
CHAPTER 9

DOCUMENTATION, REVIEW, AND MANAGEMENT TOOLS FOR THE ASSESSOR, REVIEWER, AND MANAGER

This chapter provides tools for the documentation, review, and management of the baseline risk assessment. These tools will help ensure completeness and consistency throughout the risk assessment and in the reporting of assessment results. Section 9.1 provides documentation tools (for risk assessors), Section 9.2 provides review tools (for risk assessment reviewers), and Section 9.3 provides management tools (for remedial project managers [RPMs] and other decision-makers concerned with the site).

9.1 DOCUMENTATION TOOLS

Throughout Chapters 4 to 8 of this manual, guidance is provided to the risk assessor on how to summarize and document many beginning, intermediate, and final steps of the risk assessment. The purpose of this section is to consolidate that guidance, provide a final check to ensure that all appropriate documentation has been completed, and provide additional information that should be helpful. This section addresses (1) basic principles of documenting a Superfund site risk assessment (e.g., key "dos" and don'ts", the rationale for consistency), (2) a suggested outline and guidance for the risk assessment report, and (3) guidance for providing risk assessment summaries in other key reports.

9.1.1 BASIC PRINCIPLES

There are three basic principles for documenting a baseline risk assessment:

- (1) address the main objectives of the risk assessment;
- (2) communicate using clear, concise, and relevant text, graphics, and tables; and
- (3) use a consistent format.

Addressing the objectives. The objectives of the baseline risk assessment -- to help determine whether additional response action is necessary at the site, to provide a basis for determining residual chemical levels that are adequately protective of public health, to provide a basis for comparing potential health impacts of various remedial alternatives, and to help support selection of the "no-action" remedial alternative (where appropriate) -- should be considered carefully during the documentation of the risk assessment. Recognizing these objectives early and presenting the results of the risk assessment with them in mind will assist the RPM and other decision-makers at the site with readily obtaining and using the necessary information to evaluate the objectives. Failing to recognize the importance of the objectives could result in a risk assessment report that appears misdirected and/or unnecessary.

Communicating. Clearly and concisely communicating the relevant results of the risk assessment can be one of the most important aspects of the entire RI/FS. If done correctly, a useful instrument for mitigating public health threats will have been developed. If done incorrectly, however, risks could be underemphasized, possibly leading to the occurrence of adverse health effects, or they could be overemphasized, possibly leading to the unnecessary expenditure of limited resources. See

the box below for some helpful hints on communicating the baseline risk assessment.

HELPFUL HINTS: COMMUNICATING THE BASELINE RISK ASSESSMENT

Try to:

- use a mix of well written text, illustrative graphics, and summary tables;
- explain the major steps and the results of the risk assessment in terms easily understood by the general public (and especially by members of exposed or potentially exposed populations);
- define highly technical terms early (e.g., in a glossary); and
- use a standard quantitative system -- preferably the metric system -- throughout and units that are the same where possible (e.g., ug/L for all water concentrations).

Avoid:

- the use of large blocks of text unbroken by any headings, graphics, tables, lists, or other "visual dividers";
- the presentation of much quantitative information within the text (rather than in tables); and
- the drawing of "risk management" conclusions (e.g., stating that the total or largest risk is insignificant).

Many skills for communicating the baseline risk assessment also can be learned by reviewing the literature on risk communication. The following box lists just some of the literature that is available. Courses on the subject also exist.

Using a consistent format. A consistent format for all Superfund risk assessments is strongly recommended for four important reasons:

- (1) it encourages consistency and completeness in the assessment itself;
- (2) it allows for easier review of the risk assessments;
- (3) it encourages consistent use of the

RISK COMMUNICATION GUIDANCE

Explaining Environmental Risk (EPA 1986)

Tools for Environmental Professionals Involved in Risk Communication At Hazardous Waste Facilities Undergoing Siting, Permitting, or Remediation (Bean 1987)

Improving Dialogue with Communities: A Short Guide for Government Risk Communication (NJDEP 1987)

Seven Cardinal Rules of Risk Communication (EPA 1988a)

results by RPMs and other decision-makers; and

- (4) it helps demonstrate to the public and others that risk assessments are conducted using the same framework (if not the same specific procedures).

Using other formats can lead to slower review times, different interpretations of similar results, and the charge that risk assessments are inappropriately being conducted differently from one site to another. The following subsections provide guidance on the use of consistent formats.

