United States Environmental Protection Agency Office of Solid Waste and Emergency Response OSWER 9360.4-21FS EPA 540-F-05-005 July 2006

EPA Applicability of Superfund Data Categories to the Removal Program

Office of Emergency Management Office of Superfund Remediation and Technology Innovation Quality Assurance Technical Information Bulletin No. 2 of 3

The Office of Solid Waste and Emergency Response (OSWER) is revising its 1990 *Quality Assurance/Quality Control Guidance for Removal Activities* to address changes in Agency-wide quality assurance policies and guidance documents. Additionally, concepts described in the Removal Guidance have been modified by a 1993 OSWER document, *Data Quality Objectives Process for Superfund*. The 1990 Removal Guidance referred to three "quality assurance objectives" (known as QA1, QA2, and QA3). The 1993 document replaced those codes with alternative, more descriptive terms, *screening data, screening data with definitive confirmation*, and *definitive data*, known collectively as Superfund data categories. For each data collection activity, the Superfund data category or categories should be specified to correspond to the data use objectives.

INTRODUCTION

In April 1990, the Office of Emergency and Remedial Response (OERR) prepared the Office of Solid Waste and Emergency Response (OSWER) Directive 9360.4-01, *Quality Assurance/Quality Control Guidance for Removal Activities* (the Removal Guidance), which was based on then-current Agency-wide quality assurance (QA) policies.

Since then, the following Agency-wide quality documents were issued in May 2000:

- EPA Order 5360.1 A2, *Policy and Program Requirements for the Mandatory Agency-Wide Quality System* (the revised Quality Order); and
- EPA 5360 A1, the EPA Quality Manual for Environmental Programs (the Quality Manual).

In addition, beginning in 1997, OSWER spearheaded an Intergovernmental Data Quality Task Force (IDQTF) to address issues related to the management of environmental data quality at Federal facilities. The IDQTF has produced the Uniform Federal Policy for Implementing Environmental Quality Systems and the multi-part Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP). OSWER has adopted the UFP-QAPP for federal facility hazardous waste activities and highly recommends that it be considered more broadly for data collection projects conducted under Superfund. Regions are strongly encouraged to consider the use of the UFP-QAPP for other purposes. (See OSWER 9272.0-17.)

OSWER has recognized the need to update the Removal Guidance in light of these Agency-wide and OSWER-specific policy changes as well as organizational changes within OSWER through 2004.* As part of the process of revising the Removal Guidance, the Office of Emergency Management (OEM) and the Office of Superfund Remediation and Technology Innovation (OSRTI) are issuing three QA Technical Information Bulletins focusing on some of the more significant QA changes now impacting the Removal Program. †

DATA CATEGORIES

There are two Superfund data categories described in the September 1993 OSWER Directive 9355.9-01, *Data Quality Objectives Process for Superfund*. The data categories are *definitive data* and *screening data with definitive confirmation*. Although OSWER Directive 9344.9-01 used the terms "screening data with definitive confirmation" and "screening data" essentially

[†] The discussion in this document is intended solely as guidance. This document is not a regulation. It does not impose binding legal requirements. EPA retains the right to adopt approaches on a case-by-case basis that differ from those described in this guidance, where appropriate. This guidance document interprets Agency policies on QA. This guidance document may be revised without notice.

^{*} In January 2003, the Assistant Administrator of OSWER proposed an organizational structure to better meet new responsibilities related to homeland security. The organizational change included moving the emergency response (including emergency and time-critical removals) and oil spill programs, then in OERR, into the Chemical Emergency Preparedness and Prevention Office (CEPPO), and the Technology Innovation Office (TIO) into OERR. The final phases of the reorganization were completed by January 2004 for the former OERR, now renamed the Office of Superfund Remediation and Technology Innovation (OSRTI), and by September 2004 for the former CEPPO, now renamed the Office of Emergency Management (OEM).

interchangeably, there is a distinction based on the availability of confirmation data. In addition to the two Superfund data categories identified in OSWER Directive 9344.9-01, the Removal Program uses a third category, "screening data without definitive confirmation"; throughout the remainder of this Quality Assurance Technical Information Bulletin, the third category will be referred to simply as "screening data." The UFP-QAPP Part 1 also discusses *definitive data* and *screening data* in a fashion consistent with OSWER Directive 9355.9-01. For each data collection activity, the data category or categories should be specified to correspond to the data use objectives.

