathway; and therefore if assessors determine that a potential exposure pathway is incomplete, they will generally document and drop the exposure from the risk assessment.

The exposures to be assessed depend on the needs articulated in the planning and scoping and problem formulation steps, including the specific laws and regulations that mandate a potential decision. For example, air toxics risk assessments commonly rely primarily on current land uses when evaluating exposures, while risk assessments conducted in the Superfund program commonly assess current and future land uses (i.e., air toxics risk assessments usually presume that the current land use within the area of impact of a source(s) will remain unchanged into the foreseeable future). The need, reasons, and methodology to evaluate alternate (e.g., future) land use conditions may be carefully considered and fully articulated during the problem formulation and planning/scoping phase of the assessment. As will be discussed later, in screening-level air

toxics risk assessments, it is common to assess exposures at the point of maximum offsite ambient concentrations, whether or not someone actually lives there (the maximum exposed individual or MEI location).

In addition, advanced tools (such as the RAIMI approach; see Volume III of this reference library) allow exposure assessments to evaluate the contemporaneous impact of multiple sources on a assessment area, identify the main contributors to the impact, and evaluate "what if" scenarios (e.g., what if this source cut its emissions by half; what if a roadway doubled its traffic?). Ultimately, the needs of the risk manager will drive such decisions.

For inhalation risk assessments, assessors evaluate only one exposure pathway (inhalation); multipathway risk assessments, on the other hand, focus on all relevant pathways (i.e., inhalation *and* any other relevant pathway, such as ingestion or dermal; see Part III of this Reference Manual for a description of how multipathway analyses are done). Exhibit 6-5 illustrates the exposure pathways/routes that are commonly assessed for air toxics inhalation risk assessments. Note that depending on the types of sources and specific COPCs they release, some of these pathways may or may not be relevant for any particular study.

Exhibit 6-5. Most Commonly Assessed Exposure Pathways/Routes for Air Toxics Inhalation Risk Assessments

Outdoor emissions of vapor phase chemicals
- → outdoor air
- → indoor air (by penetration of outdoor air into indoor spaces)

Outdoor emissions of particles
- → outdoor air
- → indoor air (by penetration of outdoor air into indoor spaces)

Note:
- Other media/routes may be applicable for particular risk assessments;
- When available, information on indoor source contributions may also be considered.

Whether the exposures to be assessed include workers depends on the needs articulated in the planning/scoping and problem formulation steps. For example, the Department of Labor's Occupational Safety and Health Administration (OSHA) generally regulates the exposures of workers to the chemicals they are exposed to in their workplace, and therefore these exposures generally are not considered in an air toxics risk assessment. When workers are exposed to chemicals not generated in their workplace (e.g., office workers exposed by a nearby factory), a decision may be made to consider the risks.

Exhibit 6-6 provides an example of an exposure pathway evaluation summary for a hypothetical study. The exposure pathways identified for further assessment will depend on the specific types of chemicals released (including their chemical and physical form), the physical relationship of the sources to the human receptors, meteorological conditions, and the relationship between indoor and outdoor air for the chemicals under study (for indoor exposure component).

Exhibit 6-6. Example Illustrating Possible Complete Exposure Pathways for a Hypothetical Inhalation Air Toxics Risk Assessment			
Potentially Exposed Population	**Exposure Route, Medium, and Exposure Point**	**Pathway Selected for Evaluation?**	**Reason for Selection or Exclusion**
Current Land Use Residents living in Smallville, USA	Inhalation of vapor phase chemicals during outdoor activities	Yes	Residents live year-round in Smallville
	Inhalation of particulate matter during outdoor activities	No	Preliminary analysis suggests that no significant particulate matter is released from sources in the assessment area and that the chemicals released remain in the vapor phase
	Inhalation of vapor phase chemicals during indoor activities	Yes	Residents live year-round in Smallville and released chemicals have the potential to penetrate indoors; the COPC are also released by indoor sources
	Inhalation of particle phase chemicals during indoor activities	No	Residents live year-round in Smallville and no significant particulate matter is released from sources in the assessment area and the chemicals released remain in the vapor phase. There are no known indoor sources.
Note: Assessment of completed non-inhalation exposure pathways are discussed in Part III of this reference manual.			

The approach for characterizing exposure pathways/routes in the analysis plan usually considers a variety of information about the assessment area (as articulated in the conceptual model), including how it will be bounded for the analysis. The analysis plan also specifies how exposure will be estimated and quantified, including whether modeling and/or monitoring will be used. The following subsections discuss:

- Characteristics of the assessment area;
- Scale of the assessment area;
- Use of modeling versus monitoring; and
- Quantification of exposure.

