Chapter 6 Risk Characterization

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6.0 Introduction

In the risk characterization step, information from the preceding steps of the assessment (exposure and toxicity data) is integrated to develop risk conclusions that are complete, informative, and useful for decision making (see Exhibit 6-1). Quantitative and qualitative statements of risk are presented in the context of uncertainties and limitations in the underlying data and methodology. The basics of risk characterization and uncertainty analysis are provided in ATRA Volume 1, Chapter 13, and analysts are encouraged to review this information. This chapter introduces some of the ways in which the results of the multisource assessment can be graphically and tabularly presented. Chapter 7 elaborates on this topic by discussing additional risk communication techniques.

The risk characterization will commonly describe the risk results in terms of both individual risk and population risk (e.g., estimates of the number of people at different risk levels). The risk assessment team will usually also identify the percentage of the cumulative risk attributable to each of the sources evaluated. The cumulative multi-source risk estimates and results of the source apportionment are commonly displayed in both tabular format as well as graphically (e.g., using GIS formats).

EPA has developed several key documents about how to characterize and present risk assessment information, including EPA's Policy for Risk Characterization.(1) The purpose of the policy is to help ensure that risk management decisions are well-supported and well-understood, both inside the EPA and outside the Agency, and that the confidence in the data, science policy judgments, and the uncertainties are clearly communicated. The *Handbook for Risk Characterization*(2) provides additional background and approaches to presenting the risk characterization results. The assessment team should become familiar with the information provided in both the policy and handbook before beginning a risk assessment. Section 3.5 of the *Residual Risk Report to Congress*(3) provides additional discussion on risk characterization for air toxics.

6.1 Quantification of Multisource Risk and Hazard

As noted above, the process for calculating hazard and cancer risk was discussed in detail in ATRA Volume 1, Chapter 13, and readers are referred to that chapter for an in-depth discussion of the inhalation risk and hazard calculation equations. The only difference between the process described in ATRA Volume 1 and a multisource analysis is that in a multisource inhalation analysis, risk and hazards are combined not only across chemicals, but across sources as well. For example, at a particular receptor of interest, carcinogenic risks from Source A will be combined with carcinogenic risks from Source B and Source C, etc. The result is a cumulative

The Basic Equations for Calculating Chemical-Specific Risk and Hazard

Chemical-specific cancer risk = EC × IUR

Chemical-specific noncancer hazard = EC/RfC

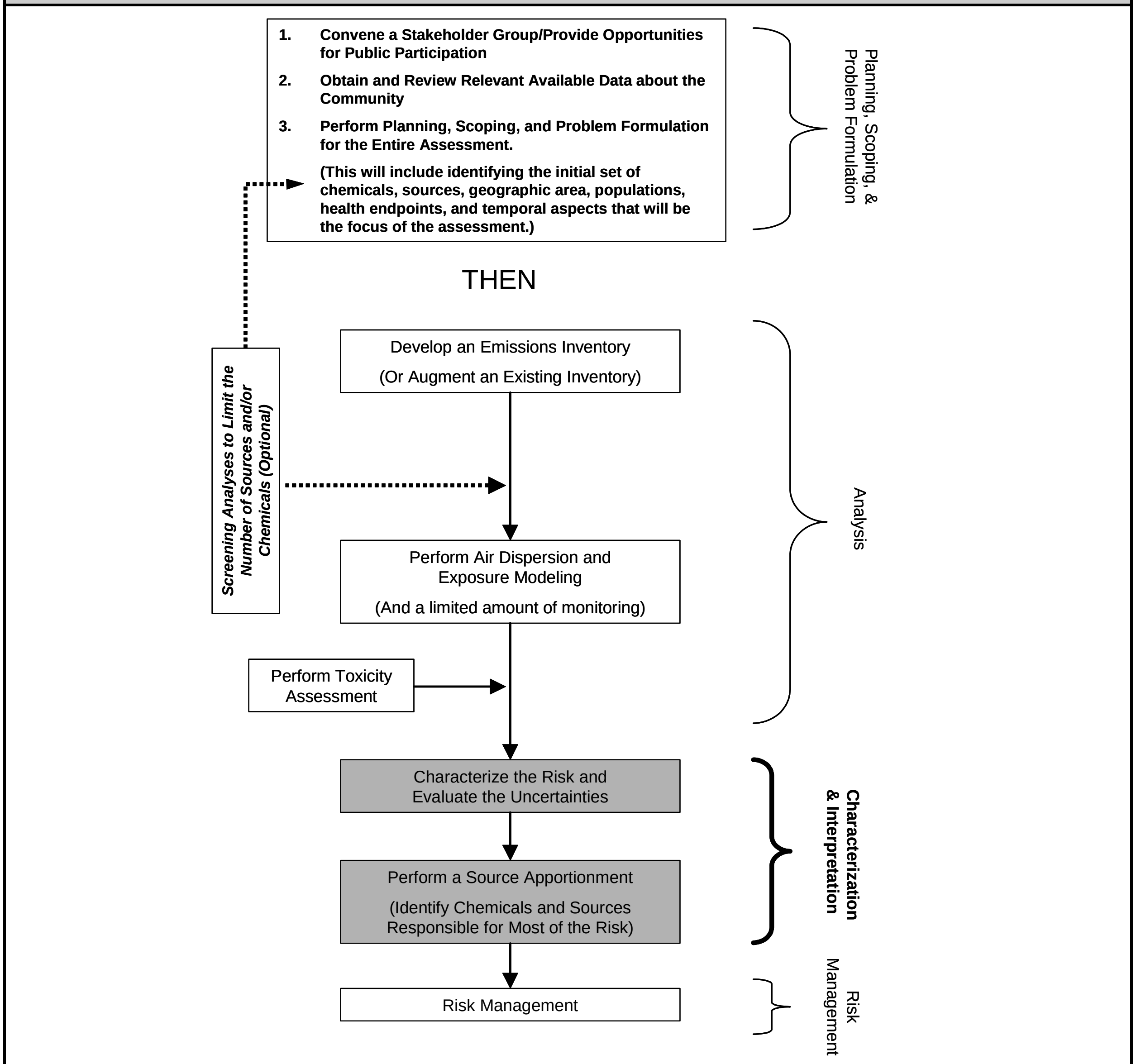
where:

EC = lifetime estimate of continuous inhalation exposure to an individual air toxic (ug/m^3)
IUR = the corresponding inhalation unit risk estimate for that air toxic (ug/m^3)
RfC = the corresponding reference concentration for that air toxic (ug/m^3)

incremental carcinogenic risk associated with breathing air impacted by emissions from all those sources. A similar approach is used for hazard.

In addition to the information provided in ATRA Volume 1, Chapter 13, further detail on multi-chemical assessment is provided in the *Agency's Guidelines for the Health Risk Assessment of Chemical Mixtures* [4] and the *Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures*.[5] It is noted that the Agency guidance recommends that the "combining" or component-by-component approach to multipollutant exposures be performed for mixtures with "approximately a dozen or fewer chemical constituents" (see reference 5). Larger groups of chemicals may be considered in an initial screening step which allows the identification of the more important subset of chemicals that likely pose most of the risk and that should be included in the actual risk assessment.

