QUALITY MANAGEMENT PLAN

HAZARDOUS SITE CLEANUP DIVISION

July 2005 -- Revised Draft

APPROVALS

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Introduction

The Hazardous Site Cleanup Division Quality Management Plan (QMP) has been prepared in accordance with Chapter 3 of the US EPA Quality Manual for Environmental Programs (EPA 5360 A1, May 2000).

This QMP identifies the mission, roles and responsibilities of personnel in the Hazardous Site Cleanup Division (HSCD) with regard to quality assurance (QA), quality management (QM), communications structure and the measures of effectiveness of the Hazardous Site Cleanup Division. Components of the Division's Quality System are also addressed.

HAZARDOUS SITE CLEANUP DIVISION
QUALITY MANAGEMENT PLAN

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I. MANAGEMENT AND ORGANIZATION

A. Mission

The Hazardous Site Cleanup Division conducts and oversees assessment, remedial, and removal activities at hazardous waste sites in US-EPA's Region III. The Division is responsible for the development and management of the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) Program and the implementation of the Clean Water Act, Section 311 Oil and Spill and Response Program.

In support of the CERCLA Program, the Division conducts and/or coordinates the assessment and investigation of waste sites and other potential response actions. It also directs the preparation of remedial action plans for Superfund sites in Region III. The Division also manages the preparation and review of detailed technical feasibility studies, final remedial measure design(s) and other necessary activities for the amelioration of threats to human health and the environment.

In support of the Section 311, the Division is responsible for the implementation of the Regional and sub-Regional Contingency Plans for combating spillage of oil and hazardous materials in cooperation with the US Coast Guard and State and local agencies. The Division conducts and coordinates cooperating agency and industry responses to oil and hazardous material spills pursuant to the requirements of the Clean Water Act and CERCLA/Superfund Amendments and Reauthorization Act (SARA), including containment and cleanup actions, assistance to enforcement investigations and assessment of environmental damage.

B. Quality Assurance Policy and Position

The Quality Assurance/Quality Management (QA/QM) goals of the Division are to ensure that all environmental data generated and processed, including that generated by contractors, States, and other funding recipients, will be scientifically valid, of known and documented precision, accuracy, completeness, representativeness and comparability, and, where appropriate, legally defensible. Specifically, it is the policy of the Division that:

a. All parts of the Division that generate environmental data will develop and implement QA programs that comply with the EPA Quality Manual (5360.1 A1) and EPA Order 5360.1 A2.

b. Data quality information developed with all environmental data will be documented and available as requested for purposes of audits;

c. Intended data uses will be defined before data collection begins, so that appropriate QA measures may be included. The determination of this level of data quality shall also consider the prospective data needs of secondary users. Data Quality Objectives (DQOs) will be established to ensure the

utility of environmental data for its intended use. The intended data uses, level of quality, specific QA activities, and data acceptance criteria needed to meet the data quality needs of these uses will be described in each project or activity's QA Project Plan;

d. All projects that generate environmental data will have an approved Quality Assurance Project Plan (QAPP) in place before field sampling starts. The QAPPs will be reviewed by the Analytical Services and Quality Assurance Branch (ASQAB) and approved by the RPM.

e. QA activities will be designed in the most cost-effective fashion possible without compromising DQOs.

f. HSCD will develop a method of assessing the effectiveness of this QMP on an annual basis.

C. Hazardous Site Cleanup Division Organization

HAZARDOUS SITE CLEANUP DIVISION
DIVISION DIRECTOR: Abraham Ferdas
DEPUTY DIRECTOR: Kathryn Hodgkiss

The Hazardous Site Cleanup Division Programs, under the supervision of the Division Director, is responsible for all managerial and programmatic functions of the Superfund Program in Region III. The Superfund Program administers CERCLA and the Superfund Amendments and Reauthorization Act of 1986 (SARA). The Division is also responsible for the Regional implementation activities of the SARA Title III Chemical Emergency Preparedness and Prevention (CEPP) program and carries out the Regional Oil Program pursuant to the Oil Pollution Act (OPA) of 1990.

The Division consists of five Offices: Federal Facility Remediation and Site Assessment, Superfund Site Remediation, Technical and Administrative Support, Preparedness and Response, Brownfields and Outreach, and Enforcement.

