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Agency

Office of Solid Waste and
Emergency Response
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EPA

Risk Assessment Guidance for Superfund: Volume I -- Human Health Evaluation Manual (Part A)

Office of Emergency and Remedial Response
Hazardous Site Evaluation Division, OS-230

Quick Reference Fact Sheet

The overarching mandate of the Superfund program is to protect human health and the environment from current and potential threats posed by uncontrolled releases of hazardous substances. To help meet this mandate, the U.S. Environmental Protection Agency's (EPA's) Office of Emergency and Remedial Response (OERR) has developed a human health evaluation process as part of its remedial response program. EPA's *Human Health Evaluation Manual* describes the process of gathering information and assessing the risk to human health, and together with the *Environmental Evaluation Manual* comprise a two-volume set (Volumes I and II, respectively) called *Risk Assessment Guidance for Superfund* (RAGS). RAGS replaces two previous EPA guidance documents: the *Superfund Public Health Evaluation Manual* (SPHEM; 1986) and the *Draft Endangerment Assessment Handbook* (1985).

The *Human Health Evaluation Manual* has three main parts: baseline risk assessment (Part A), refinement of preliminary remediation goals (Part B), and risk evaluation of remedial alternatives (Part C). Part A of this manual is being distributed as an Interim Final document. Remedial project managers (RPMs) should ensure that the procedures in this guidance be used for all new human health risk assessments conducted as part of the remedial investigation/feasibility study (RI/FS) process. Copies of Part A can be obtained by calling EPA's Center for Environmental Research Information at 513-569-7562 (FTS 684-7562). Parts B and C are targeted for completion in 1990.

This fact sheet is designed to alert RPMs and other personnel to (1) new aspects of the *Human Health Evaluation Manual* (Part A), (2) the purpose and steps of the baseline risk assessment, and (3) where additional help can be obtained.

PURPOSE OF THE HUMAN HEALTH EVALUATION

The human health evaluation is used in the Superfund program to:

- help identify which sites warrant remedial action;
- provide a consistent process for evaluating and documenting human health risk;
- ensure protectiveness by the refinement of risk-based, site-specific remediation goals;
- provide focus for the FS;
- help to measure the effectiveness of remedial alternatives; and
- aid in priority setting for remedial design/ remedial action.

HUMAN HEALTH EVALUATION IN THE RI/FS PROCESS

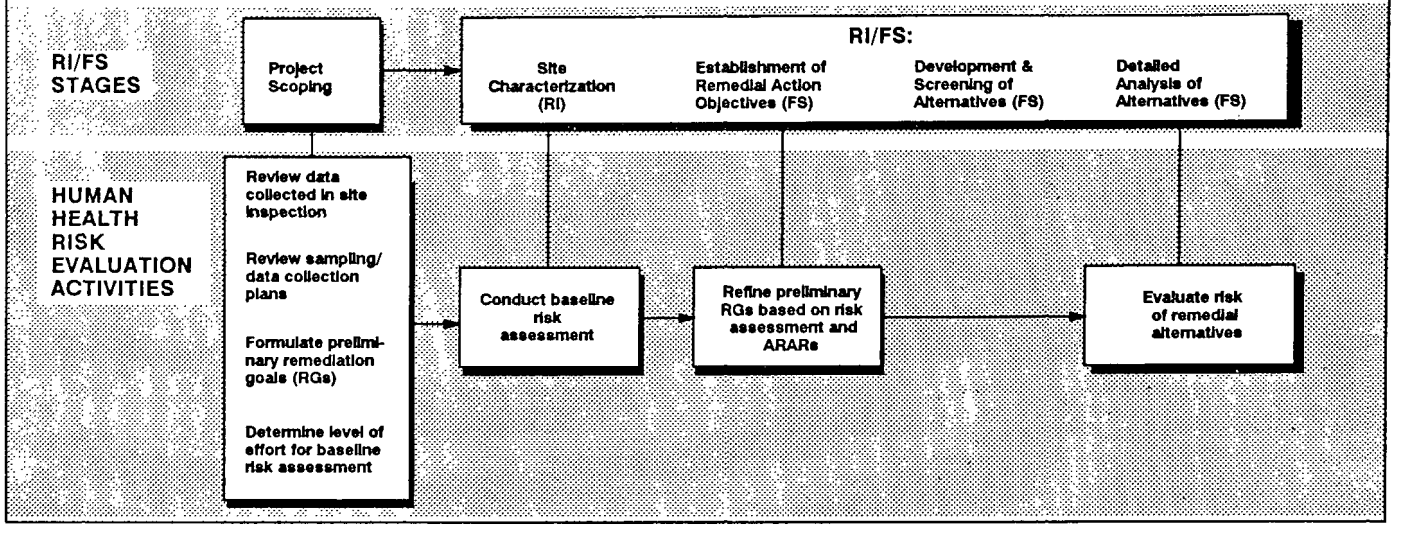
The RI/FS is the methodology that the Superfund program has established for characterizing the nature and extent of risks posed by uncontrolled hazardous waste sites and for developing and evaluating remedial options. The Superfund Amendments and Reauthorization Act of 1986 reemphasized the original statutory mandate that remedies meet the threshold requirement to protect human health and the environment. Because the RI/FS is an analytical process designed to support risk management decision-making, the assessment of health and environmental risk plays an essential role in the RI/FS. Highlight 1 shows the stages of the RI/FS, relating health risk evaluation activities to each stage. Although the RI/FS process and related risk evaluation activities are presented in a fashion that makes the steps appear sequential and distinct, in practice the steps are usually highly interactive.