Exhibit 6-1. The General Multisource Cumulative Assessment Process for a Community Assessment - Focus on Risk Characterization and Interpretation



Steps in an Inhalation Risk Characterization

1. Organize outputs of inhalation exposure assessment and toxicity assessment.
2. Derive inhalation cancer risk estimates and hazard quotients for each pollutant for each exposure scenario receptor being studied (e.g., modeling grid receptors, special receptor sites such as hospitals and schools, etc).
3. Derive cumulative inhalation cancer risk estimates and hazards estimates for each receptor for all chemicals.
4. Display the risks both in written form (usually as a narrative and in tabular form) and graphically.
5. Apportion the risks among the sources that contribute to the risk.
6. Identify key features, limitations and assumptions of exposure and toxicity assessments.
7. Assess and characterize key uncertainties and variabilities associated with the assessment.
8. Consider additional relevant information.

Risk characterization should be transparent, clear, consistent, and reasonable (TCCR). A discussion of the TCCR principles is provided in Section 6.4.

6.2 Approaches for Characterizing and Presenting Multisource Risk and Hazard

ATRA Volume 1, Section 13.3, provides an overview of presenting inhalation risks and hazards. The concept for multisource analysis is the same. As such, the following discussion emphasizes the elements that are particular to multisource analysis.[a]

6.2.1 Common Risk Descriptors

Similar to all other aspects of the risk assessment, the way in which risk characterization is performed will depend on the scope, goals and purpose of the overall analysis. For example, the purpose may include identifying the sources and chemicals posing the greatest risk in the study area to assist the community in prioritizing risk reduction actions. Another goal could be to identify the locations associated with the highest risks for the siting of air monitoring stations. The risk characterization will have to be crafted to meet these needs in a way that is acceptable to the decision makers, particularly from the standpoint of their need to avoid errors in their decision making process. Part III of the EPA's Risk Characterization Guidance, available at http://www.epa.gov/osa/spc/pdfs/rcguide.pdf, provides additional information on the subject of risk descriptors.

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[a] Standard rules for rounding apply which will commonly lead to an answer of one significant figure in both risk and hazard estimates. For presentation purposes, hazard quotients (and hazard indices) and cancer risk estimates are usually reported as one significant figure.

Automating the Process: The RAIMI Risk-MAP

EPA developed Risk-MAP (Risk Management and Analysis Platform) to support the data-intensive and analytically complex nature of multisource cumulative assessments. The design and functionality of Risk-MAP has been driven by the need to go a step beyond analysis and serve as a direct and seamless platform to support solution selection, implementation, and tracking. As such, Risk-MAP represents a unique shift in risk tool design. Risk-MAP has the ability to:

- Calculate exposure pathway-specific values in a spatially layered data environment (e.g., source and receptor locations, concentrations at grid locations, etc.);
- Support the needed capacity (number of sources and contaminants) typically required of cumulative-type studies conducted at a high level of resolution;
- Provide custom visual displaying of interim and final results in traditional (tabular, etc.) and mapped (isopleths, spatial attributes, etc.) formats; and
- Link results directly to source attributes to support solution consideration, implementation, and tracking.

For more information on the RAIMI Risk-MAP, see:
http://www.epa.gov/Arkansas/6pd/rcra_c/raimi/raimi.htm.

Another Tool in the Toolbox: EPA's Human Exposure Model

EPA's Human Exposure Model (HEM) is another tool that can be used to generate risk results for multisource cumulative assessments. The HEM is available in two versions, HEM-Screen and HEM-3. Both versions model dispersion using EPA's ISC model and built-in meteorological data, calculate exposure concentrations for U.S. Census block internal points via interpolation, and generate risk and population outputs for the modeling region. HEM-Screen has lower input data requirements, a short run time, and incorporates a relatively simple dispersion algorithm that estimates only long-term average concentrations. By contrast, HEM-3 uses more advanced dispersion algorithms and more refined meteorological data that allow for more accurate dispersion modeling and both short- and long-term exposure outputs, but the input data requirements are greater, run time is longer, and there are limitations on the geographic scale that can be modeled. Although neither of the HEM versions can provide the level of refinement (including visual displays, source information, and other automated capabilities) that the RAIMI Risk-MAP provides, the HEM is a relatively non-resource-intensive option that analysts may want to consider, as long as they are aware of the limitations of HEM. *As with all aspects of risk assessment, it is important that the analyst use the appropriate tool for the questions that the assessment is addressing.* For more information on HEM, see:
http://www.epa.gov/ttn/fera/human_hem.html.

One of the important data quality objectives for risk characterization is the need to present multiple descriptors of risk, given the likely *distribution* of exposure for the study area population. Except where these descriptors clearly do not apply, all Agency risk assessments are expected to address or provide descriptions of:

- **Individual Risk (central tendency** and **high-end** estimates of individual risk and hazard). Such measures are intended to give a sense of the risks posed to a typical individual in the community as well as more highly exposed individuals. Specifically, the **central tendency estimate** might describe the exposure and risk experienced by people in the community with average exposures to air toxics. One way to do this is to rank order all the risk values calculated across all modeling nodes in the study area and use the 50th percentile value as the measure of central tendency. Another method is to identify the arithmetic average of all calculated risks. There is no prescribed way of representing the "average person" and risk managers will often find it helpful to see several different ways of representing central tendency.

> **MIR and MEI -**
> **What Do These Terms Mean?**
>
> **Maximum Individual Risk (MIR) -** An MIR represents the highest estimated risk to an exposed individual in areas that people are believed to occupy.
>
> **Maximum Exposed Individual (MEI) -** The MEI represents the highest estimated risk to an exposed individual, regardless of whether people are expected to occupy that area.
>
> These concepts are discussed more fully in EPA's *Residual Risk Report to Congress* (http://www.epa.gov/ttn/oarpg/t3/reports/risk_rep.pdf).

The **high-end** estimates of individual risk and hazard are intended to give a sense of the risk that is expected to occur for individuals in the upper range of risk values across the study area (e.g., risk at the 90th or 95th percentile of risk across the study area). The intent is to "convey an estimate of risk in the upper range of the distribution, but to avoid estimates which are beyond the true distribution."[(6)] Similar, but slightly different, concepts are the MIR and MEI (see text box). If air quality modeling is performed only at census tract (or block) internal points, the internal point with the highest concentration may be used to describe the exposure scenario with the highest risk. (Note that these various risk metrics can be presented in a variety of ways, such as individual values, individual values with uncertainty bounds, or probabilistic distributions. The method chosen to describe the results depends on the information needs of the end user and the ability of the analyst to develop the data to describe the variability and uncertainty associated with the exposures. This topic is discussed in Section 6.4.)

- **Population Risk (e.g., the number of people at different risk and hazard levels).** These measures are particularly important for risk managers because they answer the broad question "are many people at high risk, or only a few?" For example, the analyst might decide to select risk bins (e.g., Bin 1 includes all people with a risk below 1E-06, Bin 2 includes all people with a risk of 1E-06 to 1E-05, etc.) and determine the numbers of people in each bin. The populated bins could then be displayed as a bar graph (see Exhibit 6-2).