9.1.2 BASELINE RISK ASSESSMENT REPORT

The baseline risk assessment report references and supports the RI/FS report. Depending on the site, the risk assessment report can range from a small, simple document with no appendices that can simply be added to the RI/FS report as a chapter, to a large, complex document with many appendices that can "stand alone." This subsection provides general guidance on how to organize the baseline risk assessment report and which information should be included in the report. More detailed guidance, however, is found by following the guidance in previous chapters of this manual. Careful use of that guidance will ensure a well-documented baseline risk assessment report.

Exhibit 9-1 provides a suggested outline for the full baseline risk assessment report. This outline generally follows the flow of the risk assessment and the organization of this manual. The "bulleted" items are not necessarily section headings, but rather are often items that should be considered when writing the report. Note that, as with the manual, not all components of the outline are applicable to all sites. This is especially true if the risk assessment report will be a chapter in the RI/FS report. At some sites, and especially when the risk assessment report will be a stand-alone document, more site-specific items could be added to the report.

Examples of tables and graphics that should be included in the report are presented as exhibits in previous chapters of this manual. Note, however, that additional tables and graphics may be useful.

This suggested outline may be used as a review guide by risk assessors (and risk assessment reviewers) to ensure that all appropriate components of the assessment have been addressed. Section 9.2 addresses review tools in greater detail.

9.1.3 OTHER KEY REPORTS

Two important reports that must include summaries of the baseline risk assessment are (1) the remedial investigation/feasibility study (RI/FS) report and (2) the record of decision (ROD) report.

Summary for the RI/FS report. One of the chapters of the RI/FS typically is devoted to a summary of the baseline risk assessment. Part of this summary should address the human health evaluation (the other part should address the environmental evaluation). The human health summary should follow the same outline as the full baseline risk assessment report, with almost each section of the summary being a distillation of each full report chapter. The risk characterization chapter is an exception, however, in that it could be included in the RI/FS report essentially unchanged. Most tables and graphics should be included unchanged as well. For more information, see *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (EPA 1988b).

Summary for the ROD report. The ROD documents the remedial action selected for a site. It consists of three basic components: (1) a Declaration; (2) a Decision Summary; and (3) a Responsiveness Summary. The second component, a Decision Summary, provides an overview of the site-specific factors and analyses that led to the selection of the remedy. Included in this component is a summary of site risks. As with the risk assessment summary for the RI/FS report, the summary for the ROD report should follow the same outline as the full risk assessment. This summary, however, should be much more abbreviated than the RI/FS summary, although care must be taken to address all of the relevant site-specific results. For more information, see *Interim Final Guidance on Preparing Superfund Decision Documents: The Proposed Plan, the Record of Decision, Explanation of Significant Differences, and the Record of Decision Amendment* (EPA 1989).

9.2 REVIEW TOOLS

This section provides guidelines on reviewing a risk assessment report. A checklist of many essential criteria that should be adequately addressed in any good risk assessment is provided (Exhibit 9-2). The checklist touches upon issues that are often problematic and lead to difficulty and delay in the review of risk assessments. Principal questions are presented in the checklist with qualifying statements or follow-up questions, as well as references to appropriate chapters and sections of this manual. The checklist is intended as a guide to assist the preliminary reviewer by ensuring that critical issues concerning the quality and adequacy of information are not overlooked at the screening level review of risk assessments. Experience has shown that reviewers should pay particular attention to the following concerns.

- Were all appropriate media sampled?
- Were any site-related chemicals (e.g., human carcinogens) eliminated from analysis without appropriate justification?

EXHIBIT 9-1

SUGGESTED OUTLINE FOR A BASELINE RISK ASSESSMENT REPORT

1.0 INTRODUCTION

1.1 Overview

- General problem at site
- Site-specific objectives of risk assessment

1.2 Site Background

- Site description
- Map of site
- General history
 - Ownership
 - Operations
 - Contamination
- Significant site reference points
- Geographic location relative to offsite areas of interest
- General sampling locations and media