6.3.3.1 Characteristics of the Assessment Area

The physical characteristics of the assessment area provide a basis for identifying potential exposure pathways/routes and receptor populations of concern. They also are important considerations for selecting and providing input parameters for the air quality models to be used and/or for establishing monitoring sites. There is no universal classification system for describing the characteristics of the assessment area, but the following information is generally important for inhalation exposure assessments:

- **Urban versus rural setting**. This distinction provides general information about the way that air toxics will disperse in the environment once released and the expected number and types of receptors. For example, releases in rural areas may tend to move downwind with a relatively simple dispersion pattern, while releases in a large city are likely to disperse in very complex patterns depending the size and placement of buildings. Additionally, some of the newer dispersion models can adjust both for direction dependencies as well as time of year due to changes in foliage.

- **Simple versus complex terrain**. Terrain affects both the way that air toxics will disperse in the environment once released and the amount of dilution that will occur before they reach receptors. For example, a plume might pass over nearby receptors in simple terrain, but might intercept receptors located on elevated terrain (e.g., a plateau or hill) at the same distance from the source. Assessors can determine the terrain of any area in the United States from topographic maps available from the USGS (see below).

- **Climate and meteorology**. Climate features such as temperature and precipitation patterns, and meteorological features such as wind speed and direction will affect the fate and movement of air toxics in the atmosphere and after deposition. Seasonal and diurnal conditions may be major factors affecting rates of contaminant migration where precipitation rates or temperatures vary greatly according to the season or time of day. It also is important to note whether unusual weather conditions occur frequently within the assessment area, as these can have significant effects on contaminant fate and transport (see Appendix G).

- **Other important geographic features**. Nearby geographic features such as a lake or ocean can have significant effects on contaminant dispersion and may require the use of special dispersion models (see Chapter 9). For multipathway human health and/or ecological risk assessments, exposure setting also may include such elements as water bodies and associated watersheds, ecological receptors, and agricultural lands (see Parts III and IV).

Current land use (and in limited instances, potential future land use) is an important factor to consider in determining the exposure pathways and specific exposure points that are commonly evaluated in the risk assessment (particularly for higher-tier risk assessments). Land use can typically be identified by reviewing hard copy and/or electronic versions of land use land classification (LULC) maps, topographic maps, and aerial photographs. Sources and general information associated with each of these data types or maps are presented below. Also, assessors may want to verify the Universal Transverse Mercator (UTM) coordinate system format (North American Datum 27 (NAD27) or NAD83) to ensure consistency and prevent erroneous geo-referencing of locations and areas.

- **Land Use Land Cover (LULC) Maps**. LULC maps can be downloaded directly from the U.S. Geological Survey website (http://edc.usgs.gov/geodata/), at a scale of 1:250,000, in a file type Geographic Information Retrieval and Analysis System (GIRAS) format. LULC maps can also be downloaded from the website (http://www.epa.gov/ngispgm3/spdata/EPAGIRAS/egiras/), at a scale of 1:250,000, in an Arc/Info export format. It is recommended that the exact boundaries of polygon land use area coverages, in areas being considered for evaluation, be verified using available topographic maps and aerial photographic coverages.

- **Topographic Maps**. Topographic maps are readily available in both hard copy and electronic format directly from USGS (http://mapping.usgs.gov/index.html) or numerous other vendors. These maps are commonly at a scale of 1:24,000, and in a TIFF file format with TIFF World File included for georeferencing.

- **Aerial Photographs**. Hard copy aerial photographs can be purchased directly from USGS (http://mapping.usgs.gov/index.html) in a variety of scales and coverages. Electronic format aerial photographs or Digital Ortho Quarter Quads (DOQQs) can also be purchased directly from USGS, or from an increasing number of commercial sources, such as Microsoft's® areal photo map server called "terraserver" (http://www.terraserver.com).

While these data sources do not represent the full universe of information available on human activities or land use, they are readily available from a number of government sources (typically accessible via the Internet), usually can be obtained at no or low cost, and when used together provide a good starting point to identify and define, in a defensible manner, land use areas to be considered for evaluation in the risk assessment. However, while the use of these or other data can be very accurate, verifying identified land use areas "on the ground" may be important for higher-tier risk assessments. Discussions with representatives of private and government organizations which routinely collect and evaluate land use data (e.g., agricultural extension agencies, U.S. Department of Agriculture, natural resource and park agencies, and local governments) can also be helpful in updating current land use information or providing information regarding future land use. Information on reasonable potential future land use can also be obtained from local planning and zoning authorities, which may help determine what level of development is now allowed under current regulations and what development is expected in the future. EPA's Superfund program has developed a specific directive on the process of how to go about determining future land use in a particular place.[2] This directive may be consulted for information on how to formulate realistic assumptions regarding future land use.

6.3.3.2 Scale of the Assessment Area

The scale of the assessment area is determined to a large part by the specific question(s) or problem(s) being addressed in the risk assessment. In determining the scale of the assessment area, both the capabilities of the tools to be used and the physical characteristics of the assessment area are considered by assessors. For example, some commonly used air dispersion models are only considered by EPA to be valid out to about 50 km because of limitations in their conceptual basis (e.g., Gaussian plume modeling has this limitation). A 50-km limit may be sufficient for assessments that focus on highly impacted areas occurring within a few kilometers of the emissions sources. However, other situations may involve a more distant area of significant impact. For example, if there are unusual source characteristics such as very tall stacks or unusual physical characteristics such as a nearby plateau where people live, modeling may need to be extended to these more distant areas.