- **Sensitive Subpopulations.** In its risk assessments and risk characterizations, the EPA attempts to identify the universe of people that may be affected, including potentially sensitive populations (e.g., children, ethnic groups, or people of a given age, gender, nutritional status, or genetic predisposition).[(b)] Accordingly, in the planning and scoping phase of the risk assessment process, the potential for higher exposures or for other increased susceptibility to adverse effects among some populations should be noted. Any potentially

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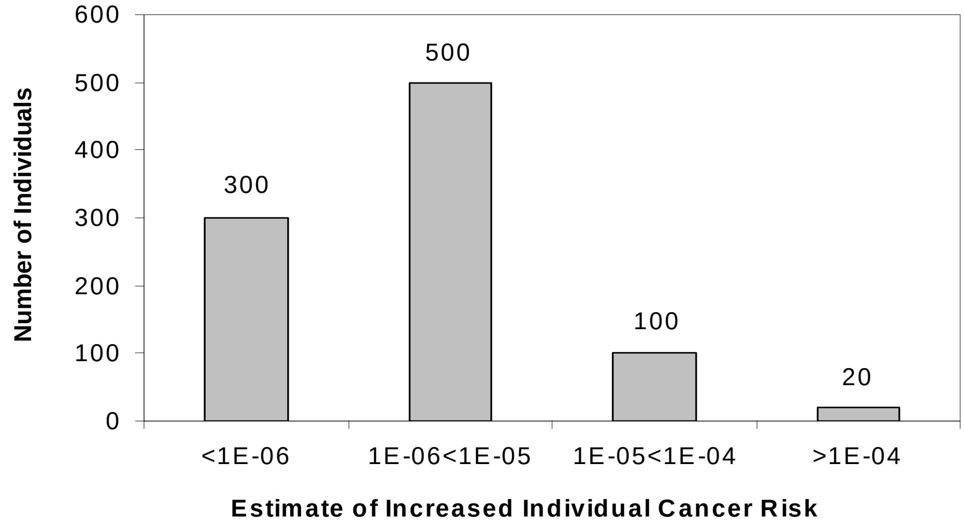
[b] Two terms that are related to sensitive populations are susceptibility and susceptible subgroups. The term susceptibility is used to mean an increased likelihood of an adverse effect over that of the general population, and susceptible subgroups are those population subgroups with the susceptibility. The subgroups may be described by demographic features which contribute to the susceptibility, such as age, gender, race, socioeconomic status, and including pre-existing medical conditions, genetic characteristics, etc. Diet can also be an important feature of susceptibility, particularly with respect to tribes.

Exhibit 6-2. Example Description of Population Risk Estimates



sensitive populations that are identified should be evaluated in the risk assessment, and the assessment should contain an appropriate characterization.[c] It may not be necessary or possible to do a quantitative risk assessment on each one. For instance, where there are many sensitive population groups for a given pollutant, it may be sufficient to estimate risks for the most sensitive group, with the idea that as long as they are protected by the associated risk management action, other groups may be protected adequately.

While all potentially sensitive populations need to be considered, Executive Order 13045 entitled "Protection of Children from Environmental Health Risks and Safety Risks" (http://www.epa.gov/fedrgstr/eo/eo13045.pdf) and the Administrator's "Policy on Evaluating Health Risks to Children" (http://bronze.nescaum.org/committees/aqph/memohlth.pdf) specifically require that EPA risk assessments, risk characterizations, and environmental and public health standards characterize health risks to infants and children, as appropriate. In addition, the Agency has issued specific guidance for rule writers about how to address children's risk pursuant to Executive Order 13045. This is found in the "EPA Rule Writer's Guide to Executive Order 13045" issued as interim final guidance in April 1998 (http://yosemite.epa.gov/ochp/ochpweb.nsf/content/rrguide.htm/$File/rrguide.pdf).

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[c] Note that the EPA's traditional dose-response tools for air toxics (e.g., inhalation reference concentration and inhalation unit risk for cancer) are derived with consideration of potentially susceptible subgroups. For example, the derivation of a reference concentration typically incorporates specific factors to account for sensitive subgroups. Accordingly, proper use of these tools will usually provide risk metrics that account for any subpopulations with increased susceptibility. The exposure assessment (and subsequent risk characterization), however, will need to include consideration of any subpopulations that have different exposures than the general population. (For inhalation exposures, evaluating different types of people within a population is usually done by applying an exposure model – see ATRA, Volume 1, Section 11.3.) An important document that can provide guidance in this area is EPA's *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants* (2005), which can be found at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=146583.

6.2.2 Presenting Risk Results

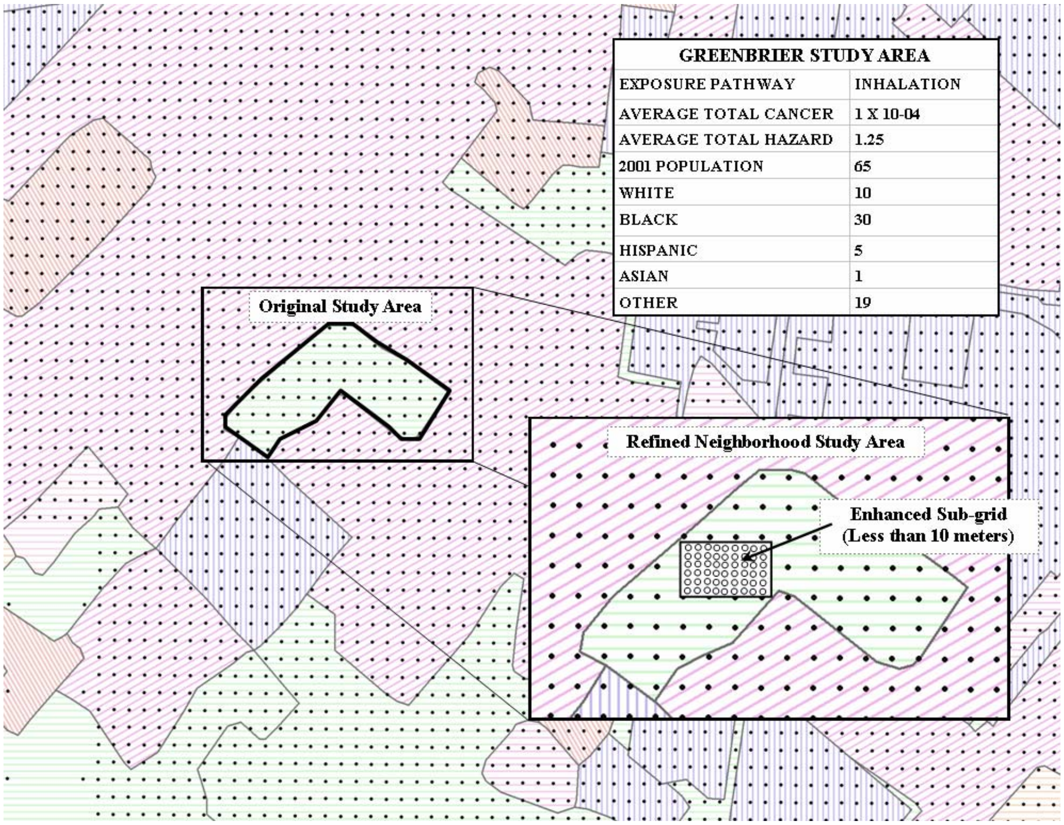
Different graphical presentations can help to effectively convey the risk characterization results to the risk management team members and others in ways particularly suited to the goals and purpose for the overall analysis. Pie charts, bar charts, tabular formats, and other methods that show risk contributions of different sources can be used. Presentation using GIS formats is particularly useful.

