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

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MEMORANDUM

SUBJECT: Implementation of *Risk Assessment Guidance for Superfund (RAGS) Volume 1 - Human Health Evaluation Manual (Part D, Standardized Planning, Reporting, and Review of Superfund Risk Assessments)* (Interim)

FROM: Stephen D. Luftig, Director *Steve Luftig*
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TO: Superfund National Managers, Regions 1 - 10

PURPOSE

The purpose of this memorandum is to:

- o convey *Part D* of *Risk Assessment Guidance for Superfund (RAGS) Volume 1 - Human Health Evaluation Manual*
- o request that you assure its implementation in all risk assessment planning and development, effective January 1, 1998.

BACKGROUND

The March 21, 1995 memorandum on Risk Characterization Policy and Guidance from Administrator Browner directed improvement in the transparency, clarity, consistency, and reasonableness of risk assessments at EPA. We, over the years, have looked for opportunities for improving Superfund risk assessments and also have received criticisms from the General Accounting Office (GAO), members of Congress, and others. Most of these criticisms questioned the transparency or consistency of our risk assessments at sites across the country. The October 1995 Superfund Reform #6A directed EPA to establish national criteria to plan, report, and review Superfund risk assessments. *RAGS Part D* responds to these challenges and fulfills the Reform #6A mandate.

An Agency workgroup of regional and headquarters risk assessors (the *RAGS Part D* Workgroup) has been active since the second quarter of FY 96 developing Standard Tools and other approaches to support standardization. Preliminary draft Standard Tools developed by the Workgroup in 1996 were tested and subjected to regional and state review in the fourth quarter of FY 96. Additional development and testing were performed by the Workgroup in FY 97, and a second regional review occurred in fourth quarter of FY 97. The Workgroup also coordinated extensively with the development team for the National Superfund Database (CERCLIS 3) during FY 97, concurrent with CERCLIS 3 development and testing efforts. The Standard Tools in *RAGS Part D (Technical Approach for Risk Assessment, Standard Tables, and Instructions for the Standard Tables)* reflect the results of continued development, testing, and CERCLIS 3 interaction, and are now available for use immediately.

Elements of the *RAGS Part D* Approach

The *RAGS Part D* approach consists of three basic elements: Use of Standard Tools, Continuous Involvement of EPA Risk Assessors, and Electronic Data Transfer to a National Superfund Database. Brief descriptions of the three components follow:

- **Use of Standard Tools** - The Standard Tools developed by the *RAGS Part D* Workgroup and refined through regional review include a *Technical Approach for Risk Assessment* or *TARA*, *Standard Tables*, and *Instructions for the Standard Tables*.
 - The *Technical Approach for Risk Assessment (TARA)* is a road map for incorporating continuous involvement of the EPA risk assessor throughout the CERCLA remedial process for a particular site. Risk-related activities, beginning with scoping and problem formulation, extending through collection and analysis of risk-related data, and supporting risk management decision making and remedial design/remedial action issues are addressed. The *TARA* should be customized for each site-specific human health risk assessment as appropriate.
 - The *Standard Tables* have been developed to clearly and consistently document important parameters, data, calculations, and conclusions from all stages of human health risk assessment development. Electronic templates for the *Standard Tables* have been developed in LOTUS® and EXCEL® for ease of use by risk assessors. For site-specific risk assessments, the *Standard Tables*, related *Worksheets* and *Supporting Information* should first be prepared as Interim Deliverables for EPA risk assessor review, and should later be included in the Draft and Final Baseline Risk Assessment Reports.
 - *Instructions for the Standard Tables* have been prepared corresponding to each row and column on each *Standard Table*. Definitions of each field are supplied in the Glossary, and example data or selections for individual data fields are provided. The *Instructions* should be used to complete and/or review *Standard Tables* for each site-specific human health risk assessment.