HUMAN HEALTH EVALUATION AND ENDANGERMENT FINDINGS

One of EPA's goals in the Superfund program is to use more CERCLA section 106 (i.e., imminent and substantial endangerment) orders to compel potentially responsible parties to design and conduct the remedial actions. In order for EPA to issue and enforce a section 106 order, the baseline risk assessment must be sufficient to support the finding that there may be an imminent and substantial endangerment to public health or welfare or the environment because of an actual or threatened release of a hazardous substance. By requiring careful adherence to the *Human Health Evaluation Manual* (together with the *Environmental Evaluation Manual*), the resulting baseline risk assessment should be adequate to support an endangerment finding and thus a CERCLA section 106 order.

Highlight 1

Human Health Risk Evaluation Activities in the RI/FS Process



PART A OF THE MANUAL: BASELINE RISK ASSESSMENT

The baseline risk assessment process described in Part A of the manual consists of four main steps as shown in Highlight 2. Relevant information identified through data collection and evaluation (Step 1) is used to develop exposure and toxicity assessments (Steps 2 and 3). Risk characterization (Step 4) summarizes and integrates both the toxicity and exposure steps into quantitative and qualitative expressions of risk.

WHAT'S NEW IN THE MANUAL

The *Human Health Evaluation Manual* revises and builds upon the health evaluation process established in SPHEM. Provided are new information and techniques gleaned from several years of program experience conducting risk assessments at hazardous waste sites. Policies established and evolved over the years — including those resulting from the revised National Oil and Hazardous Substances Pollution Contingency Plan (NCP) — have been updated and clarified. In addition, the link between the human health evaluation, the environmental evaluation, and the RI/FS has been strengthened.

HIGHLIGHTS OF THE REVISION

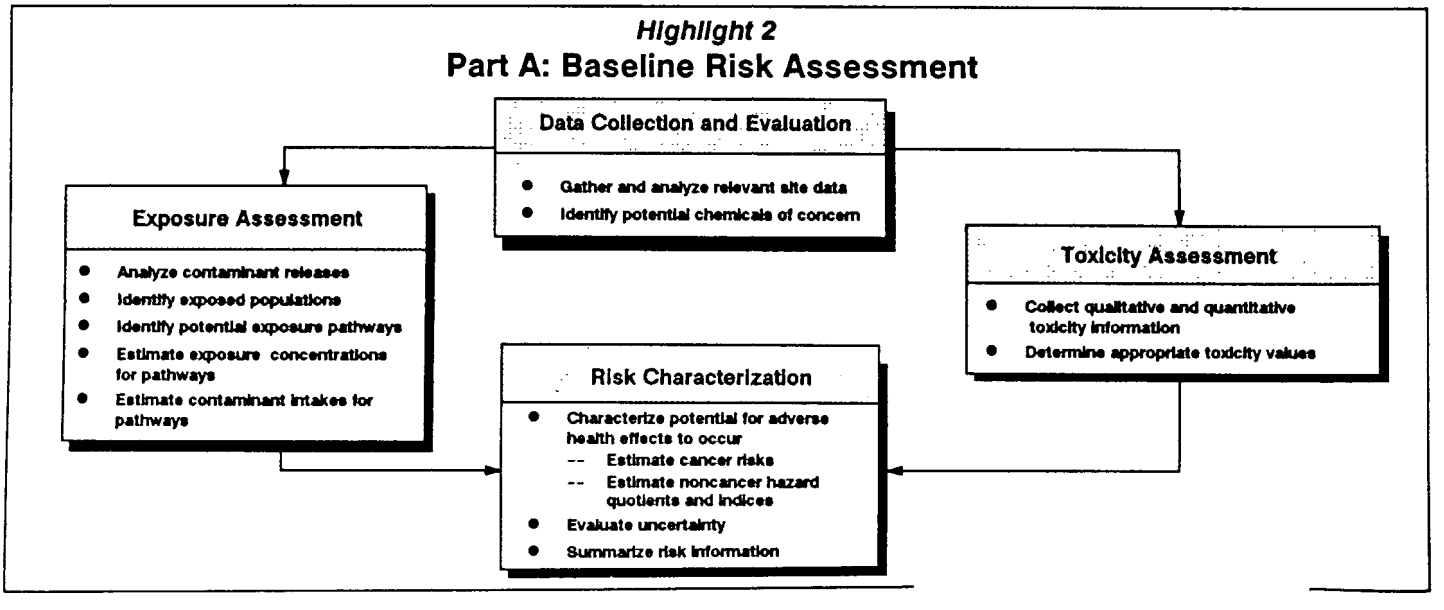
Introduction. Emphasizes shift in NCP and RI/FS philosophy toward efficiency, effectiveness, and a bias for action.