1.3 Scope of Risk Assessment

- Complexity of assessment and rationale
- Overview of study design

1.4 Organization of Risk Assessment Report

2.0 IDENTIFICATION OF CHEMICALS OF POTENTIAL CONCERN

2.1 General Site-specific Data Collection Considerations

- Detailed historical information relevant to data collection
- Preliminary identification of potential human exposure
- Modeling parameter needs
- Background sampling
- Sampling locations and media
- Sampling methods
- QA/QC methods
- Special analytical services (SAS)

2.2 General Site-specific Data Evaluation Considerations

- Steps used (including optional screening procedure steps, if used)
- QA/QC methods during evaluation
- General data uncertainty

2.3 Environmental Area or Operable Unit 1 (Complete for All Media)

- Area- and media-specific sample collection strategy (e.g., sample size, sampling locations)
- Data from site investigations

(continued)

EXHIBIT 9-1 (continued)

SUGGESTED OUTLINE FOR A BASELINE RISK ASSESSMENT REPORT

- Evaluation of analytical methods
- Evaluation of quantitation limits
- Evaluation of qualified and coded data
- Chemicals in blanks
- Tentatively identified compounds
- Comparison of chemical concentrations with background
- Further limitation of number of chemicals
- Uncertainties, limitations, gaps in quality of collection or analysis

2.4 Environmental Area or Operable Unit 2 (Repeat for All Areas or Operable Units, As Appropriate)

2.X Summary of Chemicals of Potential Concern

3.0 EXPOSURE ASSESSMENT

3.1 Characterization of Exposure Setting

- Physical Setting
 - Climate
 - Vegetation
 - Soil type
 - Surface hydrology
 - Ground-water hydrology
- Potentially Exposed Populations
 - Relative locations of populations with respect to site
 - Current land use
 - Potential alternate future land uses
 - Subpopulations of potential concern

3.2 Identification of Exposure Pathways

- Sources and receiving media
- Fate and transport in release media
- Exposure points and exposure routes
- Integration of sources, releases, fate and transport mechanisms, exposure points, and exposure routes into complete exposure pathways
- Summary of exposure pathways to be quantified in this assessment

3.3 Quantification of Exposure

- Exposure concentrations
- Estimation of chemical intakes for individual pathways

(continued)

EXHIBIT 9-1 (continued)

SUGGESTED OUTLINE FOR A BASELINE RISK ASSESSMENT REPORT

3.4 Identification of Uncertainties

- Current and future land-use
- Environmental sampling and analysis
- Exposure pathways evaluated
- Fate and transport modeling
- Parameter values

3.5 Summary of Exposure Assessment

4.0 TOXICITY ASSESSMENT

4.1 Toxicity Information for Noncarcinogenic Effects

- Appropriate exposure periods for toxicity values
- Up-to-date RfDs for all chemicals
- One- and ten-day health advisories for shorter-term oral exposures
- Overall data base and the critical study on which the toxicity value is based (including the critical effect and the uncertainty and modifying factors used in the calculation)
- Effects that may appear at doses higher than those required to elicit the critical effect
- Absorption efficiency considered

4.2 Toxicity Information for Carcinogenic Effects

- Exposure averaged over a lifetime
- Up-to-date slope factors for all carcinogens
- Weight-of-evidence classification for all carcinogens
- Type of cancer for Class A carcinogens
- Concentration above which the dose-response curve is no longer linear

4.3 Chemicals for Which No EPA Toxicity Values Are Available

- Review by ECAO
- Qualitative evaluation
- Documentation/justification of any new toxicity values developed

4.4 Uncertainties Related to Toxicity Information

- Quality of the individual studies
- Completeness of the overall data base

4.5 Summary of Toxicity Information

5.0 RISK CHARACTERIZATION

5.1 Current Land-use Conditions

- Carcinogenic risk of individual substances
- Chronic hazard quotient calculation (individual substances)
- Subchronic hazard quotient calculation (individual substances)

(continued)

EXHIBIT 9-1 (continued)

