



DIRECTIVE NUMBER: 9295.4-01

TITLE: MOU Between ORD and OERR

APPROVAL DATE: 11/5/90

EFFECTIVE DATE: 11/5/90

ORIGINATING OFFICE: OERR/BSED

FINAL

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STATUS:

REFERENCE (other documents):

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OSWER Directive Initiation Request

9295.4/01

2. Originator Information

Name of Contact Person David Bennett	Mail Code OS-230	Office HSED	Telephone Code 475-9486
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3. Title
MOU Between ORD and OERR

4. Summary of Directive (include brief statement of purpose)

Transmits MOU between OSWER and ORD for implementation of a communications and technical support network between Regions, Laboratories and HQ management units

5. Keywords
MOU

6a. Does This Directive Supersede Previous Directive(s)? No Yes What directive (number, title)

b. Does It Supplement Previous Directive(s)? No Yes What directive (number, title)

7. Draft Level

A - Signed by AA/DAA B - Signed by Office Director C - For Review & Comment D - In Development

8. Document to be distributed to States by Headquarters? Yes No

This Request Meets OSWER Directives System Format Standards.

9. Signature of Lead Office Directives Coordinator Betti C. VanEpps, OERR Directives Coordinator	Date 11/5/90
10. Name and Title of Approving Official Henry L. Longest II, Director, OERR	Date 11/5/90

EPA Form 1315-17 (Rev. 8-87) Previous editions are obsolete.

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

NOV 5 1990

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

OSWER Directive 9295.4-01

MEMORANDUM

SUBJECT: Memorandum of Understanding Between ORD and OERR

FROM: Henry L. Longest II *H. Longest II*
Director, OERR

TO: Addressees

PURPOSE: The purpose of this memorandum is to transmit for your records a copy of the Memorandum of Understanding (MOU) between the Office of Solid Waste and Emergency Response (OSWER) and the Office of Research and Development (ORD) which was signed on March 10, 1990.

BACKGROUND: In 1987, the Office of Solid Waste and Emergency Response, the Regional Superfund Offices, and the Office of Research and Development established the Superfund Technical Support (TSP) project to organize and implement a network for communications and technical support among the Regions and Laboratories. Currently the project consists of five Technical Support Centers (TSCs), each with its own specialty. The attached document creates a sixth TSC to be located in the Office of Health and Environmental Assessment (OHEA), with Environmental Criteria and Assessment Office (ECAO), Cincinnati identified as the focal point to coordinate the assessment of human health and risk issues. The Toxics Integration Branch of OERR is the designated contact to work with the TSP project manager to establish and monitor the conduct and performance of this Center.

OBJECTIVE AND IMPLEMENTATION: The addition of this specialized Center will begin to meet the objective of establishing a consistent approach to the coordination of assessment of human health and risk issues. Toward this end, all Superfund managers are directed to become familiar with this Memorandum of Understanding and to begin immediately to utilize the program outlined herein. Questions with respect to this program should be directed to David Bennett, Director, Toxics Integration Branch, OERR at 475-9486.

ADDRESSEES:

Waste Management Division Directors
Superfund Regional Branch Chiefs
OERR Division Directors and Branch Chiefs

MEMORANDUM OF UNDERSTANDING
BETWEEN
THE OFFICE OF RESEARCH AND DEVELOPMENT
AND
THE OFFICE OF SOLID WASTE AND EMERGENCY RESPONSE

I. Purpose

The Office of Emergency and Remedial Response has proposed the establishment of the Technology Support Center (TSC) in the Office of Health and Environmental Assessment (OHEA), Environmental Criteria Assessment Office, Cincinnati, OH (ECAO-Cin) to address the human health risk assessment issues pertinent to Superfund-related activities. This memorandum of understanding (MOU) establishes functions and responsibilities for the TSC.

II. Authority

The Office of Solid Waste and Emergency Response (OSWER), Regional Superfund Offices, and Office of Research and Development (ORD) established the Superfund Technical Support Project (TSP) in 1987. The broad objectives of the TSP are to provide technical support and assistance to regional staff; improve communications among regions and ORD laboratories; ensure consistency in applications of technologies; and furnish state-of-the-art science information for remedial project managers (RPMs) and on-scene coordinators (OSCs). The project consists of a network of Regional Forums, four specialized technology support centers (TSCs) located in ORD laboratories, and one TSC at the Emergency Response Team (ERT). The specialties and locations of the five TSCs are as follows: groundwater fate and transport (RSKEL, Ada, OK); engineering and treatment (RREL, Cincinnati, OH); monitoring and site characterization (EMSL, Las Vegas, NV); exposure and ecorisk assessment (ERL, Athens, GA); and hazardous substances releases and response (ERT, Edison, NJ).