For example, the RAIMI Risk-MAP tool can be used to depict both the risk across the study area as a whole or can zoom in to display what is predicted at smaller geographic scales. Exhibit 6-3 illustrates how an analyst has used this tool to focus on one specific neighborhood (Greenbriar) for emphasis. The dots represent the modeling nodes across the neighborhood and the risk results have been highlighted in a box to the side. For this neighborhood, the analyst has decided to display the average risk (i.e., the average risk and hazard across all the modeling nodes) along with relevant demographic data. The analyst could have chosen to display information for this neighborhood in a number of other ways, including information about risk variation across the modeling nodes (e.g., highest to lowest) or providing risk estimates for different segments of the population (e.g., if an exposure model has been used). The way in which the analyst chooses to display the information will depend on the message that is trying to be communicated.

Another important method for displaying risk is graphic presentation of risk "isopleths" to represent study area potential risk gradients. However, analysts need to carefully consider how to select "breaks" in the data (e.g., what risk value they will use to show contour lines) since it is easy to create different impressions about the meaning of the data depending on the way the data breaks are chosen. When using this type of presentation format it is particularly important to clarify there is no risk without the presence of people and a completed exposure pathway. In other words, depicting an isopleth implies risk at every point within the contour lines. It is only when people are present and contacting contaminated air, however, that risk is actually a possibility. Further, the risk shown is particular to the exposure conditions assumed in the analysis. **This is another reminder that it is important to clearly describe assumptions, limitations and uncertainties accompanying such graphical representations in order to convey the intended message and to avoid being misunderstood.** An example of a figure depicting risk isopleths is provided in Exhibit 6-4.

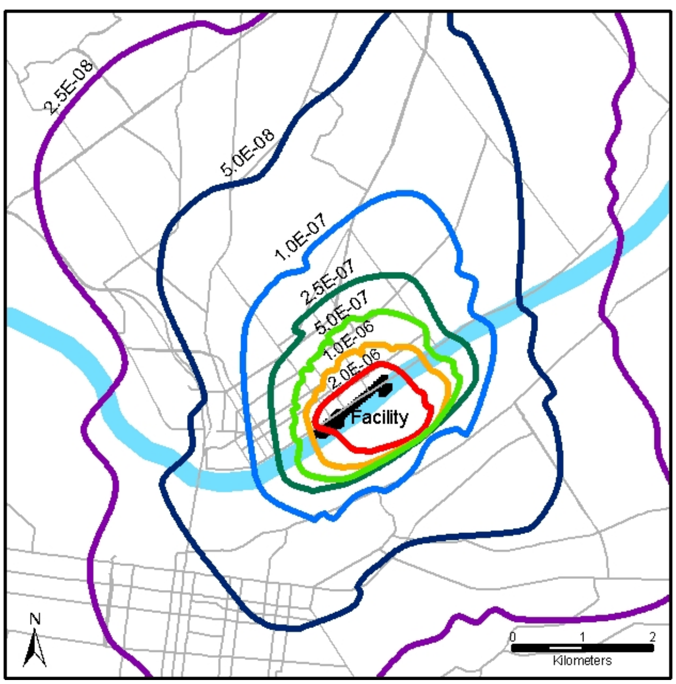
If background concentrations were included as a "source" of air toxics during the risk characterization, a bar chart is usually the most appropriate way to represent their contribution to the overall risk estimate for a study area. Specifically, the background risk is depicted along side the risk attributable to the local source(s) being evaluated (see Exhibit 6-5). It generally is not appropriate to subtract background exposures from exposures associated with local sources because background concentration information is typically limited and may be unrepresentative of all external air contaminants influencing the study area.

Exhibit 6-3. Example Depiction of Average Risk within a Subarea of a Larger Study Area



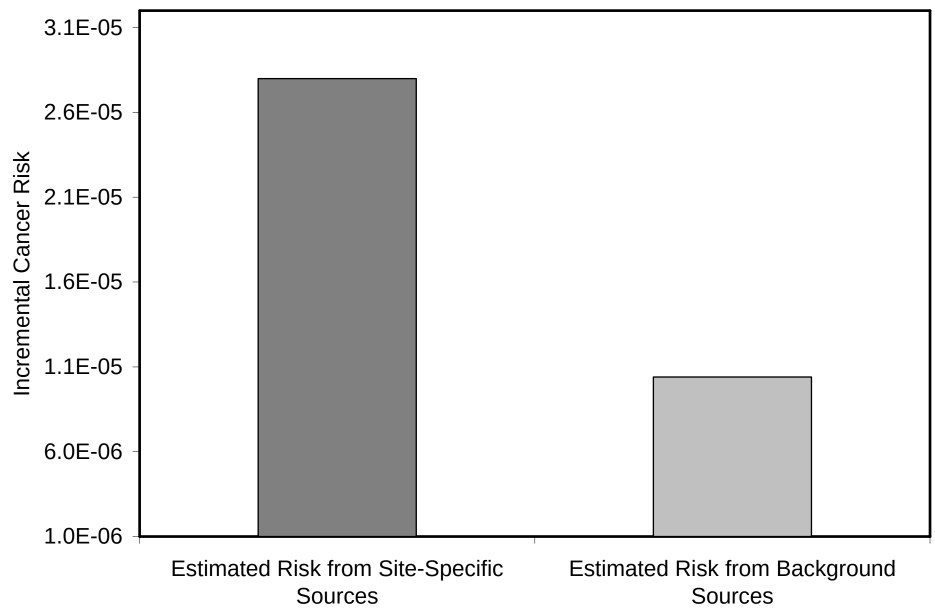
Source: EPA's *Regional Air Impact Modeling Initiative (*see: http://www.epa.gov/Arkansas/6pd/rcra_c/raimi/raimi.htm.

Exhibit 6-4. Example Display of Risk Across a Study Area Using Isopleths



In this example, estimated individual lifetime cancer risk has been estimated for a study area based on modeled ambient air concentrations in the vicinity of a single facility. (See Exhibit 6-9 for an example of isopleths resulting from multiple sources simultaneously impacting an area.)

Exhibit 6-5. Example Comparison of Risk Estimates from Study-Specific and Background Sources



In this example, the estimated risk from the specific sources being evaluated a modeling study (2.8×10^{-5}) and the estimated risk from background sources (1.0×10^{-5}) using upwind monitoring are compared side-by-side. This places the risk estimates from the sources of concern in an appropriate regional context. Note that an individual's total inhalation risk is due to both air contaminants released from all sources impacting the study area (both those in the study area and those more distant). Depending on the situation, risk managers may or may not include background concentrations in the decision making process.

6.3 Identifying Risk Contributors (Source Apportionment)

Once the risk characterization has been performed, a natural follow-on question (particularly if the risk managers indicate the risks are unacceptably high) is to identify the sources and chemicals that are responsible for the majority of the risk, a technique known as **source apportionment analysis**. When ambient concentrations are used as a surrogate for exposure concentrations, the general approach is to work backwards from the ambient concentrations developed in the air dispersion modeling step at points where the risk is unacceptably high.

Specifically, this approach uses the results of an air dispersion model to estimate the relative contribution of each source (or source category) to the ambient concentration estimate at each modeling location of concern. The basic approach conceptually includes the following steps:

- Identify the locations at which source apportionment will be performed (usually selected modeling nodes, groups of modeling nodes, and any special receptors);
- Use an air dispersion model (e.g., ISCST3) estimate of ambient concentrations of each chemical at each location for each source (or source category);
- Sum the ambient concentrations for each chemical at each location; and
- Calculate the percentage contribution of each source to the predicted ambient concentration.

