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Changes in Quality Assurance Policies for the Removal Program

Office of Emergency Management
Office of Superfund Remediation and Technology Innovation

Quality Assurance Technical Information Bulletin
No. 1 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. Removal Program quality assurance (QA) elements are contained in the National Contingency Plan (40 CFR Part 300) as well as Agency-wide documents. For each non-time-critical and time-critical response action, Regional Removal Program personnel should perform systematic, project-specific planning and document the results of that planning in QA Sampling Plans. These plans should be approved prior to any data collection. Response-specific QA Sampling Plans can refer to standard language in a programmatic Regional Removal Program QA Project Plan. QA Sampling Plans for emergency responses are encouraged, but do not require approval prior to implementation. Following an emergency response, a report of the sampling protocols and QA specifications implemented is recommended.

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. †

* 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).

† 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.

ORIGINS OF QUALITY POLICY

QA policies for the Removal Program come from a variety of sources, including Agency-wide policies and the National Contingency Plan (NCP). Ideally, information from these different sources is integrated by OSWER, and issued to the Regional offices implementing the Removal Program activities.

This bulletin was written to provide detailed practical guidance and clarification to the Removal Program in implementing QA policies.

As stated in the revised Quality Order, it is Agency policy that all environmental programs performed by or directly for EPA through EPA-funded extramural agreements be supported by quality systems based on a uniform standard.

In July 1998, EPA issued a revised Quality Order (EPA Order 5360.1 CHG 1), which re-affirmed the policy defined by EPA Order 5360.1 (April 1984), and expanded the policy to accommodate the current and evolving needs of the Agency. Subsequently, EPA issued EPA Order 5360.1 A2 (May 5, 2000), which addressed QA administrative reporting changes within the Agency, but made no additional substantive changes to the Quality Order revised in 1998.

The revised Quality Order defines the minimum quality systems supporting EPA environmental programs that encompass the following:

- The collection, evaluation, and use of environmental data by or for EPA; and
- The design, construction, and operation of environmental technology by EPA.

This revised Quality Order also applies to any collection and use of environmental data pertaining to the occupational health and safety of personnel in the field.

According to the revised Quality Order, “[a] consistent, Agency-wide Quality System will provide, when implemented, the needed management and technical practices to assure that environmental data used to support Agency decisions are of adequate quality and usability for their intended purpose.” *Data quality and usability are directly related to planning and performing a sufficient level of QA and quality control (QC) activities.*

PROGRAM-LEVEL QUALITY PLANNING

As part of their participation in the Agency-wide quality system, National Program Offices such as OSWER established their own Quality Management Plans (QMPs). A QMP is an evolution of the QA Program Plan, and should be prepared and updated at least every five years. A QMP should specify the organizational structure, policy and procedures,

functional responsibilities of management and staff, lines of authority, and interfaces for those planning, implementing, documenting, and assessing all activities performed by or overseen by the organization.

The QMP is established at the EPA Headquarters level. For the Removal Program, the initial responsibility for the QMP lies within OSWER. In addition to OSWER’s QMP, each Region should develop a QMP. These plans are tailored to the specific operational needs of the Regional office. The OSWER QMP, in conjunction with the OEM Quality Management Implementation Plan, issues Removal Program QA parameters to the Regions; the Regional QMPs then address them.

NEW POLICIES FOR PROJECT-SPECIFIC PLANNING

The revised Quality Order sets forth the use of a systematic planning process to design an effective data collection and evaluation program. One such planning process is the Agency’s Data Quality Objectives (DQO) Process. The results of systematic planning, including the data use objectives and the collection strategies decided upon, should be documented in a QA project plan. A separate QA Technical Information Bulletin, *Systematic Planning Processes for the Removal Program*, describes the purposes and components of systematic planning in more detail.

PROJECT-SPECIFIC PLANS

This revised Quality Order also calls for QA Project Plans (QAPPs), or equivalent documents defined by the prevailing QMP, to be developed for all applicable projects and tasks involving environmental data. Additionally, the QAPPs or QAPP-equivalents should be reviewed and approved by the EPA QA Manager (or an authorized representative defined in the QMP). QAPPs or QAPP-equivalents should be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

Importance of the QAPP

According to the Agency Quality Manual (also updated in May 2000), the QAPP is a critical planning document for any environmental data operation. The QAPP documents how environmental data operations are planned, implemented, documented, and assessed during the life cycle of a program, project, or task. The ultimate success of an environmental program or project depends on the adequacy and sufficiency of the quality of the environmental data collected and used in decision making. This may depend significantly on the adequacy of the QAPP and its effective implementation.