Office Of Federal Facility Remediation And Site Assessment
Office Director: Hank Sokolowski

The Office consists of two Branches: the NPL/BRAC Federal Facilities Branch is responsible for the development and implementation of CERCLA and SARA activities associated with compliance and cleanup of federal facilities listed on the Superfund National Priorities List (NPL); the Site Assessment and Non-NPL Federal Facilities Branch is responsible for similar activities at federal facilities not listed on the NPL and at formerly used defense sites. The latter Branch is also responsible for screening potential hazardous waste sites for listing on the NPL.

a. NPL/BRAC Federal Facilities Branch. The Branch prepares and negotiates Section 120 Interagency Agreements with other Federal Facilities and State Agencies for Remedial Investigation/Feasibility Study and Remedial Design/Remedial Action. It also oversees the investigation and cleanup of federal facilities listed on the National Priorities List and implements the requirements of the Base Realignment and Closure Act (BRAC) Program for the Region. The Project Managers in this Branch manage the Regional Oversight Contract (ROC) contractors that support the federal facilities program's activities.

b. Site Assessment and Non-NPL Federal Facilities Branch. The Branch is responsible for hazardous waste site discovery, assessment, investigation and ranking of sites for the NPL. The Branch also manages the oversight of investigation and cleanup of non-NPL Federal Facilities and formerly used defense sites. This Branch manages state cooperative agreements and performs oversight of State pre-remedial programs. The project managers in this Branch perform Brownfields assessments at targeted sites identified by EPA, states and local communities, including review of Brownfields sampling and QA plans to ensure compliance with appropriate requirements.

Office Of Superfund Site Remediation
Office Director: Peter Schaul

The Office is responsible for the development and implementation of CERCLA and SARA remedial programs for sites throughout the Region and manages the Superfund monetary expenditures at remedial action sites. The Office maintains cooperative relationships with the States and oversees the implementation of remedial grants or cooperative agreements with the States. The Office consists of three Branches, organized geographically: the Eastern PA Remedial Branch, the Western PA and MD Remedial Branch, and the DE, VA, WV Remedial Branch.

a. Eastern PA Remedial Branch: The Branch is responsible for the Superfund remedial response actions at NPL sites located generally in the part of Pennsylvania served by Regions 1 and 2 of the Pennsylvania Department of Environmental Protection (PADEP) and for coordinating with those regional Offices. Specific responsibilities include: directing the preparation of remedial action plans for Superfund sites, preparing and reviewing technical site investigation and feasibility studies, evaluating final remedial measures, directing cleanup construction, and other necessary activities to address threats to human health and the environment. Project Managers in this Branch also oversee contractors that support the remedial program's activities, such as the Remedial Action Contracts (RACs), and oversee State activities at NPL sites that are undertaken through EPA state cooperative agreements and contracts. Enforcement activities include conducting negotiations with PRPs for taking the lead at NPL sites. Five-year-reviews of sites where waste was left in place are also done in this Branch.

b. Western PA and MD Remedial Branch: The Branch is responsible for Superfund response actions at NPL sites generally located in the part of Pennsylvania served by Regions 3, 4, 5, and 6 of PADEP and at sites in Maryland. The Branch also has the lead for coordinating with those PADEP Offices and the State of Maryland. The Branch has the same specific responsibilities as the Eastern PA Remedial Branch.

c. DE, VA, WV Remedial Branch. The Branch is responsible for Superfund response actions at NPL sites in Delaware, Virginia and West Virginia and for coordinating with these states on remedial actions. The Branch has the same specific responsibilities as the Eastern PA Branch.

Office Of Preparedness And Response
Office Director: Dennis Carney

The Office is responsible for the development and implementation of the Regional Emergency Response and Removal Programs under CERCLA and OPA, as well as response and preparedness activities for Homeland Security and natural disasters. The Office also has lead responsibility for operating and maintaining the Regional Response Center, providing a 24-hour emergency spill notification network to facilitate Regional response activities relating to oil and hazardous material spills, hazardous air pollutant incidents, citizens' reports, pesticides accidents, and radionuclide incidents. The Office consists of three Branches: two Response Branches, organized geographically, and the Preparedness and Support Branch.

a. Eastern Response Branch The Branch is responsible for emergency response and time critical removal actions under CERCLA/SARA and emergency response actions under Section 311 of the Clean Water Act (CWA) in Eastern Pennsylvania (generally characterized as PADEP Regions 1,2, and 3), Maryland, Delaware, and the District of Columbia. Specific responsibilities include: performing removal assessments and initiating emergency response operations at sites; coordinating and directing efforts on-scene; initiating time critical removal operations at NPL and non-NPL sites; conducting and coordinating responses to oil and hazardous materials spills; and, monitoring cleanups for compliance with enforcement-related conditions where PRPs have taken the lead at removal sites.

b. Western Response Branch: The Branch is responsible for emergency response and planned removal actions under CERCLA/SARA and emergency response actions under Section 311 of the Clean Water Act (CWA) in Western Pennsylvania (generally characterized by PADEP regions 4, 5, and 6), Virginia and West Virginia. The Branch has the same specific responsibilities as the Eastern Response Branch.

c. Preparedness and Support Branch: The Branch is responsible for developing, coordinating and implementing responses for both traditional oil and chemical spills, and for natural disasters and counter terrorism. The Branch also is responsible for the SARA Title III preparedness program. The Branch provides contract management support to the Office. Specific responsibilities include: maintaining the Regional Response Center, ensuring a timely spill notification process, maintaining the readiness of the alternate Regional Response Center at the Boothwyn Field Office, developing and updating the Regional Contingency Plan, and, in cooperation with the US Coast Guard, State and Federal agencies, conducting regular meetings of the Region III Regional Response Team. The Branch manages the Office's contracts, including the Emergency and Remedial Response Services (ERRS) contract, the Superfund Assistance and Response Technology (START) contract, and the Equipment Management contracts.