In an assessment in which the exposure concentration is set equal to the ambient concentration and the same exposure scenario is assumed at all locations, the percent of the ambient concentration for a given chemical contributed by a particular source corresponds to the percent risk potentially posed by that chemical from that source at that point.

The results of source apportionment analyses can be presented in a number of ways, including tabular formats (e.g., Exhibit 6-6), bar or pie charts, and GIS overlays. The use of bar charts or pie charts is a particularly simple, effective way to communicate the relative contribution of sources to exposure concentrations or estimated risk (Exhibit 6-7). The height of a bar or size of each "slice" of the pie is proportional to the relative contribution of each source. This technique is most effective when the total number of sources is relatively small.

Additional spatial and temporal details of individual source contributions can be illustrated using GIS overlays (e.g., ambient concentration contribution depicted using the RAIMI tool Risk–MAP). Exhibit 6-8 shows one way to depict the contribution of sources to emissions in the study area (tons per year of a chemical released) while Exhibit 6-9 illustrates how different sources contribute to the cumulative risk (as risk isopleths) across a study area.

Keep in mind that in a multisource cumulative assessment, analysts will typically be apportioning risk among many chemicals emitted from large and small businesses, mobile sources, and other potential sources. Depending on the site-specific circumstances, any of these chemicals or types of sources may be the main risk driver. In other cases, there may be no one particular chemical or source that is the primary contributor to an area's risk.

Source Apportionment Using Monitoring Data

In addition to using air dispersion modeling results to apportion air concentrations among sources, air monitoring data may also sometimes be used. In limited cases, a fairly straightforward analysis of source contribution might be made through evaluation of concentration, time of measurement, meteorological conditions, and other information. More commonly, a process such as *receptor modeling* would need to be used for determining the quantitative impact of a particular air-pollution source on ambient air quality (as measured by a monitoring device). Receptor modeling seeks to avoid the detailed knowledge of emissions inventories and meteorology that is necessary to apply dispersion modeling, the traditional method of predicting the air-quality impact of identifiable sources. Classical receptor models are conservative in nature, so that pollutant species which reach the receptor site are assumed to have been emitted in the same chemical form by a source. More information on receptor modeling can be found at: http://www.epa.gov/scram001/tt23.htm.

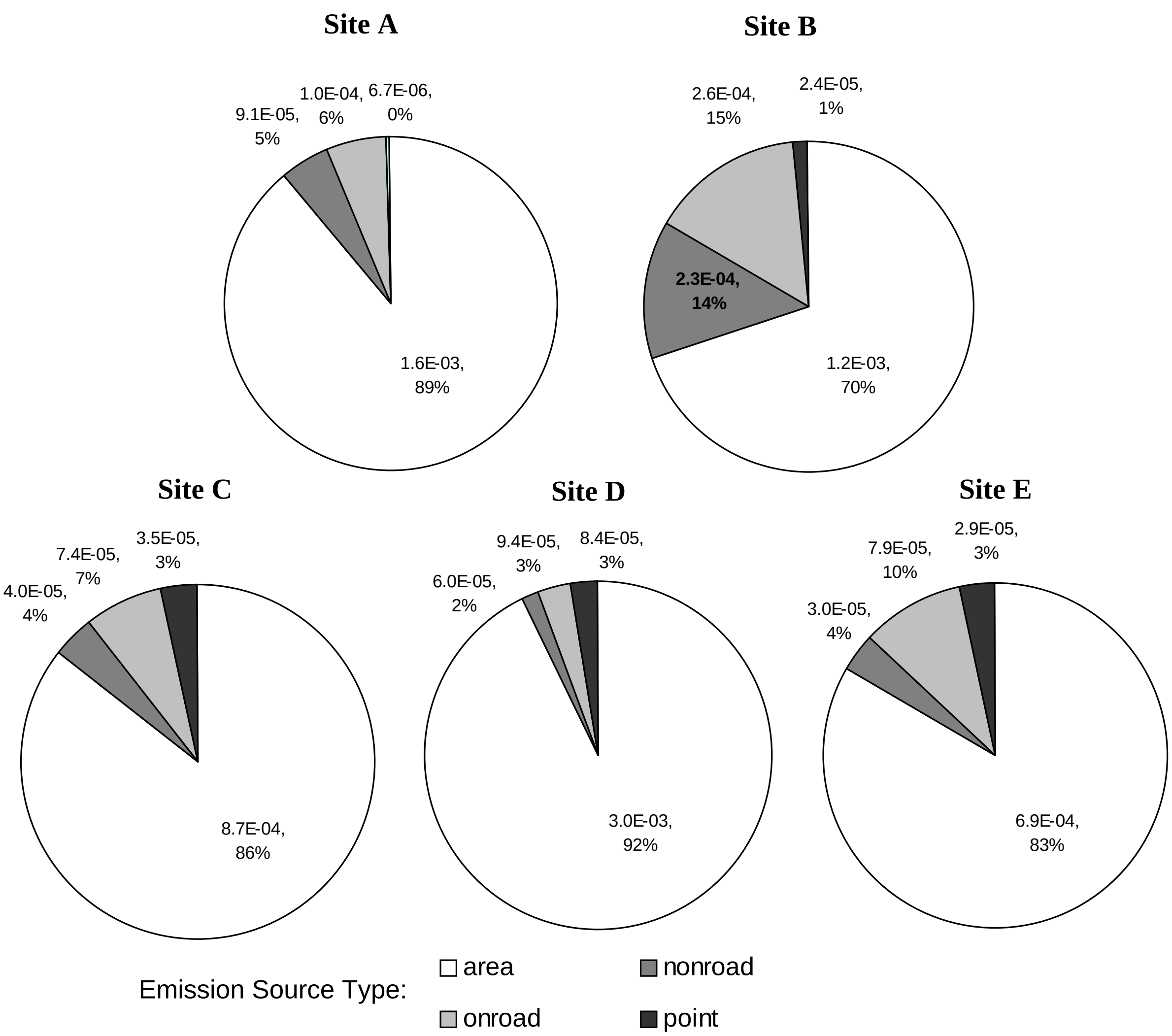
Exhibit 6-6. Example Source Apportionment Profile of 1,3-Butadiene Emissions and Risk-Based Prioritization at a Location of Predicted Maximum Impact In the Happydale Neighborhood

	Source Description	Permit Status	Source-Specific Percentage of Pathway Risk Estimate	Cancer Risk Estimate	Chronic Hazard Quotient Estimate
1	*Big Air Corporation, Wastewater JWWDP Blending Station #B4-14* FIN: JWB14 EPN: JWB14	G	23.5%	1×10^{-4}	0.1
2	*Big Air Corporation, Wastewater JWWDP Neutralization Basin #B-16* FIN: JWB16 EPN: JWB16	G	14.9%	7×10^{-5}	0.07
3	*Big Air Corporation, South B.D.E. Equipment Fugitives* FIN: BDFUGS EPN: BDFUGS	P	12.4%	6×10^{-5}	0.06
4	*Big Air Corporation Inventory Name: Fugitives* EPN: C4FU	UN	6.9%	4×10^{-5}	0.04
5	*Big Air Corporation Wastewater JWWTP Primary Clarifier #C*-6 FIN: JWC6 EPN: JWC6	G	6.8%	3×10^{-5}	0.04
Etc.	All Other Modeled Sources • 22 Individual and 14 Grouped Sources • 7 of these individual sources resulted in risk exceeding $1\text{x}10^{-5}$ (The remaining rows in this table would provide similar information to rows 1-5 above)	NA	35.4%	2×10^{-4}	0.2
		Total	**100.0%**	**5×10^{-4}**	**0.5**

Notes: Values in this Exhibit are presented for example purposes only and do not represent an actual facility. Totals may vary due to rounding.