A separate, but related issue, is how to consider scale for assessments that incorporate monitoring to characterize exposure. Since a monitor only assesses exposure at the point where the monitor is located, the "scale" that this one point represents becomes much more difficult to determine. Thus, the term "scale" can represent two different things for exposure assessment. When using modeling, the "scale" of the assessment area is simply the geographical land area around the sources within which modeling nodes will be placed and modeling will be done (for example, the model may predict ambient concentrations at every point on a 100 × 100 m grid out to 50 km in all directions from the sources). When assessors use monitoring to evaluate exposure, the "scale" refers to the area around the monitoring location (and the types of exposures) the analysts consider the monitoring data to represent (for example, a monitor located in an urban area that does not directly receive the impacted of an identifiable point source is usually designated as an "urban scale" monitor because it reflects general urban ambient air concentrations for populations not directly impacted by point sources). A full discussion of this distinction is provided in Chapter 9.

Scale can also refer more generally to the coverage of the analysis (see Exhibit 6-7). For example, the 1996 NATA risk characterization provided risk estimates, at the county level, for every county in the US. The "scale" of this analysis was nationwide. A real person, on the other hand, who was outfitted with a personal monitoring device, might be described as "personal" or "individual" scale.

6.3.3.3 Use of Modeling versus Monitoring

As this document has previously noted, risk assessors can base estimates of exposure concentrations on either actual measurements (i.e., monitoring data) or air quality modeling. Exhibit 6-8 provides a brief comparison of modeling and monitoring. Many studies may benefit by using some combination of modeling and monitoring, because the two approaches can complement one another.

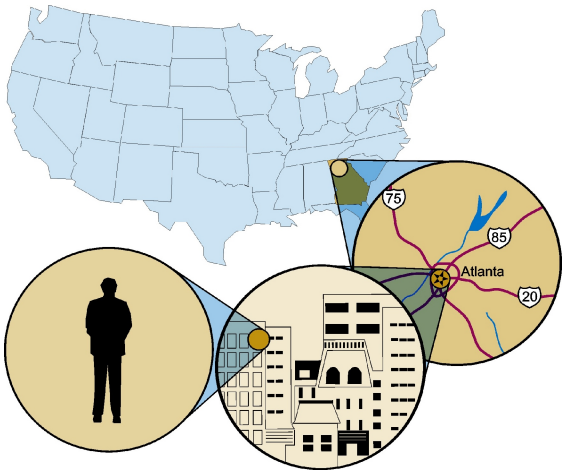
Benefits of modeling include the ability to:

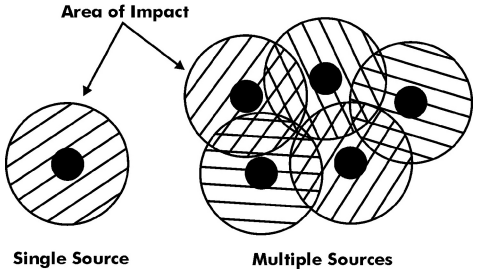
- Obtain a relatively quick, screening-level estimate of the potential for risk;
- Identify the subset of air toxics that contribute most significantly to the risk estimate;
- Identify the areas where the highest exposure concentrations are likely to occur;

- Estimate concentrations over a broad assessment area; and
- Examine individual variability in exposure.

One of the limits in the usefulness of modeling may be the accuracy of the air toxics emissions inventory (discussed in Chapter 7). Also, models can only provide estimates of exposure concentrations; often monitoring is performed to confirm model predictions.

Exhibit 6-7. Air Toxics Risk Assessments May be Conducted at Different Scales





Air toxics risk assessments may be performed on a variety of geographical levels ranging from the national level (e.g., the National-Scale Assessment), to the state, local, neighborhood, or even individual levels. Within a given scale, the risk assessment could look at the impact from a single source or multiple sources. The specific tools, approaches, and metrics used are likely to differ depending on the geographic scale of interest.

Benefits of monitoring include the ability to:

- Provide actual concentrations, which often provide a stronger basis for leveraging emissions reductions;
- Provide site-specific information to verify or calibrate model predictions;
- Provide time- and space-integrated measures of the actual concentrations at which individuals are exposed when they move from place to place within the assessment area; and
- Measure episodic releases, which are otherwise difficult to measure and quantify and are not well addressed in emissions inventories.

One of the limits in the usefulness of monitoring may be the representativeness of the location(s) in which monitors are placed (i.e., if placed in the wrong locations, monitors can provide incorrect and misleading information about exposures). Also, monitoring may not always be an effective tool to link ambient concentrations to specific sources (if, for example, one is monitoring benzene in an urban environment).