- **Continuous Involvement of EPA Risk Assessors** - The EPA risk assessor is a critical participant in the CERCLA remedial process for any site, from scoping through completion and periodic review of the remedial action. EPA risk assessors support reasonable and consistent risk analysis and risk-based decision making. 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. The EPA risk assessors will review Interim Deliverables (*Standard Tables, Worksheets, and Supporting Information*) and identify corrections needed prior to preparation of the Draft and Final Baseline Risk Assessment Reports. This will help assure high quality risk assessments and greatly reduce the potential need for rework of contractor-prepared risk assessments. Participation of the EPA risk assessors in other stages of the CERCLA remedial process will ensure human health risk issues are appropriately incorporated in the remedy selection and implementation processes.
- **Electronic Data Transfer to a National Superfund Database** - Summary-level site-specific risk information will be stored in a National Superfund Database (CERCLIS 3) to provide data access and data management capabilities to all EPA staff. These risk-related summary data represent a subset of the data presented in the *Standard Tables*. The electronic versions of the *Standard Tables* (LOTUS® and EXCEL®) are structured to be compatible with CERCLIS 3. Translation software is under development to transfer data from the *Standard Tables* to CERCLIS 3, and no additional data entry should be required in the regions to fulfill the CERCLIS 3 risk data requirements.

OBJECTIVE

The three elements of the *RAGS Part D* approach described previously achieve both the objectives of Superfund Reform #6A (i.e., establish national criteria to plan, report, and review Superfund risk assessments) and the goals of the memorandum on Risk Characterization Policy and Guidance (i.e., improved transparency, clarity, consistency and reasonableness of EPA risk assessments). The elements of the *RAGS Part D* approach provide a methodology that will improve the quality and consistency of human health risk assessment development and risk-based decision making through the following:

- Standard Tools will be used to document the planning, reporting, and review of human health risk assessments in a consistent format, to clarify the assumptions made, and to increase a reader's ability to understand the approach followed (transparency).
- Continuous Involvement of EPA Risk Assessors in the planning and review of human health risk assessments, throughout all phases of the CERCLA remedial process, will improve the reasonableness and consistency of risk assessment assumptions and conclusions as well as ensure that these conclusions are appropriately understood and applied to risk management decisions.

- Electronic Data Transfer to a National Superfund Database (CERCLIS 3) from the *Standard Tables* will efficiently accomplish reporting requirements, support program-level data consistency reviews, and make data available for other readers to review easily (transparency).

IMPLEMENTATION

Applicability of the RAGS Part D Approach

The approach contained in *RAGS Part D* is recommended for all risk assessments commencing after the issuance of *Part D*. Its use is also encouraged in on-going risk assessments to the extent it can efficiently be incorporated into the risk assessment process. *RAGS Part D* is not applicable to completed risk assessments.

Exhibit 1 provides guidelines regarding *RAGS Part D* applicability as a function of site lead and site type, so that site-specific applicability may be determined by each region.

EXHIBIT 1: GUIDELINES FOR RAGS PART D APPLICABILITY

SITE LEAD	PART D APPLICABLE
Fund Lead	✓
Federal Facility Lead	✓
PRP Lead	✓
State Lead	✓
SITE TYPE¹	
Remedial: Scoping, RI/FS, Risk Assessment, Proposed Plan, ROD, RD/RA, Presumptive Remedy	✓
Post-Remedial: ESD, Amended ROD, Five-Year Review	✓
Removal: Non-time Critical, Time-Critical, Streamlined	-- ²
SACM	✓
RCRA Corrective Action ³	-- ²

Notes:

- ¹ The *RAGS Part D* Workgroup also suggests that *RAGS Part D* could be a useful tool for quantitative risk assessment for non-NPL, BRAC, and Brownfields sites and encourages its use.
- ² *RAGS Part D* use is encouraged as appropriate.
- ³ As described in the September 1996 EPA memorandum on Coordination Between RCRA Corrective Action and Closure and CERCLA Site Activities, EPA is "...committed to the principle of parity between the RCRA corrective action and CERCLA programs..."

Implementation of the RAGS Part D Approach

In FY 98, each region will identify *RAGS Part D* phase-in schedules on a site-by-site basis using the guidelines presented above. The Standard Tools (*TARA*, *Standard Tables*, and *Instructions for the Standard Tables*) are for immediate use. Field testing and evaluation of *RAGS Part D* will take place during the remainder of FY 98 in all regions. Modifications to *RAGS Part D* will be made as necessary during FY 98 and in FY 99 in response to evaluation results and to address new human health risk assessment guidance, as appropriate.

We are attaching the list of *RAGS Part D* Workgroup members and a Quick Reference Fact Sheet, *Frequently Asked Questions: RAGS Part D*, to aid you and your staff in implementation of this directive. The Workgroup member in your region has multiple copies of *RAGS Part D*, including all Standard Tools and diskettes. These are also available to you on the Intranet, and to the public on the Internet at the following location:

<http://www.epa.gov/superfund/oerr/techres/ragsd/ragsd.html>

Training on *RAGS Part D* will be provided in each region in FY 98. Additional information will be forthcoming regarding training schedules.