Removal Program Support for QAPPs

The NCP states the following in 40 CFR 300.415(b)(4)(ii):

If environmental samples are to be collected, the lead agency shall develop sampling and analysis plans that shall provide a process for obtaining data of sufficient quality and quantity to satisfy data needs. Sampling and analysis plans shall be reviewed and approved by EPA. The sampling and analysis plans shall consist of two parts:

(A) The field sampling plan, which describes the number, type, and location of samples and the type of analyses; and

(B) The quality assurance project plan, which describes policy, organization, and functional activities and the data quality objectives and measures necessary to achieve adequate data for use in planning and documenting the removal action.

This language was included in an NCP revision on March 8, 1990. The Preamble to this regulation published in the *Federal Register* (55 FR 8694) included more explanatory language for 40 CFR 300.415, *Removal Action*, as follows:

. . . EPA believes that, when samples will be taken, it is appropriate to describe sampling requirements for non-time-critical removal actions to ensure that data of sufficient quality and quantity will be collected for this type of action.

EPA also notes that portions of the QAPP may incorporate by reference non-site-specific standardized portions of already-approved QAPPs, especially those portions addressing policy and organization, or describing general functional activities to be conducted at a site to ensure adequate data. This eliminates the necessity to reproduce non-site-specific quality assurance procedures for every site. [emphasis added]

The Elements of the QAPP

To meet the need for a QAPP in the Removal Program, the QAPP should be divided into two functional documents: a generic "Branch QAPP," and a response-specific QA Sampling Plan. When combined, both documents address the 24 elements described in the EPA Quality Manual, Chapter 5 (Table 1), as well as the content of the NCP, 40 CFR 300.415. The worksheets in the UFP-QAPP Part 2A (UFP-QAPP Workbook) can assist in the development of each document.

Table 1: General QAPP Content

Group A, Project Management

A1 Title and Approval Sheet
A2 Table of Contents
A3 Distribution List
A4 Project/Task Organization
A5 Problem Definition/Background
A6 Project/Task Description
A7 Quality Objectives and Criteria for Measurement Data
A8 Special Training/Certification
A9 Documentation and Records

Group B, Measurement/Data Acquisition

B1 Sampling Process Design (Experimental Design)
B2 Sampling Methods
B3 Sample Handling and Custody
B4 Analytical Methods
B5 Quality Control
B6 Instrument/Equipment Testing, Inspection, and Maintenance
B7 Instrument Calibration and Frequency
B8 Inspection/Acceptance for Supplies and Consumables
B9 Data Acquisition (Non-direct Measurements)
B10 Data Management

Group C, Assessment/Oversight

C1 Assessments and Response Actions
C2 Reports to Management

Group D, Data Validation and Usability

D1 Data Review, Validation, and Verification
D2 Validation and Verification Methods
D3 Reconciliation with User Needs

Source: Adapted from Chapter 5, Quality Manual, May 2000

Responsibilities for Branch-level QAPPs

The Branch QA Project Plan should be prepared by each Regional Removal branch and addresses only those elements generic to all Removal activities occurring within the Region. These might include calibration procedures for each instrument (in accordance with the manufacturer's specifications), decontamination procedures for each analyte class, and the generic corrective action process. The Branch QAPP should be reviewed annually and updated periodically to reflect any operational changes in the Region.

Elements of the Response-specific QAPP

The response-specific QA Sampling Plan should be prepared for each site where sampling will be

performed. The plan also addresses those elements specific to the site, such as sample collection and analysis. The response-specific QA Sampling Plan should be prepared for each response and amended when the scope of work changes significantly from the scope of work described in any previous plan. Elements that are not addressed in the Branch QAPP should be included in the QA Sampling Plan.

Certain elements should be addressed in the response-specific plan. For example, to meet element A7, Quality Objectives and Criteria for Measurement Data, the data use objectives during the specific effort should be known and documented. Proper use of a systematic planning process results in the identification of the “data categories” appropriate to the specific response. Refer to the QA Technical Information Bulletin, *Applicability of Superfund Data Categories to the Removal Program*, for additional discussion of data categories selection and use.

When Should the QAPP be Prepared?