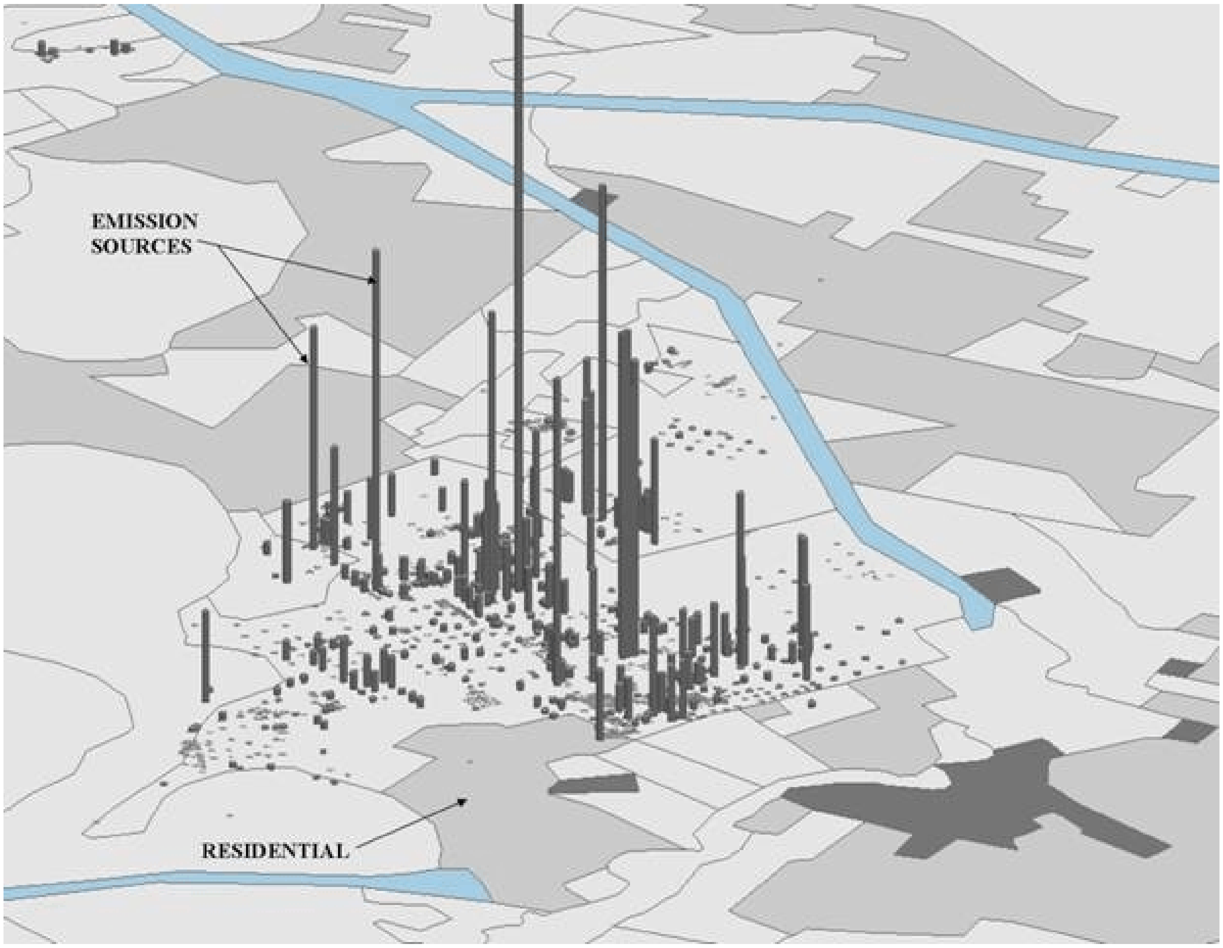
EPN: Emission Point Number
FIN: Facility Identification Number
G: Grandfathered Source
P: Permitted Source
NA: Not Applicable-grouped source category
UN: Unknown

Exhibit 6-7. Example Use of Pie Charts to Illustrate Source Contribution



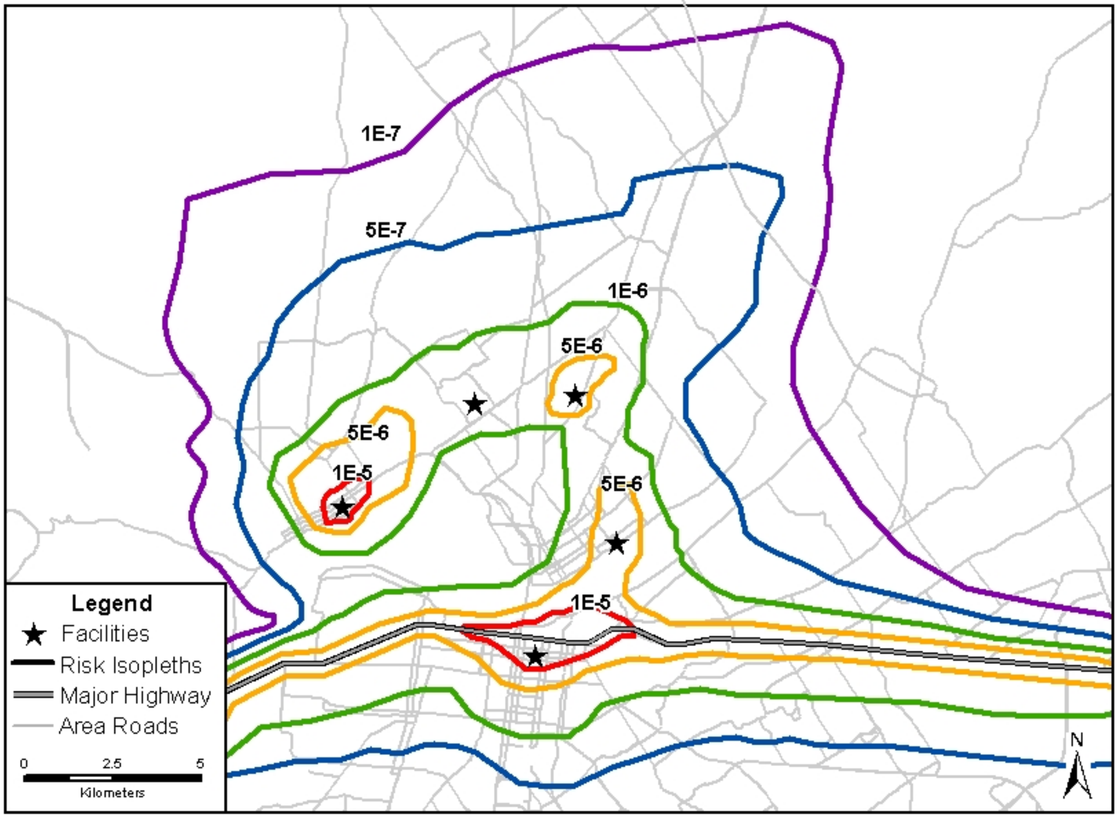
These pie charts indicate the estimated relative emission source contributions to ambient nickel concentrations at five locations in a hypothetical assessment area. The size of each "slice" is proportional to the relative amount (percent of total estimated concentration at a given site) of nickel attributable to each individual source type (e.g., area, onroad), with the concentration and percentage contribution shown for each source type. Note that similar plots could be used for cancer risk estimates (e.g., contribution of each source to total estimated individual cancer risk).