Data Collection (new chapter). Encourages assessors' early involvement in RI/FS planning and effective communication with RPMs. Describes procedures for acquiring reliable chemical release and exposure data for quantitative assessment. The topics discussed in the Data Collection chapter are shown in Highlight 3.

Data Evaluation (new chapter). Provides nine steps to organize data and to identify a set of chemicals and concentrations that are of acceptable quality for use in the quantitative risk assessment. The nine data evaluation steps are shown in Highlight 4.

Highlight 2

Part A: Baseline Risk Assessment



Highlight 3
Topics Discussed in Data Collection Chapter

- Available site information
- Modeling parameter needs
- Background sampling needs
- Preliminary identification of human exposure
- Overall strategy for sample collection
- Need for Special Analytical Services
- Activities during workplan development and data collection

Highlight 4
Data Evaluation Steps

Step 1: Gather all data available from the site investigation and sort by medium.
Step 2: Evaluate the analytical methods used.
Step 3: Evaluate the quality of data with respect to sample quantitation limits.
Step 4: Evaluate the quality of data with respect to qualifiers and codes.
Step 5: Evaluate the quality of data with respect to blanks.
Step 6: Evaluate tentatively identified compounds.
Step 7: Compare potential site-related contamination with background.
Step 8: Develop a set of data for use in the risk assessment.
Step 9: If appropriate, further limit the number of chemicals to be carried through the risk assessment.

Exposure Assessment. Gives specific equations and parameter values for common Superfund site exposure pathways. Defines the revised NCP's reasonable maximum exposure (RME) concept under both current and future land-use conditions. Highlight 5 defines the RME and describes the specific terms in the general exposure equation used to generate the RME.

Toxicity Assessment. Discusses EPA guidances, toxicity data bases, and Superfund technical assistance groups. Provides updated discussion of EPA's toxicity assessment methods. Defines hierarchy of toxicity data sources, as shown in Highlight 6.

Risk Characterization. Provides guidance for summarizing risk information for use in decision-making. Presents expanded discussion of uncertainty. Includes examples of helpful visual presentations of risk assessment as shown in Highlights 7 and 8.

Documentation, Review, and Management Tools (new chapter). Presents new tools for the RPM, risk assessor, and risk assessment reviewer. These new tools are described in Highlight 9. They include an RPM involvement checklist (see Highlight 10), recommended format for a baseline risk assessment report, and a risk assessment reviewer's checklist.

Highlight 5
Reasonable Maximum Exposure (RME)

The **reasonable maximum exposure (RME)** is defined as the highest exposure that could reasonably be expected to occur at a site. RME is calculated using the following general equation,

$$I = C \times \frac{CR \times EFD}{BW} \times \frac{1}{AT}$$

where:

- I = Intake; the amount of chemical at the exchange boundary (mg/kg body weight- dy).
- C = Concentration; the average chemical concentration contacted over the exposure period (e.g., mg/l).
- CR = Contact Rate; the amount of contaminated medium (e.g., soil, air, water) contacted per unit time or event (e.g., l/dy).
- EFD = Exposure Frequency and Duration; how often and how long exposure occurs (e.g., dy/yr, yr).
- BW = Body Weight; the average body weight over the exposure period (kg).
- AT = Averaging Time; the time period over which exposure is averaged (dy).