SUGGESTED OUTLINE FOR A BASELINE RISK ASSESSMENT REPORT

- Shorter-term hazard quotient calculation (individual substances)
 - Carcinogenic risk (multiple substances)
 - Chronic hazard index (multiple substances)
 - Subchronic hazard index (multiple substances)
 - Shorter-term hazard index calculation (multiple substances)
 - Segregation of hazard indices
 - Justification for combining risks across pathways
 - Noncarcinogenic hazard index (multiple pathways)
 - Carcinogenic risk (multiple pathways)
- 5.2 Future Land-use Conditions
- Carcinogenic risk of individual substances
 - Chronic hazard quotient calculation (individual substances)
 - Subchronic hazard quotient calculation (individual substances)
 - Carcinogenic risk (multiple substances)
 - Chronic hazard index (multiple substances)
 - Subchronic hazard index (multiple substances)
 - Segregation of hazard indices
 - Justification for combining risks across pathways
 - Noncarcinogenic hazard index (multiple pathways)
 - Carcinogenic risk (multiple pathways)
- 5.3 Uncertainties
- Site-specific uncertainty factors
 - Definition of physical setting
 - Model applicability and assumptions
 - Parameter values for fate/transport and exposure calculations
 - Summary of toxicity assessment uncertainty
 - Identification of potential health effects
 - Derivation of toxicity value
 - Potential for synergistic or antagonistic interactions
 - Uncertainty in evaluating less-than-lifetime exposures
- 5.4 Comparison of Risk Characterization Results to Human Studies
- ATSDR health assessment
 - Site-specific health studies (pilot studies or epidemiological studies)
 - Incorporation of studies into the overall risk characterization
- 5.5 Summary Discussion and Tabulation of the Risk Characterization
- Key site-related contaminants and key exposure pathways identified
 - Types of health risk of concern
 - Level of confidence in the quantitative information used to estimate risk
 - Presentation of qualitative information on toxicity
- (continued)
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EXHIBIT 9-1 (continued)

SUGGESTED OUTLINE FOR A BASELINE RISK ASSESSMENT REPORT

- Confidence in the key exposure estimates for the key exposure pathways
- Magnitude of the carcinogenic and noncarcinogenic risk estimates
- Major factors driving risk
- Major factors contributing to uncertainty
- Exposed population characteristics
- Comparison with site-specific health studies

6.0 SUMMARY

- 6.1 Chemicals of Potential Concern
 - 6.2 Exposure Assessment
 - 6.3 Toxicity Assessment
 - 6.4 Risk Characterization
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EXHIBIT 9-2

REVIEWER CHECKLIST

1.0 GENERAL CONCERNS

- Were the site-specific objective(s) of the risk assessment stated? (HHEM - 1)
- Was the scope of the assessment described (e.g., in terms of the complexity of the assessment and rationale, data needs, and overview of the study design)? (HHEM - 1.1.1, 3.5)
- Was an adequate history of site activities provided, including a chronology of land use (e.g., specifying agriculture, industry, recreation, waste deposition, and residential development at the site)? (HHEM - 2.1.4, 9.1)
- Was an initial qualitative overview of the nature of contamination included (e.g., specifying in a general manner the kinds of contaminants, media potentially contaminated)? (HHEM - 2.1.4, 9.1)
- Was a general map of the site depicting boundaries and surface topography included, which illustrates site features, such as fences, ponds, structures, as well as geographical relationships between specific potential receptors and the site? (HHEM - 2.1.4, 9.1)

2.0 CONCERNS IN REVIEWING DATA COLLECTION AND EVALUATION

2.1 Data Collection

- Was an adequate "conceptual model" of the site discussed? (HHEM - 4.2)
 - a qualitative discussion of potential or suspected sources of contamination, types and concentrations of contaminants detected at the site, potentially contaminated media, as well as potential exposure pathways and receptors
- Was an adequate Data Quality Objectives (DQO) statement provided? (HHEM - 4.1.4)
 - a statement specifying both the qualitative and quantitative nature of the sampling data, in terms of relative quality and intent for use, issued prior to data collection, which helps to ensure that the data collected will be appropriate for the intended objectives of the study
- Were key site characteristics documented? (HHEM - 4.3, 4.5)
 - soil/sediment parameters (e.g., particle size, redox potential, mineral class, organic carbon and clay content, bulk density, and porosity)
 - hydrogeological parameters (e.g., hydraulic gradient, pH/Eh, hydraulic conductivity, location, saturated thickness, direction, and rate of flow of aquifers, relative location of bedrock layer)

(continued)

EXHIBIT 9-2 (continued)