Exhibit 6-8. Tons per Year of Chemical X Released, by Source



Source: EPA's *Regional Air Impact Modeling Initiative* (see: http://www.epa.gov/Arkansas/6pd/rcra_c/raimi/raimi.htm).

Exhibit 6-9. Example of Cumulative Estimated Risk Isopleths from All Modeled Sources for a Hypothetical Study Area



This example illustrates cancer risk isopleths from the combined impact (all air toxics, all sources) of study-area stationary sources (major and area sources). The mobile sources were modeled two different ways. The study-area secondary roads were modeled by allocating mobile emissions uniformly across the study area. This allows the addition of the secondary road impacts to the overall cumulative risk. However, by allocating the emissions evenly over the entire study area, the detail of impacts in the immediate vicinity of any particular secondary road is lost. The major highway in the lower part of the figure, on the other hand, was modeled as a "linked source" [i.e., breaking the length of the highway up into short segments (links) and modeling each segment as an individual source]. This allows the analyst to provide additional detail about the risk posed in the immediate vicinity of that one roadway.

6.4 Characterization of Assumptions, Limitations, and Uncertainties

> **Some Sources of Uncertainty**
>
> - **Scenario uncertainty.** Information to fully define exposure or risk is missing or incomplete
> - **Model uncertainty**. Algorithms or assumptions used in models may not adequately represent reality
> - **Parameter uncertainty**. Values for model parameters cannot be estimated precisely
> - **Decision-rule uncertainty**. Policy and other choices made during the risk assessment may influence risk estimates

Multisource cumulative assessments make use of many different kinds of scientific concepts and data (e.g., in the areas of chemistry, engineering, meteorology, environmental fate and transport, exposure assessment, toxicology, epidemiology, etc.), all of which are used to characterize the expected risk in a particular environmental context. However, pertinent information may or may not be available for many aspects of a risk assessment. Where such information is lacking, the risk assessment framework recognizes the need to employ assumptions or surrogates. In addition, the information used may rely on a variety of professional and science policy judgments (e.g., which models to use, where to locate monitors, which toxicity studies to use as the basis of developing dose-response values). In other words, uncertainty is inherent in the risk assessment process.

The assessment team needs to understand these strengths and the limitations in each assessment, and to be explicit in communicating this information to decision makers and the larger community. They will do this uncertainty analysis during the risk characterization process. Specifically, they will perform an evaluation and presentation of the assumptions, limitations, and uncertainties inherent in the risk assessment. It is critical that this evaluation be thorough and thoroughly explained in order to place the risk estimates in proper perspective.

6.4.1 Documentation of Assumptions

During the course of a risk assessment, a number of assumptions may have been made and used in the development and analysis of the conceptual model, particularly when significant data gaps exist that require a parameter value for the risk assessment to proceed. For example, meteorological data for a specific neighborhood may not have been available so analysts decided to use data from a nearby airport instead. Based on an understanding of the local meteorology, the analysts may have assumed that the airport data was sufficiently representative of the study area to use without question.

All major assumptions made throughout the analysis should be thoroughly documented. Readers of the final report should be able to understand why an assumption had to be made, how it was made, why the assumption was appropriate for the analysis at hand, and the potential influence of the assumption on the final risk estimates.

Transparency, Clarity, Consistency, and Reasonableness (TCCR) – Transparency

The previously noted EPA Risk Characterization Policy states that "A risk characterization should be prepared in a manner that is clear, transparent, reasonable, and consistent with other risk characterizations of similar scope prepared across programs in the Agency." Risk characterization is therefore judged by the extent to which it achieves the principles of **T**ransparency, **C**larity, **C**onsistency, and **R**easonableness (TCCR).

What Are Criteria for Transparency?

Transparency provides explicitness in the risk assessment process. It ensures that any reader understands all the steps, logic, key assumptions, limitations, and decisions in the risk assessment, and comprehends the supporting rationale that lead to the outcome. Transparency achieves full disclosure in terms of :

- The assessment approach employed;
- The use of assumptions and their impact on the assessment;
- The use of extrapolations and their impact on the assessment;
- The use of models vs. measurements and their impact on the assessment;
- Plausible alternatives and the choices made among those alternatives;
- The impacts of one choice vs. another on the assessment;
- Significant data gaps and their implications for the assessment;
- The scientific conclusions identified separately from default assumptions and policy calls;
- The major risk conclusions and the assessor's confidence and uncertainties in them; and
- The relative strength of each risk assessment component and its impact on the overall assessment (e.g., the case for the agent posing a hazard is strong, but the overall assessment of risk is weak because the case for exposure is weak).

Transparency is the principal value among the four TCCR values, because, when followed, it leads to clarity, consistency and reasonableness.

(Other aspects of the TCCR principles are provided in text boxes below.)

Source: EPA's Risk Characterization Policy, which can be found in Appendix A of the following document: http://epa.gov/osa/spc/htm/rchandbk.pdf.

6.4.2 Documentation of Limitations

At the end of the risk characterization, the assessors will have developed both quantitative and qualitative expressions of risk. It is important for the analysts to carefully articulate any important limitations associated with those values. For example, if the risk characterization is performed at the county-level, the results should only be used to make statements about risks at the county-level (i.e., it might be inappropriate to try and extrapolate the results to a finer geographic resolution). As another example, if small, diffuse sources are evaluated in the aggregate, then it might not be possible to draw any conclusions about individual sources in specific locations.

6.4.3 Analysis and Documentation of Uncertainty

> **TCCR – Clarity**
>
> **What Are Criteria for Clarity?**
>
> Clarity refers to the risk assessment product(s). Making the product clear makes the assessment free from obscurity and easy to understand by all readers inside and outside of the risk assessment process. Clarity is achieved by:
>
> - Brevity;
> - Avoiding jargon;
> - Using plain language so it's understandable to EPA risk managers and the informed lay person;
> - Describing any quantitative estimations of risk clearly;
> - Using understandable tables and graphics to present the technical data; and
> - Using clear and appropriate equations to efficiently display mathematical relationships (complex equations should be footnoted or referred to in the technical risk assessment).

Uncertainty, within the context of the risk assessment process, is defined as "a lack of knowledge about specific factors, parameters, or models."[(7)] When applied to the results of a risk assessment, the term "uncertainty" refers to the lack of accuracy in the risk estimate due to unknown values or unavoidable errors in the input assumptions, models and parameter values. Accordingly, one of the key purposes of uncertainty analysis is to provide an understanding of where the estimate of exposure and risk falls within the range of possible values.

There are numerous sources of uncertainties in multisource cumulative assessments, and each merits consideration in the risk characterization step. The degree to which these sources of uncertainty need to be quantified, and the amount of uncertainty that is acceptable, varies considerably from study to study. For a simple screening-level analysis, conservative simplifying assumptions may be used to bias the risk estimate high, but at the expense of certainty that the result is at or near the actual risk posed by the air toxics exposures (i.e., the use of conservative assumptions is intended to result in a health-protective estimate where the risk assessor is confident that the actual risk posed by air toxics exposures is unlikely to be *greater* than the conservative estimate of risk). When the cost to fix an apparent problem is high, this level of uncertainty might not be acceptable.