Use a 95th upper confidence limit on the arithmetic mean concentration contacted over the exposure period, rather than the mean itself. Rationale: uncertainty in the measurements or modeling will be quantitatively considered.

Use the 95th percentile intake rate. Rationale: this will be protective of most of the population.

Use the 95th percentile estimate if available, or best professional judgment to estimate a conservative value. Rationale: statistical data on these terms are rarely available; a conservative estimate is suggested rather than a best or average estimate in order to be protective.

Use the arithmetic average body weight over the exposure period. Rationale: body weight is not always independent of intake; by using the average, error from this dependence is minimized; using the average rather than the 5th percentile body weight will also reduce the number of upper-bound values that are multiplied together.

Highlight 6
Hierarchy of Toxicity Data Sources

Integrated Risk Information System (IRIS)

- Provides verified reference doses (RfDs) and slope factors
- Updated monthly
- EPA's preferred source of toxicity information

Health Effects Assessment Summary Tables (HEAST)

- Provides interim as well as verified RfDs and slope factors
- Should be used only for chemicals not addressed in IRIS

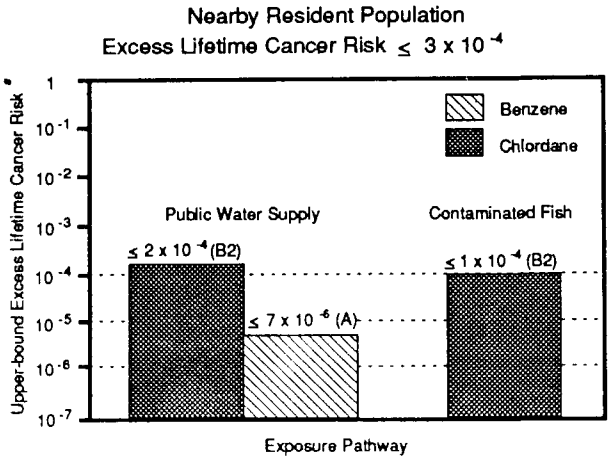
Other EPA References

- Do not necessarily provide verified RfDs and slope factors
- Should be used only for chemicals not found or referenced in IRIS or HEAST
- EPA's Environmental Criteria and Assessment Office must be contacted first (513-569-7300; FTS 684-7300)

Radiation Risk Assessment Guidance (new chapter). Provides basic principles and concepts of radiation protection and supplemental baseline risk assessment guidance for use at sites contaminated with radioactive substances.

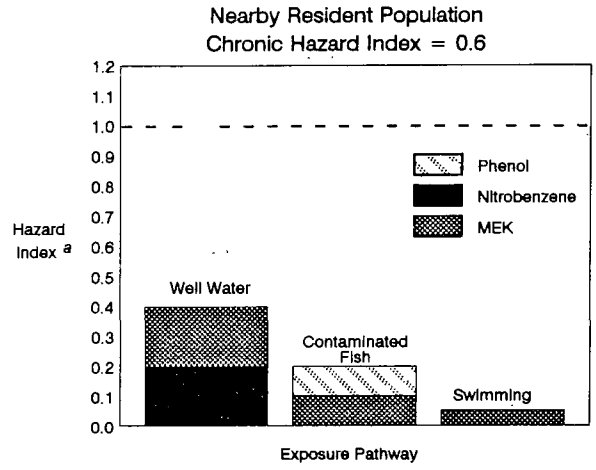
Appendices (new). Provide technical information on absorbed vs. administered dose, and a complete index for quick reference.

Highlight 7
Example of Presentation of Relative Contribution of Individual Chemicals to Exposure Pathway and Total Cancer Risk Estimates



[a] The risk of developing cancer is plotted on a log scale. A risk of 10^{-4} indicates a probability of 1 chance in 10,000 of an individual developing cancer. Risks of 10^{-5} and 10^{-6} correspond to probabilities of 1 chance in 100,000 and 1 chance in 1,000,000, respectively. Values in parentheses represent EPA's weight-of-evidence classification of the agent as a potential human carcinogen: A = human carcinogen; and B2 = probable human carcinogen (with sufficient evidence in animals and inadequate or no evidence in humans).

Highlight 8
Example of Presentation of Relative Contribution of Individual Chemicals to Exposure Pathway and Total Hazard Index Estimates



[a] The hazard index is equal to the sum of the hazard quotients (i.e., exposure level/RfD) for each chemical. It is **not** a probability; a hazard index or quotient of ≤1.0 indicates that it is unlikely for even sensitive human populations to experience adverse health effects.