REVIEWER CHECKLIST

- hydrological parameters (e.g., hardness, pH, dissolved oxygen, salinity, temperature, total suspended solids, flow rates, and depths of rivers or streams; estuary and embayment parameters such as tidal cycle, range, and area; as well as lake parameters such as area, volume, depth, and depth to thermocline)
- meteorological parameters (e.g., direction of prevailing wind, average wind speed, temperature, humidity, annual average and 24 hour maximum rainfall)
- Were all appropriate media sampled? (HHEM - 4.4, 4.5, 4.6)
 - was there adequate justification for any omissions?
 - were literature estimates employed for omissions in background sampling and were they referenced properly?
- Were all key areas sampled, based on all available information (e.g., preliminary assessment, field screening)? (HHEM - 4.4, 4.5, 4.6)
- Did sampling include media along potential routes of migration (e.g., between the contaminant source and potential future exposure points)? (HHEM - 4.5, 4.6)
- Were sampling locations consistent with nature of contamination (e.g., at the appropriate depth)? (HHEM - 4.5, 4.6)
- Were sampling efforts consistent with field screening and visual observations in locating "hot spots"? (HHEM - 4.5, 4.6)
- Were detailed sampling maps provided, indicating the location, type (e.g., grab, composite, duplicate), and numerical code of each sample? (HHEM - 5.10)
- Did sampling include appropriate QA/QC measures (e.g., replicates, split samples, trip and field blanks)? (HHEM - 4.7, 5.4)
- Were background samples collected from appropriate areas (e.g., areas proximate to the site, free of potential contamination by site chemicals or anthropogenic sources, and similar to the site in topography, geology, meteorology, and other physical characteristics)? (HHEM - 4.4, 5.7)

2.2 Data Evaluation

- Were any site-related chemicals (e.g., human carcinogens) eliminated from analysis without appropriate justification? (HHEM - 5.9)

(continued)

EXHIBIT 9-2 (continued)

REVIEWER CHECKLIST

- as infrequently detected chemicals (HHEM - 5.3.3, 5.9.3)
- as non-detects in a specific medium without employing a "proxy" concentration (HHEM - 5.3)
- as common laboratory contaminants even though sample concentrations were significantly higher than that found in blanks? (HHEM - 5.5)
- as present at a "ubiquitous level"? (HHEM - 5.7)
- Were inappropriate "proxy concentrations" assigned to site-related chemicals? (HHEM - 5.3)
 - was a value of zero or the instrument detection limit (IDL) assigned?
 - was an erroneous sample-specific quantitation limit employed?
- Were appropriate analytical methods employed for collection of data upon which risk estimates are based? (HHEM - 5.2)
 - were the methods consistent with the requisite level of sensitivity?
 - were established procedures with adequate QA/QC measures employed?
- Did the data meet the Data Quality Objectives (DQO)? (HHEM - 4.1.4)
 - were the sampling methods consistent with the intended uses of data?
- Were appropriate data qualifiers employed? (HHEM - 5.4)
- Were special analytical services (SAS) employed when appropriate? (HHEM - 5.3)
 - was SAS employed as an adjunct to routine analysis in cases where certain contaminants were suspected at low levels, as non-TCL chemicals, in non-standard matrices, or in situations requiring a quick turnaround time?

3.0 CONCERNS IN REVIEWING THE EXPOSURE ASSESSMENT

- Were "reasonable maximum exposures" considered (i.e., the highest exposures that are reasonably expected to occur)? (HHEM - 6.1.2, 6.4.1, 6.6)
- Were current and future land uses considered? (HHEM - 6.1.2, 6.2)

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EXHIBIT 9-2 (continued)