The uncertainty characterization for many analyses is commonly limited to a qualitative discussion of the major sources of uncertainty and their potential impact on the risk estimate. When the risk manager needs a refined understanding of the uncertainties associated with the risks, sensitivity analysis or other quantitative approaches may be performed to more fully describe the uncertainties associated with the analysis. Specifically, there are two generally used approaches for tracking uncertainty through the risk assessment:

- ***Qualitative Approach.*** In simpler approaches to uncertainty analysis, the assessment uncertainties may be expressed as qualitative statements or even as a subjective confidence interval within which there is a high probability that the true risk will fall.

- ***Quantitative Approach.*** There are several quantitative approaches that can be employed to try to get a more firm handle on the various uncertainties inherent in an assessment. One straightforward approach for expressing uncertainty (particularly for a given parameter) is a

TCCR – Consistency

What Are Criteria for Consistency?

Consistency provides a context for the reader and refers to the presentation of the material in the risk assessment. For example, are the conclusions of the risk assessment characterized in harmony with relevant policy, procedural guidance, and scientific rationales, and if not, why the conclusions differ. Also, does the assessment follow precedent with other EPA actions or why not. However, consistency should not encourage blindly following the guidance for risk assessment and characterization at the expense of stifling innovation. Consistency is achieved by:

- Following statutory requirements and program precedents (e.g., guidance, guidelines, etc.);
- Following appropriate Agency-wide assessment guidelines;
- Using Agency-wide information, where appropriate, from systems such as the Integrated Risk Information System (IRIS);
- Putting the risk assessment in context with other similar risk assessments;
- Defining and explaining the purpose of the risk assessment (e.g. regulatory purpose, or policy analysis, or priority setting, etc.);
- Defining the level of effort (e.g. quick screen, extensive characterization) put into the assessment and the reason(s) why this level of effort was selected; and
- Following established Agency peer review procedures.

"sensitivity analysis." This approach is used to ascertain how much the risk estimate would change as a result of a change to the values of the various input parameters (e.g., emission rate, degradation rate, exposure frequency, etc.). If a small change in a parameter results in relatively large changes in the risk outcomes, the outcomes are said to be sensitive to that parameter (see reference 3). A finding of great sensitivity to a parameter for which the assigned value is highly uncertain may lead to the risk assessment team trying to collect additional information for that parameter so as to provide a sounder base for the value chosen (thus increasing the confidence in the resulting risk estimate). More comprehensive uncertainty analyses may also be considered depending on the needs for the assessment (see below).

When a more thorough investigation of uncertainty (and variability) is necessary, more advanced techniques such as probabilistic techniques (e.g., Monte Carlo simulation analysis) can be used. Using these techniques, important variables (typically those in the exposure assessment) are specified as distributions (rather than as single values) according to what can be expressed about their underlying variability and/or uncertainty. Values are sampled repeatedly from these distributions and combined in the analysis to provide a range of possible outcomes. While this technique can offer a useful summary of complex information, it must be noted that the analysis is only as certain as the underlying data. It is important that the risk assessor clearly expresses individual modeled variables in a way that is consistent with the best information available. While quantitative statistical uncertainty analysis is usually not practical for most multisource cumulative assessments (see Exhibit 6-10), it is nevertheless important that all assessments identify those assessment components for which additional information will likely lead to improved confidence in the estimate of exposure and risk.

TCCR – Reasonableness

What Are Criteria for Reasonableness?

Reasonableness refers to the findings of the risk assessment in the context of the state-of-the science, the default assumptions and the science policy choices made in the risk assessment. It demonstrates that the risk assessment process followed an acceptable, overt logic path and retained common sense in applying relevant guidance. The assessment is based on sound judgment. Reasonableness is achieved when:

- The risk characterization is determined to be sound by the scientific community, EPA risk managers, and the lay public, because the components of the risk characterization are well integrated into an overall conclusion of risk which is complete, informative, well balanced and useful for decision making;
- The characterization is based on the best available scientific information;
- The policy judgments required to carry out the risk analyses use common sense given the statutory requirements and Agency guidance;
- The assessment uses generally accepted scientific knowledge; and
- Appropriate plausible alternative estimates of risk under various candidate risk management alternatives are identified and explained.

Exhibit 6-10. When To Perform a Quantitative Uncertainty Analysis

Quantitative uncertainty analysis is NOT recommended when:

- Conservative, screening-level calculations indicate that the risk from potential exposure is clearly below regulatory or other risk levels of concern;
- The cost of an action to reduce exposure is low; and/or
- Data for characterizing the nature and extent of contamination or exposure are inadequate to permit even a bounding estimate (an upper and lower estimate of the expected value).

Quantitative uncertainty analysis IS recommended when:

- An erroneous result in the exposure or risk estimate may lead to large or unacceptable consequences;
- It is important to understand where a screening-level or point estimate of exposure or risk falls within a range of estimates based on adequate supporting data and credible assumptions; and/or
- It is important to identify those assessment components for which additional information will likely lead to improved confidence in the estimate of exposure or risk.

Source: Adapted from NCRP (1996).[8]

What About Variability in a Multisource Cumulative Assessment?

Variability refers to true heterogeneity or diversity that occurs within a population or sample. Factors that lead to variability in exposure and risk include variability in contaminant concentrations in an environmental medium (e.g., air, water, soil) and differences in other exposure parameters such exposure frequencies.

Temporal and spatial variability in contaminant concentrations is often a very important aspect to consider in multisource cumulative assessments. Spatial variability arises from many factors, including the release forms, physical and chemical dilution and transformation processes, and physical characteristics of the source or surrounding environment. Ecological receptors and humans may exhibit spatial variability in their contact with an exposure medium. Likewise, temporal variability can result from a variety of factors. For example, a source may only emit a chemical at specific times during the year (e.g., during the processing of a batch of product). Meteorological changes between seasons also can cause variable exposure (even though source emissions remain relatively constant). Because variability is an intrinsic property of the quantities being evaluated, it cannot be reduced by data gathering or refinements in models. However, understanding and/or analysis of variability are still important, especially during problem formulation.

Additional discussion of variability in risk assessment is provided in ATRA Volume 1, Chapter 3.

Note that probabilistic analyses and higher levels of uncertainty analysis require special expertise. Accordingly, the way in which uncertainty will be characterized for the assessment should be considered in developing the analysis plan and forming the risk assessment team. Additional discussions of uncertainty analysis, including practical approaches to the assessment and presentation of the principal sources of uncertainty in risk assessments are provided in ATRA Volume 1, Chapters 3 (Section 3.4) and 13, and other documents including the *Residual Risk Report to Congress* (see reference 3); the EPA Risk Assessment Forum's *Guiding Principles for Monte Carlo Analysis* (see reference 7), NARSTO's Improving Emission Inventories for Effective Air Quality Management Across North America (Chapter 8, Appendix C)[9], and the National Research Council's Science and Judgement in Risk Assessment (Chapter 9).[10]

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10. National Research Council. 1994. *Science and Judgement in Risk Assessment*. National Academy Press. Washington, D.C.