NEED MORE HELP?

Superfund Health Risk Assessment Technical Support Center. This center provides program staff and their contractors access to the Office of Health and Environmental Assessment (OHEA) and other Agency experts in the area of health risk assessment. The center is coordinated by OHEA's Environmental Criteria and Assessment Office in Cincinnati (513-569-7300 or FTS 684-7300); it offers technical guidance in all areas of health risk assessment, including project scoping, sampling methods, exposure assessment, toxicity assessment, and risk characterization. ECAO may respond to questions directly or refer callers to other OHEA or Agency offices. In addition, callers may be referred initially to regional Toxics Integration Coordinators for responses to site-specific requests (see next section).

Highlight 9
New Documentation, Review, and Management Tools

- **RPM Involvement Checklist (see Highlight 10).** The checklist addresses risk information needs and includes pointers on planning and involvement for the RPM. Involvement of managers in the direction and development of the risk assessment helps to avoid serious mistakes or costly misdirections in focus or level of effort.
- **Recommended Format for a Baseline Risk Assessment Report.** Consistency of Superfund risk assessment format encourages completeness, consistent use of results, and allows for easier review.
- **Risk Assessment Reviewer's Checklist.** The checklist is intended as a guide to ensure that critical issues concerning the quality and adequacy of risk information are not overlooked.

Highlight 10

Checklist for RPM 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 guidances and site-specific data and reports.
- Identify available state, county, and other non-EPA resources.
- Prior to Special Notice, determine whether the PRPs will be allowed to do the risk assessment.

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;
  - -- alternate future land use;
  - -- possible exposure scenarios;
  - -- location(s) in ground water that will be used to evaluate future ground-water exposures;
  - -- the preliminary identification of environmental concerns;
  - -- strategies (including medium and location) for sample collection appropriate to site/risk assessment needs;
  - -- statistical methods;
  - -- QA/QC measures of particular importance to risk assessment; and
  - -- special analytical services needs.

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 the Agency for Toxic Substances and Disease Registry (ATSDR) if human monitoring is planned.

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 for 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 use of any major exposure, fate, and transport models (e.g., air or ground-water dispersion models);
  - -- 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 results of risk characterization have been compared with ATSDR health assessments and any 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 addressed.

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.

Regional Toxics Integration Coordinators and Headquarters Contacts. Superfund Toxics Integration Coordinators are located in each region. Questions regarding site-specific Superfund risk assessment issues should be referred to the appropriate individuals listed in Highlight 11. The Toxics Integration Branch, OERR, may be contacted at 202-475-9486 (FTS 475-9486) for technical information sources, availability of guidances, and related program directives.

Highlight 11

Regional Toxics Integration Coordinators

Region	Name and Address	Phone Number
I	Sarah Levinson Waste Management Division (HSS-CAN-7) EPA Region I John F. Kennedy Federal Building Boston, MA 02203	FTS 833-1504 617-223-5504
II	Peter Grevatt Program Support Branch ERR Division EPA Region II 26 Federal Plaza New York, NY 10278	FTS 264-8775 212-264-6323
III	Richard Brunker Hazardous Waste Management Division (3HW15) EPA Region III 841 Chestnut Street Philadelphia, PA 19107	FTS 597-0804 215-597-0804
IV	Elmer Akin Waste Management Division EPA Region IV 345 Courtland Street, NE Atlanta, GA 30365	FTS 257-1586 404-347-1586
V	Steve Ostrodka Technical Support Unit (5HSM-12) EPA Region V 230 South Dearborn Street Chicago, IL 60604	FTS 886-3011 312-886-3011
VI	Jon Rauscher EPA Region VI (6H-SR) First Interstate Bank Tower 1445 Ross Avenue Dallas, TX 75202-2733	FTS 255-2198 214-655-2198
VII	Superfund Branch EPA Region VII 726 Minnesota Avenue Kansas City, KS 66101	FTS 236-7052* 913-551-7052
VIII	Chris Weis EPA Region VIII (8HWM-SR) 999 18th Street, Suite 500 Denver, CO 80202-2405	FTS 330-7655 303-294-7655
IX	Gerald Hiatt Technical Support Section (H-8-4) Superfund Program EPA Region IX 1235 Mission Street San Francisco, CA 94103	FTS 484-1914 415-744-1914
X	Pat Cirone EPA Region X (ES-098) 1200 Sixth Avenue Seattle, WA 98101	FTS 399-1597 206-442-1597

* Caller must have FTS 2000. If not, use commercial number.