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

Interim Final

Office of Emergency and Remedial Response
U.S. Environmental Protection Agency
Washington, D.C. 20450

NOTICE

The policies and procedures set forth here are intended solely as guidance to EPA and other government employees and contractors. This guidance does not constitute rulemaking by the Agency, and cannot be relied on to create a substantive or procedural right enforceable by any party in litigation with the United States. EPA may take action that is at variance with the policies and procedures in this manual and may change them at any time without public notice.

This interim final guidance is based on policies in the proposed revisions to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which were published on December 21, 1988 (53 *Federal Register* 51394). The final NCP may adopt policies different than those in this manual and should, when promulgated, be considered the authoritative source. A final version of this manual will be published after the revised NCP is promulgated.

Following the date of its publication, this manual is intended to be used as guidance for all human health risk assessments conducted as part of Superfund remedial investigations and feasibility studies. Issuance of this manual does not invalidate human health risk assessments completed before (or in progress at) the publication date and based on previously released Agency guidance.

This document represents an annotated version of the Risk Assessment Guidance for Superfund (RAGS) Part A. Since the original publication of this guidance in 1988, EPA has issued a number of guidance documents, directives and other policy documents that update, supplement, supersede or otherwise affect RAGS Part A, or contain new information about one or more topics that are substantially addressed in RAGS Part A. There may be additional supplemental guidance available on EPA's Superfund risk assessment website (see http://www.epa.gov/swerrims/riskassessment/risk_superfund.html)

The underlying text of RAGS Part A remains unchanged; any typographical errors or missing text reflects the PDF original. Annotations have been added to this document as electronic 'sticky notes.' To view the information contained in a sticky note, simply place your cursor over it or click it and the text will expand. To close the note, press the escape key or click on the 'X' in the upper righthand corner of the note header. In addition, the word 'link' appears in parentheses near each sticky note. This text is a hyperlink that users can click to open the relevant document that serves as the source of the information provided in the note.

All sections of RAGS Part A that have at least one annotation are marked in the Table of Contents with a blue arrow and highlighted in yellow. Click on the highlighted text in the Table of Contents to jump to the annotated section of the guidance.

Annotations added: April 2010

Comment [A1]: The latest revisions to the NCP were finalized in 1994. An overview of the final NCP and a link to the full text are available at:
http://www.epa.gov/oem/content/lawsregs/ncp_over.htm

ABOUT THE REVISION . . .

WHAT IT IS EPA's *Human Health Evaluation Manual* is a revision of the *Superfund Public Health Evaluation Manual* (SPHEM; October 1986); it is Volume I of the two-volume set called *Risk Assessment Guidance for Superfund*. This manual has three main parts: the baseline risk assessment (Part A); refinement of preliminary remediation goals (Part B); and evaluation of remedial alternatives (Part C). (Only Part A is included in the first distribution; see below.)

WHO IT'S FOR Risk assessors, risk assessment reviewers, remedial project managers (RPMs), and risk managers involved in Superfund site cleanup activities will benefit from this revision.

WHAT'S NEW This revision builds upon the process established in SPHEM and provides more detailed guidance on many of the procedures used to assess health risk. New information and techniques are presented that reflect the extensive Superfund program experience conducting health risk assessments at Superfund sites. Policies established and refined over the years -- especially those resulting from the proposed National Oil and Hazardous Substances Pollution Contingency Plan (NCP) -- have been updated and clarified. Additionally, the links between the human health evaluation, the environmental evaluation, and the remedial investigation/feasibility study (RI/FS) have been strengthened.

In Part A you will find:

For the risk assessor -- Updated procedures and policies, specific equations and variable values for estimating exposure, and a hierarchy of toxicity data sources.

For the risk assessment reviewer -- A baseline risk assessment outline for consistent presentation of risk information and format, and a reviewer's checklist to ensure appropriate quality and content of the risk assessment.

For the RPM -- A comprehensive overview of the risk assessment process in the RI/FS, a checklist for RPM involvement throughout the process, and a complete index for quick reference.

For the risk manager -- An expanded chapter on risk characterization (Chapter 8) to help summarize and present risk information for the decision-maker, and more detailed descriptions of uncertainties in the assessment.

DISTRIBUTION PLAN This manual is being distributed as an interim final document while the proposed NCP is being finalized. After the final NCP is published, the manual will be updated and finalized. Parts B and C -- which were not distributed as interim final because they are highly dependent on possible revisions to the NCP -- will be added. Periodically, updates of portions of the manual will be distributed.