REVIEWER CHECKLIST

- Was residential land use considered as an alternative future land use? (HHEM - 6.2.2)
 - if not, was a valid rationale provided?
- Were all potential sensitive subpopulations considered (e.g., elderly people, pregnant or nursing women, infants and children, and people with chronic illnesses)? (HHEM - 6.2.2)
- Were all significant contaminant sources considered? (HHEM - 6.3.1)
- Were all potential contaminant release mechanisms considered, such as volatilization, fugitive dust emission, surface runoff/overland flow, leaching to ground water, tracking by humans/animals, and soil gas generation? (HHEM - 6.3.1)
- Were all potential contaminant transport pathways considered, such as direct air transport downwind, diffusion in surface water, surface water flow, ground-water flow, and soil gas migration? (HHEM - 6.3)
- Were all relevant cross-media transfer effects considered, such as volatilization to air, wet deposition, dry deposition, ground-water discharge to surface, and ground-water recharge from surface water? (HHEM - 6.3)
- Were all media potentially associated with exposure considered? (HHEM - 6.2, 6.3)
- Were all relevant site-specific characteristics considered, including topographical, hydrogeological, hydrological, and meteorological parameters? (HHEM - 6.1, 6.3)
- Were all possible exposure pathways considered? (HHEM - 6.3)
 - was a valid rationale offered for exclusion of any potential pathways from quantitative evaluation?
- Were all "spatial relationships" adequately considered as factors that could affect the level of exposure (e.g., hot spots in an area that is frequented by children, exposure to ground water from two aquifers that are not hydraulically connected and that differ in the type and extent of contamination)? (HHEM - 6.2, 6.3)
- Were appropriate approaches employed for calculating average exposure concentrations? (HHEM - 6.4, 6.5)
 - was a valid rationale provided for using geometric or arithmetic means?
- Were appropriate or standard default values used in exposure calculations (e.g., age-specific body weights, appropriate exposure frequency and duration values)? (HHEM - 6.4, 6.5, 6.6)

(continued)

EXHIBIT 9-2 (continued)

REVIEWER CHECKLIST

4.0 CONCERNS IN REVIEWING THE TOXICITY ASSESSMENT

- Was the exclusion of any carcinogen from analysis adequately justified (e.g., were "weight-of-evidence" classifications and completeness of exposure pathways considered in this decision)? (HHEM - 5.9, 7.3)
- Were appropriate "route-to-route" extrapolations performed in cases where a toxicity value was applied across differing routes of exposure? (HHEM - 7.5.1, 8.1.2)
 - were the extrapolations based on appropriate guidance?
- Were appropriate toxicity values employed based on the nature of exposure? (HHEM - 7.4, 7.5)
 - were subchronic vs. chronic RfDs applied correctly based on the duration of exposure?
 - were all sensitive subpopulations, such as pregnant or nursing women potentially requiring developmental RfDs (RfD_{at}s), considered in the selection of the toxicity values used?
- Were the toxicity values that were used consistent with the values contained within the Integrated Risk Information System (IRIS) or other EPA documents? (HHEM - 7.4, 7.5)

5.0 CONCERNS IN REVIEWING THE RISK CHARACTERIZATION

- Were exposure estimates and toxicity values consistently expressed as either intakes or absorbed doses for each chemical taken through risk characterization? (HHEM - 8.1.2)
 - was a valid rationale given for employing values based on absorbed dose?
 - Were all site-related chemicals that were analyzed in the exposure assessment considered in risk characterization? (HHEM - 8.1.2)
 - were inconsistencies explained?
 - Were risks appropriately summed only across exposure pathways that affect the same individual or population subgroup, and in which the same individual or population subgroup faces the "reasonable maximum exposure," based on the assumptions employed in the exposure assessment? (HHEM - 8.3)
 - Were sources of uncertainty adequately characterized? (HHEM - 8.4)
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- Were current and future land uses considered?
- Were all significant contaminant sources considered?
- Were appropriate or standard default values used in exposure calculations?
- Were the toxicity values that were used consistent with the values contained within the Integrated Risk Information System (IRIS) or other EPA documents?

Although the checklist addresses many pertinent issues, it is not a complete listing of all potential concerns, since this objective is beyond the scope of a preliminary review tool. In addition, some of the concerns listed are not necessarily appropriate for all risk assessment reports.

The recommended steps in reviewing a risk assessment report are as follows:

- (1) compare the risk assessment report outline to the suggested outline in Section 9.1 of this chapter (i.e., Exhibit 9-1);
- (2) use the checklist in this section (i.e., Exhibit 9-2); and
- (3) conduct a comprehensive review.

The outline (Exhibit 9-1) and the checklist (Exhibit 9-2) are intended only as tools to assist in a preliminary review of a risk assessment, and are not designed to replace the good judgment needed during the comprehensive review. These two tools should provide a framework, however, for the timely screening of risk assessments by reviewers with a

moderate level of experience in the area. If these steps are followed in order, then some of the major problems with a risk assessment report (if any) can be identified before significant resources are expended during the comprehensive review.