If you have questions about *RAGS Part D* or its implementation, please contact Jim Konz, leader of the *RAGS Part D* Workgroup, at 703-603-8841, or David Bennett, Senior Process Manager for Risk, at 703-603-8759.

Attachments

cc: Members of *RAGS Part D* Workgroup

RAGS PART D WORKGROUP MEMBERS

Contact	Location	Phone Number	E-Mail Address
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Frequently Asked Questions: RAGS Part D

Office of Emergency and Remedial Response

Quick Reference Fact Sheet

This fact sheet summarizes frequently asked questions regarding the U.S. Environmental Protection Agency's (EPA) Risk Assessment Guidance for Superfund Volume I - Human Health Evaluation Manual (Part D, Standardized Planning, Reporting, and Review of Superfund Risk Assessments) Interim (RAGS Part D). The March 21, 1995 memorandum on Risk Characterization Policy and Guidance from EPA Administrator Browner directed improvement in the transparency, clarity, consistency, and reasonableness of risk assessments at EPA. EPA, over the years, has identified opportunities for improvement in presentation of Superfund risk assessments. Furthermore, the General Accounting Office, members of Congress, and others have called for the betterment of Superfund risk assessments. The October 1995 Superfund Administrative Reform #6A directed EPA to: Establish National Criteria to Plan, Report, and Review Superfund Risk Assessments. EPA has developed an approach to respond to these challenges, which is presented in RAGS Part D.

RAGS Part D was developed by a Workgroup of EPA Headquarters and regional risk assessors (the RAGS Part D Workgroup) in concert with the CERCLIS 3 database development team to help standardize and improve the risk assessment process. The following frequently asked questions have been developed to clarify how and when RAGS Part D should be applied to a risk assessment.

APPLICABILITY

1. To what sites will RAGS Part D apply?

RAGS Part D will apply to all Superfund risk assessments starting after January 1, 1998. In addition, the use of RAGS Part D is encouraged to the extent it can be efficiently incorporated into ongoing risk assessments started before that time. RAGS Part D is applicable to Remedial, Post-Remedial and SACM sites. The use of RAGS Part D is also encouraged for Removal and RCRA Corrective Action sites. The RAGS Part D Workgroup suggests that RAGS Part D could also be a useful tool for quantitative risk assessment at non-NPL, BRAC, and Brownfields sites, and encourages its use.

2. At what phase of investigation should the Standard Tables be used at sites?

RAGS Part D describes the value that Interim Deliverables, which include the Standard Tables, add to the CERCLA remedial process, beginning with scoping and extending through the completion of the Baseline Risk Assessment.

3. Has DOD accepted RAGS Part D? Who will be responsible for ensuring that all of the services receive and use the Standard Tables?

We are working with DOD Headquarters as well as our

EPA Federal Facilities office to introduce the elements of RAGS Part D. So far, we have received positive feedback from the management at DOD. The individual services will be responsible for implementation of RAGS Part D. We are briefing various levels of Federal Facilities (DOD and others) about RAGS Part D and are highlighting the advantages of using it.

Some Federal department staff were involved in the development of RAGS Part D. The Air Force, Navy, and Army were asked to comment on the draft Standard Table package and many of their comments were incorporated into RAGS Part D.

4. Should every EPA region use RAGS Part D?
Yes

5. Does this guidance apply to non-NPL sites?

While the guidance is specifically targeted for NPL sites, the use of RAGS Part D is also encouraged for Removal and RCRA Corrective Action risk assessments. The principles of continuous involvement of the EPA risk assessor and the use of Standard Tools to plan, report, and review risk assessments would be helpful at any site.

6. **Is RAGS Part D applicable to state agencies?**
RAGS Part D is applicable to Superfund risk assessments performed under state oversight. The use of RAGS Part D is also encouraged for Removal and RCRA Corrective Action sites.
7. **Have state agencies been involved in the development of RAGS Part D?**
Several regions have shared drafts of RAGS Part D with states in their region, and the Workgroup considered the state comments when preparing RAGS Part D.

