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

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OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

OSWER Directive No. 9200.1-85

**MEMORANDUM**

**SUBJECT:** Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use

**FROM:** James Woolford, Director
Office of Superfund Remediation and Technology Innovation

**TO:** Superfund National Policy Managers, Regions 1 - 10
Regional Science and Technology Directors, Regions 1 - 10

**Purpose**

The purpose of this memorandum is to transmit the final Office of Solid Waste and Emergency Response Directive entitled Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use. This guidance will help increase national consistency, and improve communication and understanding about the nature of validation procedures conducted on laboratory analytical data developed for Superfund use.[1]

**Background**

Each year, well over $25 million are spent through Superfund contracts to analyze soils, water, sediments, and other media for the presence of contaminants of potential concern. Additional resources are often used by U.S. Environmental Protection Agency (EPA) to review (i.e., verify and validate) the resulting laboratory analytical data packages. These reviews are conducted in part to ensure that data produced in support of EPA's environmental decision making are of adequate quality

[1] This guidance will provide information to the public and to the regulated community on how EPA intends to exercise its discretion in implementing its regulations at contaminated sites. It is important to understand, however, that this document does not substitute for statutes EPA administers or their implementing regulations, nor is it a regulation itself. Thus, this document does not impose legally binding requirements on EPA, states, or the regulated community, and may not apply to a particular situation based upon the specific circumstances. Rather, the document suggests approaches that may be used at particular sites as appropriate, given site-specific circumstances. This guidance may be modified in the future.

and usability for their intended purpose. Since there are often different procedures used to evaluate laboratory data quality by different Superfund stakeholders (e.g., EPA regions, Federal facilities, state organizations, potentially responsible parties (PRPs), supporting contractors), the manner in which these reviews are communicated to decision-makers may also vary. Such variability can create problems when data sets developed by different organizations or contractors are evaluated together in support of a particular site activity (e.g., when data are gathered over long periods of time, or when data are gathered quickly by multiple groups in support of a time-critical response action). Because of this potential variability, and because of the complex nature of commonly used analytical data verification and validation procedures, it is important to minimize ambiguity in communicating the nature of these procedures to data users.

The attached guidance recommends the use of consistent terminology by external data reviewers[2] in describing the scope and content of verification and validation conducted on laboratory analytical data packages developed in support of Superfund response actions. Through the use of this guidance, EPA decision makers should be readily able to determine what data verification or validation procedures have been performed on each laboratory analytical data package regardless of which region, program office, or contractor provided the review.

**Implementation**

Effective immediately, the attached guidance should be included among those instructions provided to entities responsible for the verification and validation of laboratory data developed for Superfund use. More specifically, this directive recommends the following:

- EPA Quality Assurance experts should use this guidance (among other relevant guidance and guidelines) when performing external review (i.e., verification and/or validation) of laboratory deliverables.
- Contract Laboratory Program and other national analytical service/quality assurance contract deliverables should include the appropriate terminology and labels presented in the attached guidance to describe the nature of data verification and validation work conducted prior to delivery to regional customers.
- EPA personnel that administer data review contracts (e.g., Response Action Contracts, Superfund Technical Assessment and Response Team, Environmental Services Assistance Team, Regional Oversight Contracts) and Interagency Agreements (IAs) should incorporate this guidance into all appropriate contractor instructions (e.g., Statements of Work (SOW), Work Assignments, Task Orders) for laboratory analytical data verification and validation activities.
- EPA personnel responsible for oversight of Potentially Responsible Party (PRP) analytical activities should incorporate this guidance into all appropriate instructions (e.g., Consent Decrees) for PRPs that may review laboratory analytical data, and for PRP oversight contractors (e.g., SOWs, Work plans) that may perform laboratory data verification and validation activities.

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[2] For the purposes of this guidance, external parties are defined as organizations (including Governmental entities, contractors, or vendors) that conduct analytical data review, verification, and validation activities and that are not part of the immediate laboratory that generates the subject analytical data.

- EPA personnel responsible for the oversight of Federal facilities analytical activities should incorporate this guidance into all appropriate instructions (e.g., IAs) for Federal facilities that may review laboratory analytical data, and for Federal facilities oversight contractors (e.g., SOWs) that may perform data verification and validation activities.

This guidance *does not* require specific levels (or tiers) of verification or validation for EPA or contractor products. Generally, these questions are addressed on a project-specific basis in Quality Assurance Project Plans and/or other project-specific documents.

This document can be found on the internet at http://www.epa.gov/superfund/policy/pdfs/EPA-540-R-08-005.pdf. Please direct any questions to Eric Reynolds of my staff at 703-603-9928 (reynolds.eric@epa.gov).

Attachment

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