Regional technical personnel have established forums in engineering and treatment, and groundwater fate and transport. Acting as technical resources, forum members work to improve communications and assist in technical transfer between the Regions and the Centers. Monthly teleconferences and periodic TSP meetings are held by the project manager in OSWER'S Office of Program Management and Technology.

In setting up the TSCs, ORD designated the above laboratories to respond to technical questions with respect to the laboratory's specialties and expertise. Resources of such assistance usually come from technical assistance and enforcement support projects funded by the Agency's Superfund Research Subcommittee. Even on an ad hoc basis, however, such projects have limited abilities to be flexible or to fashion more extensive site-specific support. TSP is intended to address this inadequacy by encouraging the regions to utilize their in-house expertise (through the formation of regional technical support forums), and by providing the TSC access to a pool of OSWER funds to "procure" specific support from TSCs, or through the TSCs to obtain certain expertise inside or outside the Agency.

This MOU proposes the establishment of the 6th TSC in the Office of Health and Environmental Assessment with ECAO-Cin identified as the focal point to coordinate OHEA- and Agency-wide assessment of the human health and risk issues. The Toxics Integration Branch (TIB) in the Office of Emergency and Remedial Response (OERR) will work with the TSP project manager to establish and monitor the conduct and performance of the Center.

III. Scope of Responsibility

This MOU covers the specific tasks and functions to be conducted by ECAO-Cin as a TSC for the Superfund program.

Risk assessments are used to determine baseline risk and remedial alternatives and contribute to development of cleanup levels at Superfund sites. They are performed by many different contractors, and are reviewed in the regional offices for adherence to program guidance and consistency of approach. Those reviewers, with various levels of program experience, are required to evaluate the contractor's performance on calculating and characterizing risks from chemicals and chemical mixtures. There may be data gaps associated with these chemicals regarding their toxicities, chemical interactions, exposure uncertainties, extrapolation methods, and the use of default values in various parts of the risk assessment process. There are stages during the process where expert judgment is necessary, and there are many areas where inconsistency can occur.

It is important to the Superfund program that the regions, contractors and potentially responsible parties (PRPs) use a consistent process to characterize risk; and that selection of remedies to meet a health-based cleanup level for a specific chemical is reasonably comparable across regions. Toward that end, the program has updated the guidance on Superfund human health evaluation, has added checklist and reporting format to the guidance, and has been

working with ORD and other offices to develop policy and guidance on exposure scenarios or risk assessment procedures for certain chemical classes. Despite these efforts, the Superfund program does not always have the most current information concerning the state-of-the-science on risk assessment methodologies, chemical-specific toxicity values or characteristics, or the status of review or assessment for Superfund priority chemicals.

The Superfund program is proposing that ORD designate ECAO-Cin as a TSC on health risk assessment to respond to the needs of Superfund regional and headquarters staff. ECAO-Cin has a long history of providing support to different regulatory programs, has experience on chemical review and toxicity validation, and has an excellent working relationships with other ORD labs and program offices; all of these are critical elements for the success of the TSC.

In addition to the proposal for establishment of a TSC in ECAO-Cin, TIB/OERR will work with the regions to formalize a regional risk assessment forum as an integral part of coordinating technical support and assistance through all TSCs. All requests for technical assistance should be funneled through appropriate regional forum representatives. Forum representatives from every region will also participate in regularly scheduled teleconferences with TIB staff and representatives to TSCs to ensure that consistent approaches are applied across all the NPL sites and to identify any issues for which policies or recommendations need to be developed.

A. Functions of the TSC

Generic categories of functions of the TSC for health risk assessment are as follows:

1. To provide direct client services on a rapid turnaround basis by use of available in-house expertise to minimize additional referrals. At a minimum, the TSC should be able to access most data bases and quickly assemble a panel of risk assessment experts to meet a particular need.
2. Where such expertise is not available [e.g., air toxics, radiation, structure activity relationship (SAR) review], the TSC must be able to work with the project manager, regional forum representatives, ORD Office of Technology Transfer and Regional Support (OTTRS), and other program offices (for example, AirRisc at OAQPS and Chemical Assessment Desk at OTS) to have the service delivered when needed.