IMPLEMENTATION

8. **Rather than save time and money, it seems that the use of RAGS Part D will slow down the process. How will use of the Standard Tables save time and money? Adding another major review of Interim Deliverables will cause major delays in projects.**
Initially, implementation may take longer than traditional risk assessments; there is a learning curve associated with any new guidance. The road map for continuous involvement of the EPA risk assessor, presented in Chapters 2 through 5 of RAGS Part D, and the Standard Tables, are standard tools to perform a risk assessment that should ultimately make the process more efficient. Specifically, review of Interim Deliverables will increase the likelihood that deliverables will be right the first time and will reduce rework because EPA's expectations for the risk assessment are clear at project initiation to both PRP and EPA contractors.

Preparation, review, and approval time will be shortened when each risk assessment presents information in a consistent manner using the Standard Table format. Consistency of presentation between risk assessments should also lead to better quality risk assessments.

Eliminating manual data entry into CERCLIS 3 will greatly reduce time and resources spent on reporting risk information. On the regional level, eliminating manual data entry will save the regions from having to provide hard copies of risk assessments to EPA Headquarters. In addition, EPA should be able to respond more easily to information requests, such as Congressional inquiries, by accessing electronic databases.

Regarding Interim Deliverables, another review is not being added; instead existing reviews are being phased to occur at the most critical times. Early and continuous involvement of the EPA risk assessor will lead to fewer data gaps and less rework associated with the Draft Baseline Risk Assessment.

9. **The risk assessors in our region are so busy now, how can they possibly be involved in every step of the RI, FS, and other parts of the process? We are**

going to need more risk assessors if this is the case. EPA Headquarters has canvassed the regions and requested resource requirements to implement the elements of RAGS Part D. EPA Headquarters is attempting to supplement the staff in the regions to meet those demands. In addition, the standard reporting formats (Standard Tables) provided in this guidance will make it easier for RPMs to identify risk assessment data requirements if a regional risk assessor is not available to review a risk assessment.

10. **It seems that implementation of RAGS Part D will cost more money, since most PRPs and contractors already have their own standard formats for risk assessments. Why are we reinventing the wheel? How can we estimate the initial increase in cost of this guidance for our contractors?**

Initially, PRPs and contractors may have to amend their spreadsheets to provide appropriate data for the Standard Tables. Regional risk assessors should be able to estimate the initial cost for amending spreadsheets. After this initial effort, the cost should actually decrease because of the standardization of requirements. EPA is implementing RAGS Part D in response to concerns by Congress (and the public) regarding the problems with transparency, clarity, consistency, and reasonableness of risk assessments. Without Standard Table formats, risk assessment information would continue to vary in completeness and clarity, and the data would have to be entered into CERCLIS 3 manually.

11. **Why are the Standard Tables so long and redundant? Why not "nest" information within columns?**
The Standard Table format promotes transparency in data presentation and facilitates subsequent electronic data transfer to CERCLIS 3. The electronic format will enable risk assessors to copy columns rather than retype information, so any repetition should not be burdensome. In addition, because of the eventual link between the Standard Tables and CERCLIS 3, it is necessary to segregate distinct pieces of information in order to make electronic transfer possible.

12. **How will implementation of RAGS Part D add to consistency in risk assessments when we say that risk assessors should refer to regional guidance?**
RAGS Part D adds to consistency of reporting of risk information. Where there is not overarching National guidance, regional differences exist. The risk assessor should refer to the regional office for appropriate guidance on topics such as variations in fish consumption rates, models used for showering scenarios, and selection of default exposure parameters.

TRANSITION

13. **If I am asking my contractors to implement the use**

of Standard Tables, I will have to amend statements of work for all my sites. This will be a lot of work. Sites with risk assessments already underway will be handled on a case-by-case basis and may not need amended SOWs. EPA Headquarters has offered assistance to regions in amending SOWs for EPA contractors performing risk assessments. For PRP lead sites, regions will be responsible for amending consent decrees as needed.

14. Will RPMs, contractors, etc. be trained in the use of RAGS Part D?

There will be training in each region in FY 98 for Federal and state risk assessors, RPMs, and contractors regarding the elements of RAGS Part D.

15. How will the format of the Standard Tables change in years ahead as new guidance is released?

The format of the Standard Tables is the result of an extensive development effort, and we do not expect major changes to the Standard Tables except for additions resulting from new guidance (e.g., lead guidance, Monte Carlo/Probabilistic Analysis, and ecological guidance).

16. If I have questions on how to complete one of the Standard Tables, who do I contact?

The Instructions for the Standard Tables offer detailed guidance for completion of these Tables. EPA is also developing a website and telephone Helpline to assist users in implementing RAGS Part D and as a source of update information. In addition, the RAGS Part D Workgroup member from your region (listed at the end of this Fact Sheet) should be able to assist you and answer questions about the Standard Tables.