**WHERE TO
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Comment [A2]: The latest revisions to the NCP were finalized in 1994. An overview of the final NCP and a link to the full text are available at:
<http://www.epa.gov/oem/content/lawsregs/ncp/over.htm>

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PREFACE

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) requires that actions selected to remedy hazardous waste sites be protective of human health and the environment. CERCLA also mandates that when a remedial action results in residual contamination at a site, future reviews must be planned and conducted to assure that human health and the environment continue to be protected. As part of its effort to meet these and other CERCLA requirements, EPA has developed a set of manuals, together entitled *Risk Assessment Guidance for Superfund*. The *Human Health Evaluation Manual* (Volume I) provides guidance for developing health risk information at Superfund sites, while the *Environmental Evaluation Manual* (Volume II) provides guidance for environmental assessment at Superfund sites. Guidance in both human health evaluation and environmental assessment is needed so that EPA can fulfill CERCLA's requirement to protect human health and the environment.

The *Risk Assessment Guidance for Superfund* manuals were developed to be used in the remedial investigation/feasibility study (RI/FS) process at Superfund sites, although the analytical framework and specific methods described in the manuals may also be applicable to other assessments of hazardous wastes and hazardous materials. These manuals are companion documents to EPA's *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (October 1988), and users should be familiar with that guidance. The two Superfund risk assessment manuals were developed with extensive input from EPA workgroups comprised of both regional and headquarters staff. These manuals are interim final guidance; final guidance will be issued when the revisions proposed in December 1988 to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) become final.

Although human health risk assessment and environmental assessment are different processes, they share certain common information needs and generally can use some of the same chemical sampling and environmental setting data for a site. Planning for both assessments should begin during

the scoping stage of the RI/FS, and site sampling and other data collection activities to support the two assessments should be coordinated. An example of this type of coordination is the sampling and analysis of fish or other aquatic organisms; if done properly, data from such sampling can be used in the assessment of human health risks from ingestion and in the assessment of damages to and potential effects on the aquatic ecosystem.

The two manuals in this set target somewhat different audiences. The *Environmental Evaluation Manual* is addressed primarily to remedial project managers (RPMs) and on-scene coordinators (OSCs), who are responsible for ensuring a thorough evaluation of potential environmental effects at sites. The *Environmental Evaluation Manual* is not a detailed "how-to" type of guidance, and it does not provide "cookbook" approaches for evaluation. Instead, it identifies the kinds of help that RPMs/OSCs are likely to need and where they may find that help. The manual also provides an overall framework to be used in considering environmental effects. An environmental evaluation methods compendium published by EPA's Office of Research and Development, *Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory Reference Document* (EPA/600/3-89/013), is an important reference to be used with the manual.

The *Human Health Evaluation Manual* is addressed primarily to the individuals actually conducting health risk assessments for sites, who frequently are contractors to EPA, other federal agencies, states, or potentially responsible parties. It also is targeted to EPA staff, including those responsible for review and oversight of risk assessments (e.g., technical staff in the regions) and those responsible for ensuring adequate evaluation of human health risks (i.e., RPMs). The *Human Health Evaluation Manual* replaces a previous EPA guidance document, *The Superfund Public Health Evaluation Manual* (October 1986), which should no longer be used. The new manual incorporates lessons learned from application of the earlier manual and addresses a number of issues raised since the earlier manual's publication. Issuance of the new manual does not invalidate

Comment [A3]: The latest revisions to the NCP were finalized in 1994. An overview of the final NCP and a link to the full text are available at:
<http://www.epa.gov/oem/content/lawsregs/ncp-over.htm>

human health risk assessments completed before (or in progress at) the publication date.

The *Human Health Evaluation Manual* provides a basic framework for health risk assessment at Superfund sites, as the *Environmental Evaluation Manual* does for environmental assessment. The *Human Health Evaluation Manual* differs, however, by providing more detailed guidance on many of the procedures used to assess health risk. This additional level of detail is possible because of the relatively large

body of information, techniques, and guidance available on human health risk assessment and the extensive Superfund program experience conducting such assessments for sites.

Even though the *Human Health Evaluation Manual* is considerably more specific than the *Environmental Evaluation Manual*, it also is not a “cookbook,” and proper application of the guidance requires substantial expertise and professional judgment.

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