The revised Agency-wide Quality Order states: “QAPPs must be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.” Applying this to the Removal Program, only emergency responses would be included in this exemption. Although the NCP specifically calls for sampling and analysis plans (e.g., QA Sampling Plans) for *non-time-critical* responses (responses with at least 6 months lead time), the revised Quality Order does not exempt *time-critical* responses (responses with less than 6 months lead time). Thus, *time-critical* responses should also have a QA Sampling Plan prepared.

Historically, Superfund policy for *emergency* responses, where the release *requires* that response activities begin on-site *within hours* of the Agency’s determination that a removal action is appropriate, has been that a QA Sampling Report (or equivalent) be submitted no later than 30 days after the response date for documentation purposes. It is recommended that this QA Sampling Report describe the sampling event that occurred by containing the types of information that would have been included in a QA Sampling Plan.

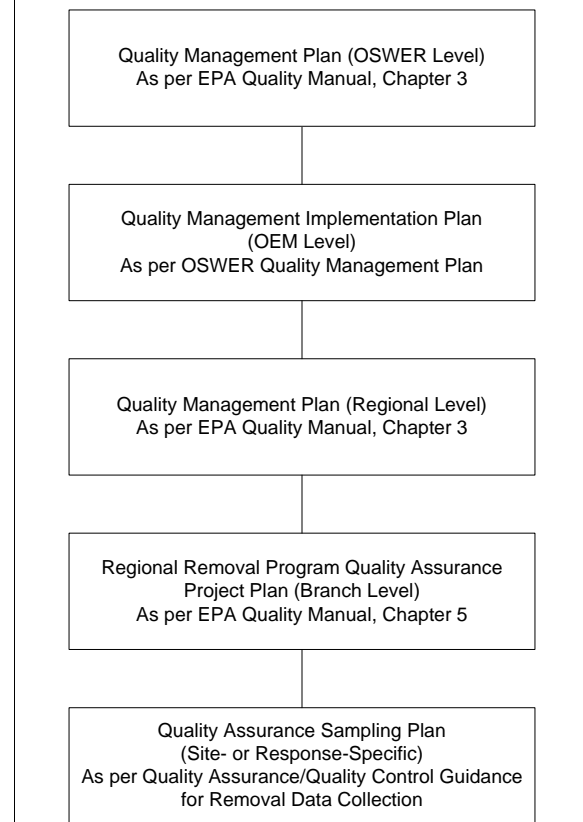
In practice, some Regions are using QA Sampling Plan templates, filled in by hand if necessary, for real-time emergency response sampling and QA planning.

In all other cases, as stated above, the QA Sampling Plan should be written and approved prior to initiating the response activities.

SUMMARY OF HIERARCHY OF QA DOCUMENTATION

Quality assurance planning, implementation, and assessment for the Removal Program are documented

Figure 1: EPA Quality Assurance Documentation



at several levels (Figure 1). Source documents at each level are also depicted.

NOTE: the 1990 *Quality Assurance/Quality Control Guidance for Removal Activities* is under revision as *Quality Assurance/Quality Control Guidance for Removal Data Collection*.

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. Intergovernmental Data Quality Task Force, *Uniform Federal Policy for Quality Assurance Project Plans, Part 2A: UFP-QAPP Workbook*, EPA-505-B-04-900C, Version 1, March 2005.
4. Intergovernmental Data Quality Task Force, *Uniform Federal Policy for Quality Assurance Project Plans, Part 2B, Quality Assurance/Quality Control Compendium: Minimum QA/QC Activities*, EPA-505-B-04-900B, Version 1, March 2005.

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6. U.S. Environmental Protection Agency, *National Oil and Hazardous Substances Contingency Plan*, 40 CFR Part 300, as amended.
7. U.S. Environmental Protection Agency, *EPA Quality Manual For Environmental Programs*, EPA Manual 5360 A1, Office of Environmental Information, May 2000.
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9. U.S. Environmental Protection Agency, *OSWER Quality Management Plan*, Office of Solid Waste and Emergency Response, August 2003.
10. 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.
11. U.S. Environmental Protection Agency, *Systematic Planning Processes for the Removal Program*, Quality Assurance Technical Information Bulletin, July 2006.
12. U.S. Environmental Protection Agency, *Applicability of Superfund Data Categories to the Removal Program*, Quality Assurance Technical Information Bulletin, July 2006.