PROCEDURES/APPLICATION

17. Are there comparable tables for ecological risk assessment?

Standard Tables for ecological risk assessment are on a different track than the human health Standard Tables. EPA Headquarters representatives are working with regional risk assessors on Standard Tables for ecological risk assessment.

18. If ecological concerns are driving the site cleanup, what Standard Tables should be used?

The Standard Tables for human health risk assessment should be completed if a human health risk assessment is being prepared. Ecological Standard Tables, once finalized, should be used to present ecological risk assessment information. Standard Tables for ecological risk assessment are being developed under another initiative.

19. EPA just released Monte Carlo guidance. How will

this be reflected in the Standard Tables?

The current version of the Standard Tables in RAGS Part D does not address Monte Carlo Analysis; however, Chapters 2 and 3 discuss probabilistic analysis. Once the Superfund program completes guidance in these areas, Standard Tables will be developed to implement the guidance. In addition, there will be updates to these tables periodically and a website and Helpline will be available for guidance on changes.

20. What is the definition of EPA risk assessor?

This term refers to the risk assessor responsible for reviewing the risk assessment on behalf of EPA. In general, the EPA risk assessor is employed by EPA. Many EPA regions may also receive contractor, inter-agency, or state support in performing the role of the EPA risk assessor. The designation is a region-specific matter.

21. How is lead exposure addressed by the Standard Tables?

A separate Standard Table documenting lead exposure, based on the IEUBK model, is under development. When completed, it will be made available through the website (<http://www.epa.gov/superfund/oerr/techres/ragsd/ragsd.html>) and through the RAGS Part D Workgroup member from your EPA region.

22. Will Interim Deliverables be subject to enforceable schedules?

Enforceable schedules of Interim Deliverables will be handled on a site-specific basis in each region.

23. Can the Standard Tables be altered?

No. The Standard Table formats can not be altered (i.e., columns can not be added, deleted, or changed); however, rows and footnotes can be added as appropriate. Standardization of the Standard Tables is needed to achieve Superfund program-wide reporting consistency and to accomplish electronic data transfer to CERCLIS 3.

24. When, in the risk assessment process, are Interim Deliverables due?

The schedule for Interim Deliverables will be determined on region-specific and site-specific bases.

25. Does RAGS Part D contradict the format outlined in RAGS Part A?

No. RAGS Part D supplements RAGS Parts A, B, and C.

26. What happens if a chemical is not originally included as a Chemical of Potential Concern, but is later detected?

The Standard Tables should reflect the information used

in the Baseline Risk Assessment to make the remedy decision. If necessary, the Standard Tables may require modification to reflect new data. The use of electronic spreadsheets makes this an easy task.

CERCLIS 3

27. **How will information be entered into CERCLIS 3?**
The Standard Tables prepared in Lotus® and/or Excel® formats will be electronically transferred to CERCLIS 3 using an upload function that is under development.

28. **Who will enter information into CERCLIS 3?**
Responsibility for entry of CERCLIS 3 risk data during FY 98 has not yet been determined. Use of Standard Tables by the risk assessor will minimize the burden of manual entry of risk data into CERCLIS 3.

29. **Who will have access to the risk data in CERCLIS 3 (e.g., public, DOD, EPA Program Managers, RPMs, risk assessors)?**
The CERCLIS 3 database managers will determine data accessibility. It has been recommended that entities contributing data to CERCLIS 3 be given access to it. At the moment, it is planned for the public to have access to non enforcement-sensitive data. The EPA regional Information Management Coordinators will have information on CERCLIS 3 data accessibility.

FOR FURTHER INFORMATION

The technical details (e.g., equations and assumptions) necessary to complete a risk assessment are available in RAGS. Additional information and guidance can be found in the various OSWER directives that have been released on risk assessment. For additional copies of this Frequently Asked Questions Fact Sheet, or any of the aforementioned risk assessment guidance documents, call the National Technical Information Service (NTIS) at (703) 487-4650 or 1-800-553-NTIS (6847). Alternately, you can access information on RAGS Part D via the Internet at the following location:

<http://www.epa.gov/superfund/oerr/techres/ragsd/ragsd.html>

The following members of the EPA RAGS Part D Workgroup may also be contacted:

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REFERENCES

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