

memorandum

DATE: November 13, 1998

REPLY TO: Office of Environmental Policy and Assistance (EH-41):Bascietto:6-7917
ATTN OF:

SUBJECT: **RISK ASSESSMENT GUIDANCE FOR SUPERFUND (RAGS):** Volume I, Human Health Evaluation Manual (Part D, Standardized Planning, Reporting, and Review of Superfund Risk Assessments) - Interim

TO: Distribution

**PURPOSE
OF THIS
MEMO**

To notify DOE elements of the availability of the U.S. Environmental Protection Agency (EPA) guidance on standardized risk assessment planning, reporting, and periodic review in the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) remediation process; and to explain how interested parties can obtain the interim final guidance and other risk-related information.

BACKDROP

A significant component of the CERCLA remedial investigation/feasibility study (RI/FS) is the site-specific baseline risk assessment, which consists of a human health risk assessment and an ecological risk assessment, and which qualitatively and quantitatively presents the existing or potential risks that may be posed by the site if no remedial action is taken.

In December 1989, EPA issued *Part A* in a series of guidance manuals titled *Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual* (also known as "RAGS I"). It was designed to assist the regulated community in completing RI/FSs by providing detailed guidance on how to conduct human health evaluations. In December 1991, EPA issued *RAGS Part B (Development of Risk-based Preliminary Remediation Goals)* and *RAGS Part C (Risk Evaluation of Remedial Alternatives)*. *RAGS Part B* furnishes guidance for calculating risk-based concentrations that may be used, along with applicable or relevant and appropriate requirements (ARARs) and other information, to develop preliminary remediation goals (PRGs) during project scoping. *RAGS Part C* presents guidance for using PRGs and selected cleanup levels to evaluate the human health risks for each remedial alternative considered or selected.

In a March 21, 1995, memorandum on Risk Characterization Policy and Guidance, the EPA Administrator directed EPA to improve the transparency, clarity, consistency, and reasonableness of risk assessments. In addition, an October 1995 Superfund Administrative Reform #6A directed EPA to establish national criteria for planning, reporting, and reviewing Superfund risk assessments. *RAGS Part D* (January 1998) responds to these challenges and constitutes the fourth part in the *RAGS I* series. It complements *RAGS Parts A, B, and C* and strives for effective and efficient implementation of risk assessment practices by presenting approaches that standardize risk assessment planning, reporting, and review. *RAGS Part D* does not discuss standardizing ecological risk assessments, nor does it discuss the risk management decisions that are necessary at a CERCLA site (e.g., selection of final remediation goals).

**KEY
ELEMENTS
OF THE
GUIDANCE**

The *RAGS Part D* approach consists of three basic elements: (1) Use of Standard Tools, (2) Continuous involvement of EPA risk assessors, and (3) Electronic data transfer to a national Superfund database. Brief descriptions of these three components follow:

- **Use of Standard Tools** - Comprised of: (a) A Technical Approach for Risk Assessment or TARA [presented for the remedial investigation/feasibility study (RI/FS) process phases: During Project Scoping, During the Remedial Investigation, During the Feasibility Study, and After the Feasibility Study]; (b) Standard Tables, including electronic templates in LOTUS® and EXCEL®, which are designed to facilitate clear and consistent documentation of important parameters, data, calculations, and conclusions from all stages of human health risk assessment development; and (c) Instructions for Preparing the Standard Tables.

- **Continuous Involvement of EPA Risk Assessors** - Stresses that early and continuous involvement by the EPA risk assessors should include scoping, workplan review, and customization of the TARA for each site to identify all risk-related requirements. Highlights the submittal of Interim Deliverables as EPA's recommended approach to reducing the Baseline Risk Assessment Report preparation and review time.
- **Electronic Data Transfer to a National Superfund Database** - Summary-level site-specific risk information will be stored in a national Superfund database (CERCLIS 3) and represents a subset of the data presented in the Standard Tables. By submitting to CERCLIS 3 electronic Standard Tables that are structured to be compatible, risk data reporting requirements will be met electronically and additional data entry should not be required.

Be aware that EPA has responded to concerns regarding a *RAGS Part D* recommendation that sites be required to submit Interim Deliverables. Concerns focus on the possibility that regulators interpreting this guidance could require multiple interim submittals. Each interim submittal could then enter a lengthy review cycle, necessitating regulator comment on a Table, for example, followed by submitter's response to comments, resubmission and regulator approval prior to proceeding to the next Interim Deliverable. This potential for a piecemeal approach could negatively impact project budgets and schedules. EPA, however, responds to this concern in a fact sheet titled *Frequently Asked Questions: RAGS Part D* (OSWER Dir. 9285.7-01DFS) in which EPA contends (1) that another review is not being added, rather that existing reviews are being phased to occur at the most critical times; and (2) these deliverables will increase the likelihood that subsequent deliverables will be correct the first time, thereby reducing rework because EPA's expectations will be made clear at project initiation. Regardless, DOE risk assessors should recognize that individual EPA risk assessors appear to have some latitude in how they implement the Interim Deliverable requirement.

APPLICABILITY

As of January 1, 1998, the risk assessment planning and development approach contained in *RAGS Part D* has been recommended by EPA for Remedial, Post-Remedial, and Superfund Accelerated Cleanup Model (SACM) sites, as well as been encouraged at Removal and RCRA Corrective Action sites. Its use is also being encouraged in ongoing risk assessments to the extent it can efficiently be incorporated into the risk assessment process. *Part D* is not applicable to completed risk assessments.

AVAILABILITY OF RAGS PART D

Copies of the subject guidance can be obtained from the National Technical Information Service (NTIS) in Springfield, Virginia at (703) 487-4650 or 1-800-553-NTIS (6847) (Order No. PB97-963-305), or through the RAGS Part D Website on the EPA Superfund World Wide Web at <http://www.epa.gov/superfund/programs/risk/ragsd/index.htm>. Also, according to EPA, users registering for the *RAGS Part D* mailing list will receive automatic notification of future updates. (Updates to Part D also appear on EPA's Website.) Finally, users are encouraged to access the "DOE Office of Environmental Policy and Assistance (OEPA) Dose and Risk Resources Focus Area" (<http://tis.eh.doe.gov/oeпа/risk/>) for guidance, policy, and technical assistance on dose and risk issues relevant to DOE.

COMMENTS AND ADDITIONAL INFORMATION

RAGS Part D is being distributed as an interim document to allow for a period of field testing and evaluation. Questions or comments addressing the interim draft's usefulness, suggested changes, additional areas requiring guidance, or the information presented therein may be directed to John Bascietto of my staff by:

- Calling (202) 586-7917,
- Faxing messages to (202) 586-3915, or
- Communicating electronically, via Internet, to "john.bascietto@eh.doe.gov".

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