Exhibit 6-8. Comparison of Modeling and Monitoring Approaches for Estimating Ambient Air Concentrations	
Modeling	**Monitoring**
Modeling is relatively fast and inexpensive. Many screening-level models can be run in spreadsheet formats and require relatively simple input parameters. Many dispersion models, along with technical reference manuals and other support documents, are available for free download from EPA's Support Center for Regulatory Air Models (SCRAM) website (http://www.epa.gov/ttn/scram/). Resources normally need to be expended to enhance the local air toxics emission inventories to make air toxics modeling more precise.	Monitoring takes time to build data, and there are methodological limits and logistical issues. How expensive monitoring is depends on what you are trying to do and how much you have to buy or pay for. Monitoring does not always require equipment purchase and some states and local areas already have equipment. Some less expensive monitoring techniques are now available (i.e., passive samplers).
Modeling results can estimate concentration over a large spatial area (e.g., a 50-km radius from a source) and can provide a "big picture" view of the assessment area. Modeling also allows for analysis of exposure concentration at multiple points throughout the assessment area. The downside of modeling, however, is that these are predicted concentrations.	Monitoring results provide actual measured concentrations. Multiple locations may be required to characterize concentration over an area, although GIS methods facilitate interpolation between locations. The downside is that the monitoring may not be very representative of a large geographic area.
Screening-level models can provide a predicted estimate of whether significant concentrations are likely. A simple screening analysis may be sufficient to make a risk management decision that no action is required.	Monitoring can be used to identify and measure exposures for specific individuals at a specific location of concern (e.g., a school). This data can provide a quick screen to determine whether more extensive monitoring is needed.
Models can be used to identify areas where maximum concentrations are likely to occur, and thus to focus efforts for additional tiers of the assessment. Uncertainties in model parameters, and the discrete division of the wind field used in models (often with only eight wind directions) can result in incorrect identification of the locations of maximal concentration.	Monitoring can identify areas and actual levels of exposures occurring at the monitoring sites. Monitoring can also be used to indicate the point of maximal exposure if the monitoring is designed for that purpose. The selection of the monitoring locations is critical; if placed in the wrong locations, monitors can provide incorrect and misleading information about maximal exposures.
Models can be used to identify the subset of COPC and exposure pathways/routes that have the greatest contribution to risk. This can be helpful in focusing efforts for additional tiers of the assessment as well as determining appropriate risk management actions.	Monitoring can be used to confirm significant exposure pathways and routes. (Measured concentrations can be compared to risk-based screening levels.) It also can be used to identify compounds that may not have been suspected and, hence, were not included in models (i.e., monitoring allows identification of gaps in the emissions inventory).
Models allow "what if" scenarios to be evaluated (e.g., what if a permitted emission were doubled?).	Monitoring can only evaluate current conditions.
More complex modeling may allow explicit prediction and estimate of variability in exposure.	A large number of samples generally is needed to characterize variability; this may be prohibitively expensive. Monitoring, however, provides a direct and reliable means to characterize variability.
Models often use simplifying assumptions and data inputs that may or may not be representative of the specific assessment area. This introduces uncertainty into model predictions.	Monitoring can be used to confirm actual exposure levels as well as investigate assumptions or calibrate models to site-specific conditions, and to close gaps in data, reducing uncertainties.

6.3.3.4 Estimation of Exposure

An important element of the analysis plan is the specific approaches for developing numerical estimates of exposure concentrations for each of the COPC for each of the populations the assessment is studying (i.e., how exposure will be estimated and quantified). As noted in the previous subsection, this may involve the use of air quality models and/or monitoring data. Quantitation of exposure includes three general steps:

- **Characterization of releases to the air**. Characterizing the location, nature, and magnitude of emissions released from the sources being evaluated, including release parameters such as stack height and temperature of release (when modeling is being performed). This is discussed Chapter 7.

- **Estimation of chemical fate and transport**. Modeling and/or measuring the ambient concentrations of air toxics in the environment, as a result of transport, and including any physical or chemical transformations that may occur during this movement, from the emission point to the exposure points. This is discussed in Chapters 8, 9, and 10.

- **Estimation of exposure concentrations**. Developing a numerical estimate of exposure concentrations of air toxics to the selected exposure points. This is discussed in Chapter 11.

The Metrics of Exposure for Inhalation

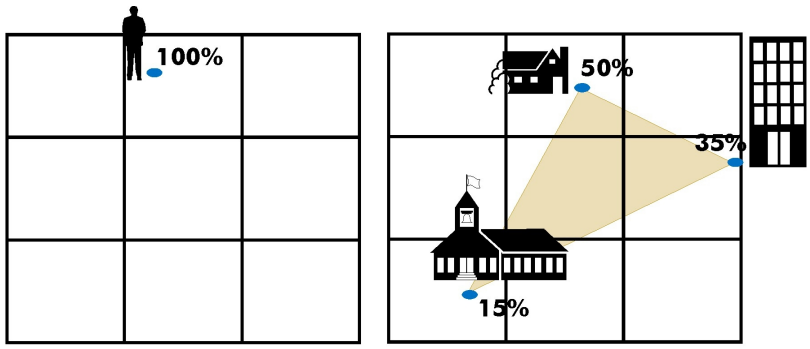
The metric of exposure for inhalation is simply the **exposure concentration (EC)** – the concentration of a chemical in the air at the point where a person breathes the air.