3. To coordinate with other TSCs to provide a "total response" to the extent feasible, using direct referral when appropriate. This includes assuming lead responsibility for integrating responses to multi-facted questions, as well as referrals to other TSCs when appropriate.
4. To work with the TIB staff and TSP project managers in conducting regularly scheduled forum teleconferences, in holding periodic meetings (to review activities, issues, major requests, etc.,) and in distributing minutes of such events.
5. To document inquiries (and responses to those inquiries) to enable the TIB to identify long-term research needs.
6. To coordinate with CERI, OTTRS, or other offices in the preparation, publication and distribution of technical updates, summaries, and other information used in risk assessment.
7. To articulate Superfund priorities in ORD so that chemical-specific information needed for risk assessment (e.g., inhalation reference doses or slope factors) will be developed for interim and final usages.

B. Specific Tasks

The following list is not at all inclusive, but does provide a good overview of the functions and responsibilities of the TSC for health risk assessment:

1. Provide rapid response by telephone and written follow-up when appropriate to regional toxics integration coordinators, RPMs, OSCs, and regional Superfund staff relating to chemical-specific health information [worker protection and protective clothing questions are to be addressed jointly with ERT.] Obtain background information about the site, provide answers rather than making referrals, as appropriate, and inform the regional Superfund staff regarding the response provided to the requestor.
2. Work with TIB in providing interpretations and clarifications regarding questions on the Risk Assessment Guidance for Superfund (RAGS): Human Health Evaluation Manual. Also to develop interim or default recommendations or rationale on issues applicable to risk assessment for Superfund sites (for example, route-to-route extrapolation, interim RfDs and dermal risk parameters).

3. Develop, working with TIB and other OERR staff as appropriate, site-specific, medium-specific and health-based trigger or cleanup levels for a contaminant, or help the Regions to justify the use of a surrogate cleanup level based on risk to human health (for all phases of Superfund Programs, such as removal and remedial programs).
4. Help TIB/OERR to compile periodic updates and notices of refinements for risk assessment methodology for the Superfund Program, to be distributed to users of RAGS. Also assist TIB/OERR in providing training tools for Regional Superfund staff in order to ensure consistency and to improve the quality of all Superfund risk assessment.
5. Provide periodic status reports regarding TSC activities to TIB/OERR. Help identify and plan future research to address issues related to the Superfund Program. Assist TIB/OERR in coordination with other TSCs to better utilize the existing expertise and resources.
6. Work with other TSCs on analysis of issues, such as the characterization of residual risks or risks posed by cleanup technology.
7. Provide review and comment on site-specific Superfund risk assessments or risk assessment methods.

IV. Period of Agreement

This MOU will continue in effect until modified or amended by the concurrence of both parties or terminated by either party upon a 30-day advance written notice of the other party. Nothing in the memorandum is intended to diminish or otherwise alter authority of the offices involved.

V. Amendments

The memorandum may be amended at any time by the agreement of both parties. Each amendment must be in writing and signed by the appropriate ORD and OSWER officials.



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

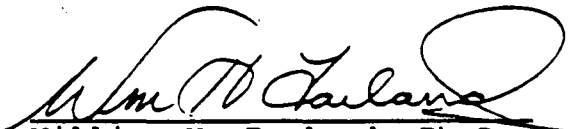
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OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

**INTERPRETATION OF TEXT IN MEMORANDUM OF UNDERSTANDING ESTABLISHING
TECHNICAL SUPPORT CENTER FOR HUMAN HEALTH RISK ASSESSMENT**

Although the last paragraph under II. Authority of the Memorandum of Understanding identifies ECAO-Cin as the focal point to coordinate OHEA- and Agency-wide assessment of human health risk issues, there is need for more explicit understanding of the role of other Office of Health and Environmental Assessment (OHEA) entities.

Our expectation is that ECAO-Cin will continue to work with and refer appropriate inquiries to the Exposure Assessment Group (EAG) and Human Health Assessment Group of OHEA and ECAO-RTP. Typically ECAO-Cin would coordinate as needed with HHAG and ECAO-RTP on toxicity issues and consult with or delegate questions on exposure assessment to EAG. EAG would serve as primary resource on topics addressed in Chapters 4, 5, and 6, "Data Collection", "Data Evaluation" and Exposure Assessment" of Risk Assessment Guidance for Superfund: Human Health Evaluation Manual.


William H. Farland, Ph.D.
Director
Office of Health and
Environmental Assessment


Larry G. Reed
Acting Director
Hazardous Site Evaluation Div.

VI. Effective Date

This memorandum will become effective at noon on the date of the last signature below.

Erich Bretthauer

Erich W. Bretthauer
Acting Assistant Administrator
for Research and Development

Date: 2/6/90

Don R. Clay

Don R. Clay
Assistant Administrator for
Solid Waste and Emergency
Response

Date: 3/9/90