UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 26 1992

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

MEMORANDUM

SUBJECT: Implementing the Deputy Administrator's Risk Characterization Memorandum

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TO: Directors, Waste Management Division
Regions I, IV, V, and VII
Director, Emergency and Remedial Response Division
Region II
Directors, Hazardous Waste Management Division
Regions III, VI, VIII, and IX
Director, Hazardous Waste Division
Region X
Directors, Environmental Services Division
Regions I, VI, and VII

Purpose

The purpose of this memorandum is to implement in the Superfund program the recommendations of the Deputy Administrator in his memorandum of February 26, 1992, "Guidance on Risk Characterization for Risk Managers and Risk Assessors."

Background

On February 26, 1992, in a memorandum to Assistant Administrators and Regional Administrators, the Deputy Administrator issued new guidance for Agency managers and risk assessors on describing risk assessment results in EPA reports, presentations, and decision packages (The "Risk Characterization Guidance"). The Risk Characterization Guidance is designed to ensure a full and complete analysis of risk in the decision-making process and to promote greater consistency and comparability in risk assessments across Agency programs. It is the culmination of a multi-year project of the EPA's Risk Assessment Council to improve the Agency's risk assessment process. Attached is a copy of the Risk Characterization Guidance and its accompanying appendix. A similar copy was provided to Regional Superfund risk assessors early in March.

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The Risk Characterization Guidance is relevant to all Superfund risk assessments since it discusses not only risk assessments performed for national regulations but also site-specific risk assessments, e.g., Superfund baseline risk assessments.

After studying the Risk Characterization Guidance and current Superfund policy, we are pleased to report that Superfund policy already addresses most of the points raised in the Risk Characterization Guidance. Implementation of current policy with minor supplementation should bring Superfund risk assessment and risk management fully in line with recommendations in the Risk Characterization Guidance.

Specifically, the Risk Characterization Guidance lists the following three principles for presenting risk assessment information in new Agency reports, presentations, and decision packages:

1) Risk assessment information should be clearly presented separate from any non-scientific risk management considerations.

2) Key scientific data and methods and their uncertainties should be identified in the risk characterization and a statement of confidence should be included that identifies all major uncertainties along with comment on their influence on the assessment.

3) Information on the range of exposures derived from exposure scenarios and on the use of multiple risk descriptors should be presented.

Our current policies address the principles set out in the Risk Characterization Guidance in the following ways:

1) The Superfund remedy evaluation and selection process is designed to keep risk assessment and risk management separate. The results of the baseline risk assessment are just one of the tools used by risk managers for making cleanup decisions.

2) The Risk Assessment Council's (RAC's) guidance states that uncertainties should be presented for each step of the risk assessment process. The Risk Assessment Guidance for Superfund, Part A is already in line with this guidance. Each chapter of Part A has a section specifically devoted to presentation of risk assessment-related uncertainties to aid risk managers. Further, we deal with uncertainty and variability in site sampling data through our Guidance on Data Useability and use of the 95 percent upper confidence

limit (95 UCL) on the arithmetic mean of site sampling data. In addition, information on the level of uncertainty in the toxicity criteria we use in our assessments is provided by the Office of Research and Development in the Integrated Risk Information System (IRIS) and the Health Effects Assessment Summary Tables (HEAST) they prepare for the Superfund program.

Thus we can meet the second principle by inclusion in the Record of Decision of appropriate highlights from a well-done baseline risk assessment completed as part of the Remedial Investigation.

3) Currently, we address two of the four risk-descriptors listed in the RAC guidance. Our "Reasonable Maximum Exposure" (RME) estimate is designed to be a measure of "high-end" exposure. Our guidance also advocates assessments of risk for sensitive subpopulations (e.g., childhood exposure to lead, recreational and subsistence fishers).

We do not, however, in our current assessments typically include an estimate of central tendency (or average) exposure or an estimate of population risk. In Regions where average exposures are estimated, findings are often presented in the uncertainty section of the risk assessment. Thus, in order to be fully in line with the third principle, the Superfund program should develop additional guidance on estimating central tendency exposures and on addressing population risk, recognizing, however that due to the lack of sufficient exposure data at most Superfund sites, it generally is not possible to estimate population risks.

Objective

The Deputy Administrator recognized that program offices must continue to make risk management decisions during the time in which changes in policy are made to reflect the principles of the Risk Characterization Guidance. Specifically he states that "we do not expect risk assessment documents that are close to completion to be rewritten." Our objective is speedy, effective updating of Superfund policies on risk assessment and risk management, while continuing to meet all remedial program objectives.

Implementation

To implement in the Superfund program the recommendations in the Risk Characterization Guidance, the following steps should be taken:

- No modifications based on the Risk Characterization

Guidance need to be made for Records of Decision (RODs) already signed or the risk assessments supporting them.

- RODs to be signed in FY 93 should consider the Risk Characterization Guidance in developing and drafting their risk management decisions. This may require some additional limited risk assessment work, particularly to provide an estimate of central tendency exposure.

- For risk assessments completed or close to completion in support of FY 92 RODs:

  A risk assessment for a site for which the Proposed Plan has been developed generally need not be revised to reflect the principles in the Risk Characterization Guidance;

  Risk assessments in draft or under development should generally include data to reflect the principles in the Risk Characterization Guidance. A supplemental discussion of average exposure as part of the uncertainty discussion, either in the risk assessment or the ROD, should generally be sufficient.

- Risk assessment guidance on performing "central tendency" exposure assessments should be developed:

  A group of Headquarters and Regional Superfund risk assessors is already working to provide guidance to be in line with the third principle and generally aid in interpreting the Risk Characterization Guidance. The group will first develop guidelines for evaluating central tendency. Any further recommendations on addressing population risk will come later, after the group has completed its work on central tendency and any other descriptors.

Regarding risk management, we will continue to use the RME scenario, as described in the preamble of the National Contingency Plan, in the remedial decision in evaluating what is necessary to achieve protection against risk to human health. The central tendency estimate will be used for informational purposes in discussing uncertainties.

Attachment

cc: Regional Branch Chiefs
HQ Division Directors