For the inhalation route of exposure, the metric of exposure is the concentration of the chemical in the air the population of interest is breathing over the period of interest. This concentration is called the **exposure concentration (EC)** and is the primary quantitative output of the inhalation exposure assessment. As we will see in Chapter 11, this metric is intended to represent the time weighted average exposure(s) to the population(s) of interest during the exposure period. (Note that exposure models are often also applied to better reflect how different people interact with contaminated air. In other words, the air quality model evaluates how chemicals move and change in the environment. The exposure model evaluates how different types of people interact with the resulting contaminated air - with the result that the EC is refined to provide more realistic estimates of exposure. A discussion of exposure modeling is provided below.)

There are two general ways to estimate the EC (Exhibit 6-9); these are discussed in greater detail in Chapter 11.

- **Ambient Air Concentrations**. For screening-level evaluations, assessors use the concentration of air toxics generated at each modeling node (or interpolated nodes) or the concentration determined by a monitor. The default assumption in such a screening assessment is that the population of interest is breathing air continuously around-the-clock at the modeled or monitor location. Proceeding in this manner, in the initial stages, is often done because of the additional cost, time, and specialized expertise needed to run the exposure model. Such results, depending on the purpose of the analysis, may be sufficient for some risk management decisions (Chapter 3 provides a discussion on how to phase or "tier" a risk assessment from simple but conservative to more complex yet realistic.)

Exhibit 6-9. Two General Ways to Estimate Inhalation Exposure Concentration

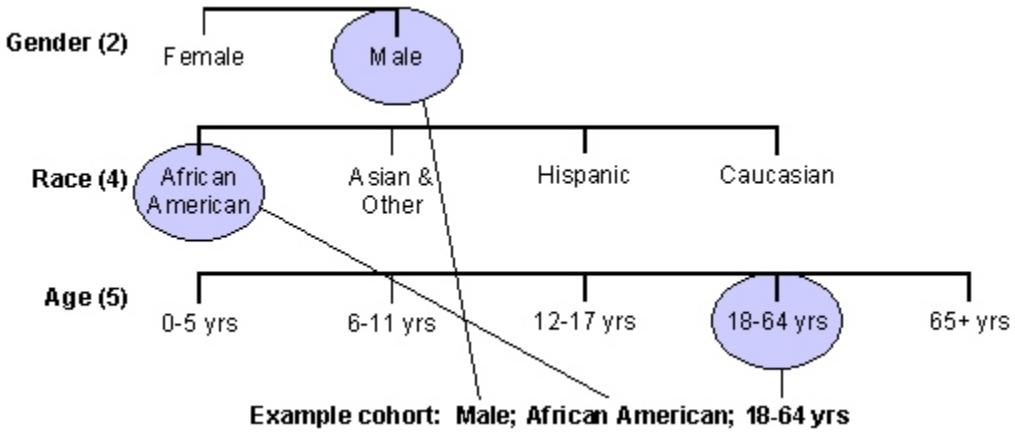


The left-hand side illustrates the use of ambient air concentrations as a surrogate for the EC. In this example, the analysis assumes that individuals spend 100 percent of their time at a given location, so the estimate of ambient concentration thus represents the EC. The right-hand side illustrates the use of exposure modeling. In this example, the analysis assumes that an individual spends 50 percent of his/her time at home; 15 percent at a school; and 35 percent at an office. The EC is the weighted sum of the product of the ambient concentrations at each location and the amount of time spent there. Both indoor and outdoor concentrations usually are considered at each location.

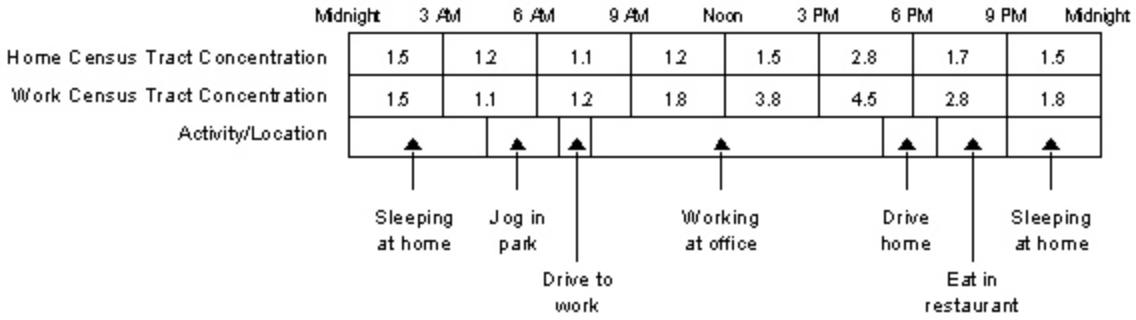
- **Exposure modeling**. More comprehensive inhalation exposure assessments combine estimates of ambient outdoor pollutant concentration (e.g., from air quality models) with information about the population of interest, including the types of people present (e.g., ethnicity, age, sex), time spent in different microenvironments, and microenvironment concentrations. The assessment objective is to obtain a representative estimate of the pollutant concentration in the inhaled air in each microenvironment. For risk assessments focusing on chronic effects resulting from chronic exposures, a long-term estimate of exposure is the EC of interest. As discussed in Chapter 9, the resulting estimate is a refined metric of personal exposure concentration (EC). This EC reflects the time spent in different microenvironments (and the activities within these microenvironments) throughout the daily routine of either representative individuals (selected statistically to be representative of the potentially exposed population) or different groups of people with similar attributes (called **cohorts**). The EC is essentially a time-weighted average exposure concentration for all of the cohorts combined (see Exhibit 6-10).