Changes in the Removal Program are structured around the

three analytical data categories (described below), which replace the three "quality assurance objectives" (i.e., QA1, QA2, and QA3) discussed in the April 1990 edition of the Removal Guidance.

What are "Definitive Data"?

Definitive data are generated using rigorous analytical methods, such as EPA reference methods. Data are analyte-specific, with confirmation of analyte identity and concentration. Methods generating definitive data produce tangible raw data (e.g., chromatograms, spectra, digital values) in the form of paper printouts or computer-generated electronic files. Data may be generated at the site or at an off-site location, as long as the quality control requirements are satisfied. For the data to be definitive,

Table 1: Requirements of the Data Categories (Analytical Data)		
Screening Data	Screening Data With Definitive Confirmation	Definitive Data
Sample documentation (location, date and time collected, batch, etc.)	Sample documentation (location, date and time collected, batch, etc.)	Sample documentation (location, date and time collected, batch, etc.)
Chain of custody (when appropriate)	Chain of custody (when appropriate)	Chain of custody (when appropriate)
Sampling design approach (systematic, simple or stratified random, judgmental, etc.)	Sampling design approach (systematic, simple or stratified random, judgmental, etc.)	Sampling design approach (systematic, simple or stratified random, judgmental, etc.)
Initial and continuing calibration	Initial and continuing calibration	Initial and continuing calibration
Determination and documentation of detection limits	Determination and documentation of detection limits	Determination and documentation of detection limits
Analyte(s) identification	Analyte(s) identification	Analyte(s) identification
Analyte(s) quantitation	Analyte(s) quantitation	Analyte(s) quantitation
		Quality control (QC) blanks (trip, rinsate, method)
		Matrix spike recoveries
		Performance Evaluation (PE) samples (when specified)
	Analytical error determination ¹	Analytical error determination ¹
	Definitive confirmation ²	Total measurement error determination ³

NOTES:

- Measures the precision of the analytical method. An appropriate number of replicate aliquots, as specified in the QA Project Plan (QAPP), are taken from at least one thoroughly homogenized sample, the replicate aliquots are analyzed, and standard laboratory QC parameters (such as variance, mean, and coefficient of variation) are calculated and compared to method-specific performance requirements specified in the QAPP.
- 2. At least 10 percent of the screening data must be confirmed with definitive data. At a minimum, at least three screening samples reported above the action level (if any) and three screening samples reported below the action level (or as non-detects) should be randomly selected from the appropriate group and confirmed.
- 3. Measures overall precision of the measurement system, from sample acquisition through analyses. An appropriate number of co-located samples as determined by the QAPP are independently collected from the same location and analyzed following standard operating procedures. Based on these analytical results, standard laboratory QC parameters such as variance, mean, and coefficient of variation should be calculated and compared to established measurement error goals. This procedure may be required for each matrix under investigation, and may be repeated for a given matrix at more than one location at the site.

SOURCE: Adapted from OSWER Directive 9355.9-01, Data Quality Objectives Process for Superfund, September 1993.

either analytical or total measurement error must be determined. (See Table 1.) Per the UFP-QAPP Part 1, definitive data "are analytical data that are suitable for final decision-making."

What are "Screening Data"?

Screening data are generated by rapid, less precise methods of analysis with less rigorous sample preparation than definitive data. Screening data provide analyte (or at least chemical class) identification and quantification, although the quantification may be relatively imprecise. According to the UFP-OAPP Part 1, screening data are "analytical data that are of sufficient quality to support an intermediate or preliminary decision but must eventually be supported by definitive data before a project is complete." For definitive confirmation, at least 10 percent of the screening data are confirmed using analytical methods, quality control procedures, and criteria associated with definitive data. Screening data without associated confirmation data are generally not considered to be data of known quality. Screening data without confirmation data are generally allowed only under limited circumstances, and will be discussed later.

Requirements for the Data Categories

Each data category is associated with a list of minimum requirements. (See Table 1.) Therefore, any method or analytical instrument that can meet the quality requirements can be used for each one of the data categories.