9.3 MANAGEMENT TOOLS

This section provides a concise checklist for the RPM to use in carrying out their role in the risk assessment process (see Exhibit 9-3). Other decision-makers at the site also may find this checklist useful. Specific points at which the managers should be involved, or may be called upon to become involved, during the risk assessment are discussed in Chapters 4 through 8 of the manual. This checklist extracts information from those chapters, and also includes pointers on planning and involvement for the manager. The purpose of the checklist is to involve managers in the direction and development of the risk assessment and thereby avoid serious mistakes or costly misdirections in focus or level of effort.

Although the checklist is shaped to suggest when and how the manager should become involved in the risk assessment process, it is assumed that part of the manager's involvement will require consultation with technical resources available in the region or state. The checklist advises consulting the "regional risk assessment support staff" at a number of points in the process. This contact may not be one person, but could be a number of different technical people in the region, such as a toxicologist, hydrogeologist, or other technical reviewer. The manager should become aware of the resources available to him or her, and use them when appropriate to ensure that the risk assessment developed is useful and accurate.

EXHIBIT 9-3

CHECKLIST FOR MANAGER INVOLVEMENT

1. GETTING ORGANIZED

- Ensure that the workplan for the risk assessment contractor support is in place (if needed).
- Identify EPA risk assessment support personnel (to be used throughout the risk assessment process).
- Gather relevant information, such as appropriate risk assessment guidances and site-specific data and reports.
- Identify available state, county, and other non-EPA resources.

2. BEFORE THE SCOPING MEETING

- Make initial contact with risk assessor.
- Provide risk assessor with available guidances and site data.
- Determine (or review) data collection needs for risk assessment, considering:
 - modeling parameter needs;
 - type and location of background samples;
 - the preliminary identification of potential human exposure;
 - strategies for sample collection appropriate to site/risk assessment data needs;
 - statistical methods;
 - QA/QC measures of particular importance to risk assessment;
 - special analytical services (SAS) needs;
 - alternate future land use; and
 - location(s) in ground water that will be used to evaluate future ground-water exposures.

3. AT THE SCOPING MEETING

- Present risk assessment data collection needs.
- Ensure that the risk assessment data collection needs will be considered in development of the sampling and analysis plan.
- Where limited resources require that less-than-optimal sampling be conducted, discuss potential impacts on risk assessment results.

4. AFTER THE SCOPING MEETING

- Ensure that the risk assessor reviews and approves the sampling and analysis plan.
- Consult with ATSDR if human monitoring is planned.

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EXHIBIT 9-3 (continued)

CHECKLIST FOR MANAGER INVOLVEMENT

5. DURING SAMPLING AND ANALYSIS

- Ensure that risk assessment needs are being met during sampling.
- Provide risk assessor with any preliminary sampling results so that he/she can determine if sampling should be refocused.
- Consult with ATSDR to obtain a status report on any human monitoring that is being conducted. Provide any results to risk assessor.

6. DURING DEVELOPMENT OF RISK ASSESSMENT

- Meet with risk assessor to discuss basis of excluding chemicals from the risk assessment (and developing the list of chemicals of potential concern). Confirm appropriateness of excluding chemicals.
- Confirm determination of alternate future land use.
- Confirm location(s) in ground water that will be used to evaluate future ground-water exposures.
- Understand basis for selection of pathways and potentially exposed populations.
- Facilitate discussions between risk assessor and EPA risk assessment support personnel on the following points:
 - the need for any major exposure, fate, and transport models (e.g., air or ground-water dispersion models) used;
 - site-specific exposure assumptions;
 - non-EPA-derived toxicity values; and
 - appropriate level of detail for uncertainty analysis, and the degree to which uncertainties will be quantified.
- Discuss and approve combination of pathway risks and hazard indices.
- Ensure that end results of risk characterization have been compared with ATSDR health assessments and other site-specific human studies that might be available.

7. REVIEWING THE RISK ASSESSMENT

- Allow sufficient time for review and incorporation of comments.
- Ensure that reviewers' comments are incorporated.

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EXHIBIT 9-3 (continued)

CHECKLIST FOR MANAGER INVOLVEMENT

8. COMMUNICATING THE RISK ASSESSMENT

- Plan a briefing among technical staff to discuss significant findings and uncertainties.
 - Discuss development of graphics, tools, and presentations to assist risk management decisions.
 - Consult with other groups (e.g., community relations staff), as appropriate.
 - Brief upper management.
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REFERENCES FOR CHAPTER 9

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