People living in the vicinity of one or multiple air toxics sources have the potential to receive exposure to emitted chemicals many different ways. For example, they might be exposed occasionally, but to very high concentrations (e.g., when an accident occurs that releases large amounts of chemical to the air in a very short amount of time). On the other hand, they might receive exposure quite often (or even continuously) to low levels that would likely go unnoticed. Air toxics inhalation exposure assessments usually focus on two of these different types of possible exposure scenarios:

Exhibit 6-10. Example Cohort Group



In this hypothetical example, cohort groups are defined based on gender (two categories); race (four categories), and age (five categories). This example illustrates an African American male aged 18-64 years.



In this hypothetical example, daily exposure scenarios are developed based on ambient air concentrations at work, and indoor and outdoor concentrations are assumed (for this example) to be equal at a given location, and home and the specific activity patterns modeled for each cohort. In this example, the African American male aged 18-64 years divides his activities among sleeping at home, jogging in the park, driving to work, working at the office, driving home, and eating at a restaurant. The daily exposure concentration is obtained by multiplying the time in each activity by the appropriate ambient air concentration(s) for the time period(s) of interest, then summing the products. For example, the product for jogging would be 1.2 (home concentration 3-6 AM) × 1.5 hours jogging (during the 3-6 AM time period) + 1.1 (home concentration 6-9 AM) × 0.5 hours jogging (during the time period 6-9 AM).

- **Chronic exposure** refers to situations in which the exposure occurs repeatedly over a long period of time (usually years to lifetime). If there is substantial variation in exposure concentration during segments of the chronic period, it may be appropriate to evaluate the segments separately using the appropriate dose-response values.

- **Sub-chronic exposure** refers to situations in which the exposure occurs repeatedly over a period of time that ranges between acute and chronic exposures (As toxicity values are less widely available for this duration, it is less routinely assessed than the others. For air toxics assessments, this exposure period is not commonly assessed.)

- **Acute exposure** refers to situations in which the exposure occurs over a short period of time (usually minutes, hours, or a day) and usually at relatively high concentrations. The averaging times commonly used to represent acute exposures concentrations (i.e., acute ECs) are a 24-hour average, a one-hour average, or a 15-minute average.

The EC values the assessor develops to represent acute and chronic exposures should match the assumptions built into the dose-response values that the assessor uses to characterize risk (see Chapter 12). For example, it would be inappropriate to compare a one-week average exposure concentration to a one-hour acute dose-response value. For chronic exposures, the scale of time-weighted averaging performed to develop the exposure estimate should be generally similar to that used in developing the dose-response value. For example, inhalation chronic RfCs are derived from studies involving regularly repeated exposures (e.g., six hours a day, five days a week in animal studies) over a chronic period. Thus, exposures occurring on a much lesser frequency (e.g., a several days a week on a handful of occasions during a couple of years), should not be averaged over the exposure period and compared to a chronic RfC. Such very infrequent exposures may be more appropriately assessed as separate shorter-term or sub-chronic exposures.

6.3.3.5 Evaluation of Uncertainty

This part of the analysis plan specifies the approach to be used to evaluate uncertainty in the exposure and risk estimates. Decision-makers will weigh the importance of the exposure (and resulting risk) estimates in the eventual decision in the context of the uncertainties inherent in these estimates. Assessment and presentation of uncertainty is discussed in Chapter 3.

6.3.3.6 Preparation of Documentation

This part of the analysis plan specifies the approach to be used to document all aspects of the risk assessment. For most individual air toxics risk assessments, the exposure assessment represents the majority of effort (and the majority of the documentation) and therefore may require the greatest amount of work. A comprehensive documentation of the methods, assumptions, and uncertainties associated with the exposure assessment is encouraged. Chapter 13 discusses documentation in greater detail.

6.3.4 Identification of the Exposed Population

This part of the analysis plan specifies the approach to be used to characterize the location and size of the populations of interest to the assessment. Additional information on population characteristics may assist in characterizing exposure, and in identifying sensitive sub-populations.

- **Population data**. In identifying and also characterizing a potentially exposed population, the U.S. Census Bureau (www.census.gov) is the primary source of population information (e.g., the most recent data on the US population is contained in the 2000 Census).