For example, if a field portable X-ray fluorescence method can meet all the "definitive data" quality requirements, the resulting data are definitive. However, if a mass spectrometer method was used, but not all "definitive data" quality requirements were met, then the resulting data are not definitive.

Data Category Most Relevant to the Removal Program

"Definitive data" and "screening data with definitive confirmation" provide useful and valid data for enforcement purposes, determination of extent of contamination, disposal and/or treatment, responsible party identification, and cleanup verification.

It is anticipated that "screening data with definitive confirmation" will satisfy most data quality requirements for the Removal Program. The "definitive data" category is expected to be used only in those cases where an error determination is needed to identify false negative or false positive values for critical decision level concentrations. The "screening data" category (without confirmation) has only limited use, specifically for the following:

- Emergencies;
- Health and safety screening using, for example, Jerome Mercury Vapor analyzer, Industrial Scientific multi-gas monitor, or RAE Systems MultiRAE organic vapor monitor (OVM), and other techniques; ‡

- Real-time field data to supplement analytical data (e.g., "sniffing" a monitoring well with an OVM prior to sampling or measuring pH, dissolved oxygen and/or conductivity at the time of sampling);
- Field sample locational decisions (i.e., collecting screening data to determine in real time where to collect confirmation samples for definitive data analysis);
- Waste profiling; and
- Preliminary identification and quantitation of pollutants.

Quality Control for Screening Data Collection

Operating procedures for OVMs, conductivity meters, and other field instruments require the use of calibration gases or solutions. The manufacturer's instructions or the Regional standard operating procedures should specify the method for and frequency of continuing calibration during use of field measurement instruments. Actual frequency during use should meet or exceed these levels.

IDENTIFICATION OF DATA CATEGORIES FOR A PROJECT

The selected data category or categories should be decided upon during the project's systematic planning process. As stated earlier, the data category or categories need to correspond to the project's data use objectives. Additionally, the data category or categories should be documented in the project's Quality Assurance Project Plan or Quality Assurance Sampling Plan. Refer to the Quality Assurance Technical Information Bulletins titled *Systematic Planning Processes for the Removal Program* and *Changes in Quality Assurance Policies for the Removal Program* for a more detailed discussion of the planning process as well as the contents and completion of QA plans for removals.

REFERENCES

- 1. Intergovernmental Data Quality Task Force, *Uniform Federal Policy for Implementing Environmental Quality Systems*, EPA-505-F-03-001, Version 2, March 2005.
- 2. Intergovernmental Data Quality Task Force, *Uniform Federal Policy for Quality Assurance Project Plans, Part 1: UFP-QAPP Manual*, EPA-505-B-04-900A, Version 1, March 2005.
- 3. U.S. Environmental Protection Agency, *Quality Assurance/Quality Control Guidance for Removal Activities*, OSWER Directive 9360.4-01, April 1990.
- U.S. Environmental Protection Agency, *Data Quality Objectives Process for Superfund*, OSWER Directive 9355.9-01 (Interim Final Guidance), (EPA540/R-93-071), Office of Emergency and Remedial Response, September 1993.
- 5. U.S. Environmental Protection Agency, *EPA Quality* Manual For Environmental Programs, EPA Manual

‡ Mention of company or product names should not be construed as an endorsement by the U.S. Environmental Protection Agency.

5360 A1, Office of Environmental Information, May 2000.

- 6. U.S. Environmental Protection Agency, *Policy And Program Requirements For The Mandatory Agencywide Quality System*, EPA Order 5360.1 A2, May 5, 2000.
- 7. U.S. Environmental Protection Agency, Implementation of the Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP) at Federal Facility Hazardous Waste Sites, Memorandum from Thomas P. Dunne, Deputy

Assistant Administrator, Office of Solid Waste and Emergency Response, to Regional Administrators, Regions I–X, OSWER Directive 9272.0-17, June 7, 2005.

- 8. U.S. Environmental Protection Agency, *Changes in Quality Assurance Policies for the Removal Program*, Quality Assurance Technical Information Bulletin, July 2006.
- 9. U.S. Environmental Protection Agency, *Systematic Planning Processes for the Removal Program*, Quality Assurance Technical Information Bulletin, July 2006.