- **Sensitive sub-populations**. Human exposure and susceptibility and sensitivity to pollutant effects may vary with factors such as age, gender, intensity and amount of activity, time spent in microenvironments, diet, overall health, lifestyle, genetic factors, and the concentration of pollutant. The extent to which these factors are considered in the risk assessment depends on the purpose of the assessment as defined in the planning/scoping and problem formulation steps, available resources, uncertainties in the assessment, and data quality and quantity.

6.3.5 Identification of the Endpoints and Metrics

This part of the analysis plan specifies which human health endpoints will be evaluated in the risk assessment and the metrics by which they will be evaluated. For inhalation exposures, EPA generally evaluates individual cancer risk and noncancer hazard (see Chapter 12 for a more detailed discussion).

- Estimated individual cancer risk is generally expressed as a numerical probability that a person will develop cancer over the course of their lifetime as a result of the exposures under study.

- Noncancer effects are generally evaluated by comparing exposure concentrations to reference concentrations (RfCs), which are estimates (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious non-cancer effects during a lifetime. Noncancer effects generally are assessed for both acute and chronic exposure times.

Risk is usually described as either the risk experienced by different individuals within a population or the risk experienced by groups of people. The former is called risk to an individual (or simply individual risk), and the latter is called risk to a population (or simply population risk). The difference between the two is that individual risk describes risk to one person at a time, while population risk generally describes the number of people in a population experiencing the same risk. Thus, in a city block containing 400 people with an estimated risk (calculated at the block internal point) of two in 10,000 (2×10^{-4}), one could describe the risk to each of the individual 400 people as "individual risk = 2×10^{-4}." Alternatively the population risk could be described as "400 people living at a risk of 2×10^{-4}." While this distinction may seem arbitrary, risk often varies substantially over the exposed population. The use of both types of risk estimates assists risk managers in balancing concerns of small numbers of highly exposed people and larger numbers of people with lower exposures.

It generally is preferable to present a range of risk estimates, particularly in higher-tier assessments. Distributions are often more useful than point estimates. However, since developing fully distributional estimates of risk is usually out of the scope of most risk assessments, a sense of the range of risks is usually provided by developing both central tendency and high end point estimates.

- **Central tendency** estimates are intended to give a characterization of risk for the typical individual in the population. This is usually either based on the arithmetic mean risk (average estimate) or the median risk (median estimate).

- **High end** estimates are intended to estimate the risk that is expected to occur in the upper range of the distribution (e.g., risk above about the 90th percentile of the population distribution).

Risk characterization is discussed in more detail in Chapter 13.

6.4 Data Quality in the Risk Assessment Process

All air toxics risk assessments involve some data collection (e.g., emissions inventories will be developed to support air quality modeling, and/or monitoring data will be collected). For data collection efforts, a central component to the analysis plan is data quality assurance. The credibility of the risk assessment depends in part on the quality of the data that it uses. EPA uses its Quality System to manage the quality of its environmental data collection, generation, and use. The EPA quality website (http://www.epa.gov/quality) is an excellent resource for quality-related information that assessors will want to become familiar with as they develop an analysis plan for a risk assessment project.

As part of its effort to develop an Agency-wide data quality program, EPA has developed a number of specific tools that have direct applicability in performing risk assessment projects, including:

- Data quality assessment;
- Systematic planning (and the Data Quality Objectives Process);
- Quality assurance project plans;
- Standard Operating Procedures;
- Technical Audits; and
- Verification and Validation.

The use of these tools will help in the development of enough high quality data to allow assessors to answer the assessment questions in a robust way. A brief discussion of each of these tools follows. More in-depth discussion of each of these tools can be found on EPA's Quality website.

- **Data Quality Assessment** helps assess the type, quantity, and quality of data. This assessment, in turn, helps to verify that assessors satisfy the planning objectives. A Quality Assurance Project Plan components and sample collection procedures help ensure that the data are suitable for its intended purpose. Data Quality Assessment is a five-step procedure for determining statistically whether or not a data set is suitable for its intended purpose. This assessment is a scientific and statistical evaluation of data to determine if it is of the type, quantity, and quality needed and may be performed either during a project to check the process of data collection or at the end of a project to check if objectives were met.

- **Systematic Planning** is necessary to define the type, quantity, and quality of data a decision maker needs before collecting or generating environmental data. The Data Quality Objectives Process is an example of a systematic planning process that assessors would use to translate a decision maker's aversion to decision error into a quantitative statement of data quality needed to support that decision. Data Quality Objectives are not required under EPA's quality system; however, EPA does require that a systematic planning process such as

the Data Quality Objectives Process be used for all EPA environmental data collection activities. EPA recommends using the Data Quality Objectives Process when decision-makers are using data to select between two opposing conditions, such as determining compliance with a standard.

- **Quality Assurance Project Plan (QAPP)** documents the planning, implementation, and assessment procedures for a particular project, as well as any specific quality assurance and quality control activities. It integrates all the technical and quality aspects of the project in order to provide a "blueprint" for obtaining the type and quality of environmental data and information needed for a specific decision or use. *Note*: **All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP.**

- **Standard Operating Procedures** are written documents that describe, in great detail, the routine procedures to be followed for a specific operation, analysis, or action. Consistent use of an approved Standard Operating Procedure ensures conformance with organizational practices, reduced work effort, reduction in error occurrences, and improved data comparability, credibility, and defensibility. Standard operating procedures also serve as resources for training and for ready reference and documentation of proper procedures.

- **Technical audits** are systematic and objective examinations of a program or project to determine whether environmental data collection activities and related results comply with the project's QAPP and other planning documents, are implemented effectively, and are suitable to achieve its data quality goals. Technical audits are not management assessments nor are they data verification/validation processes, which occur during the assessment phase of the project. Technical audits include readiness reviews, technical systems audits, surveillance, and performance evaluations.

- **Data verification and validation** is used to evaluate whether data has been generated according to specifications, satisfy acceptance criteria, and are appropriate and consistent with their intended use. Data verification is a systematic process for evaluating performance and compliance of a set of data when compared to a set of standards to ascertain its completeness, correctness, and consistency using the methods and criteria defined in the project documentation. Data validation follows the data verification process and uses information from the project documentation to ascertain the usability of the data in light of its measurement quality objectives and to ensure that results obtained are scientifically defensible.

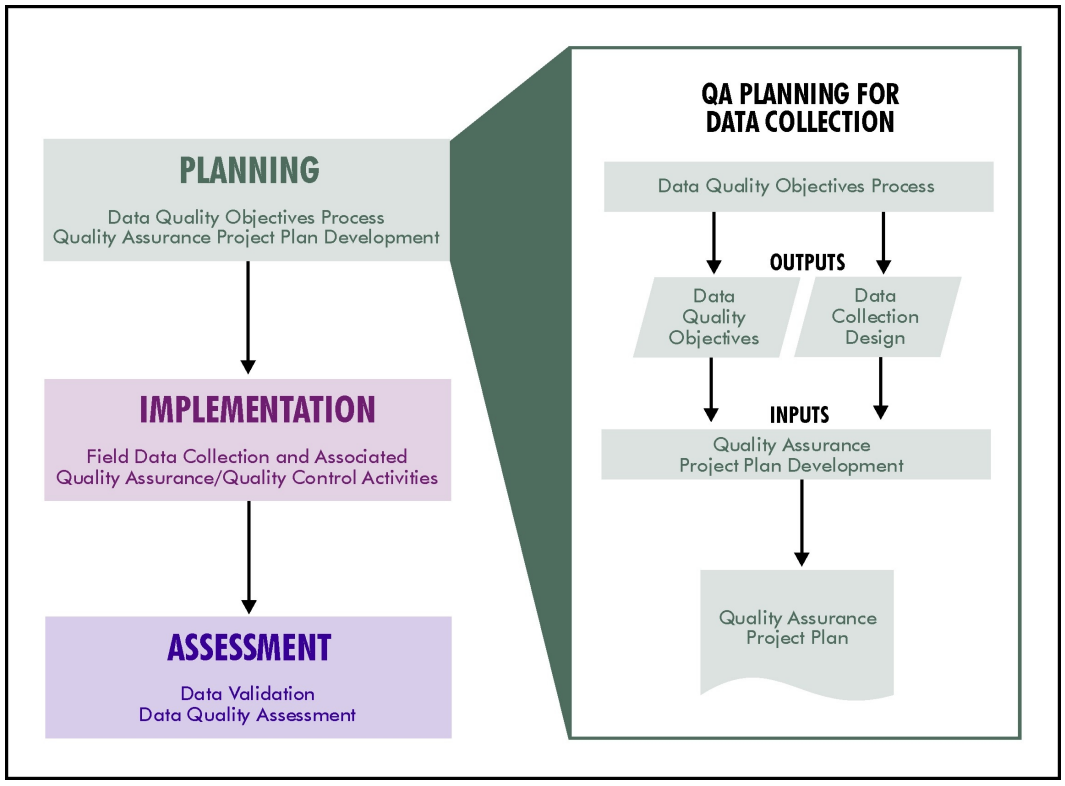
Quality Assurance is an integral part of data collection and analysis throughout the risk assessment project and the various activities addressed and documented in the QAPP cover the entire project life cycle, integrating elements of the planning, implementation, and assessment phases (Exhibit 6-11).

- **Planning**. The Data Quality Objectives (DQOs) are together a structured, systematic planning process that provides statements about the expectations and requirements of the data user (such as the decision maker).

- **Implementation**. The QAPP translates these requirements into measurement performance specifications and QA/QC procedures for the data suppliers to provide the information needed to satisfy the data user's needs.

- **Assessment**. The QAPP includes plans for data validation and data quality assessment.

Exhibit 6-11. QA Planning and the Data Life Cycle



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