Office Of Technical And Administrative Support
Office Director: Paul Leonard

The Office provides scientific, technical and information management support for the Division. The Office provides a wide range of services, including administering Superfund contracts, grants and inter-agency agreements, and providing support for risk assessment and hydrogeology for site assessment, remedial, enforcement, Brownfields, outreach and federal facilities site activities. The Office consists of two Branches: the Technical Support Branch and the Administrative Support Branch.

a. Technical Support Branch: The Branch provides technical and scientific support to the program Branches in the Office of Superfund Site Remediation, the Office of Preparedness and Response, and Office of Federal Facility Remediation and Site Assessment. Specific responsibilities include: performing toxicological reviews for issues relating to human health risk, conducting hydrogeological investigations for ground water contamination, evaluating ecological risks, performing technical reviews of remedial investigations, feasibility studies, records of decisions and remedial designs.

b. Administrative Support Branch: The Branch is responsible for providing oversight of contracts, grants and cooperative agreements used for Superfund enforcement, federal facilities, State program support and community relations. It also provides information management and Local Area Network (LAN) system support to the Division. Specific responsibilities include: administering Superfund contracts for technical support, including RACs, ROC and ESSC, managing CERCLIS and the Region III waste data system on the LAN (WASTELAN), developing cooperative agreements with Region III states, and developing interagency agreements with other Federal agencies.

Office Of Brownfields And Outreach
Office Director: Charlie Kleeman (Acting)

The Office manages the Region's Brownfields and Land Revitalization programs. The Office also provides community involvement support to the remedial, removal, and federal facility programs, manages Freedom of Information Act responses, and maintains the Division's records room. The Office includes the Regional Public Liaison (formerly known as the Ombudsman). The Office consists of two Branches: the Community Involvement and Outreach Branch, and the Brownfields and Land Revitalization Branch. The Office also serves as the point of contact for the Division's work with the Region's State environmental agencies.

a. Brownfields and Land Revitalization Branch: The Branch manages the Division's Brownfields activities, including awarding and oversight of grants, outreach, and the coordination of site-specific Brownfields assessments. The Branch manages the Division's land revitalization program, including implementation of the Revitalization Action Plan and the Agency's Revitalization Agenda.

b. Community Involvement and Outreach Branch: The Branch is responsible for ensuring that Region III meets the public involvement requirements of the Superfund Program, and provides

support to the Brownfields and land revitalization programs. The Branch makes contact with the media at Superfund sites and keeps them informed of cleanup status. The Branch also manages the Division's Freedom of Information Act (FOIA) response program and Records Room and administers the Superfund Technical Assistance Grants given to communities.

Office Of Enforcement
Office Director: Karen Melvin

The Office consists of two Branches, the Cost Recovery Branch, which conducts potentially responsible party (PRP) searches, and the Federal Facilities and Site Assessment Branch. The Branch also assures recovery of Superfund money spent at removal and remedial sites by providing support to the Office of Regional Counsel.

a. Cost Recovery Branch. The Branch's principal responsibility is to assure the recovery of Superfund money spent at removal and remedial Superfund sites by managing the cost recovery program. The Branch also collects evidence to determine PRPs for the Division's projects, and ensures that PRPs are notified of their liability with General Notice Letters.

b. Oil and Prevention Branch. The Branch is responsible for compliance and enforcement activities associated with the Clean Water Act's Spill Prevention Control and Countermeasures (SPCC) requirements. Other responsibilities include: performing SPCC Plan tasks, such as technical assistance, review and approval of industry spill prevention plans, on-site inspections of construction features and documentation of findings for enforcement actions, and managing chemical safety audits and chemical accident investigations.

D. Organizational Chart

Attached is a chart showing the organization of the Hazardous Site Cleanup Division.

E. QA/QM Roles And Responsibilities

The overall responsibility for approving and implementing the Division's Quality Management Plan rests with the office of the Division Director. Assisting in this effort are HSCD's Quality Assurance Coordinator (the Chief of the Technical Support Branch, in the Office of Technical and Administrative Support) and the other managers and supervisors in the Division. It is the Coordinator's responsibility to develop and update the Division's Quality Management Plan and to monitor its implementation.

Five of the six Offices in the Division have a QA coordinator, who assists the Project Managers with data quality issues and helps insure that the Division QMP is implemented during all site activities. Only the Office of Enforcement, which does not collect any environmental data, does not have a QA coordinator. The five Office QA Coordinators are:

Preparedness and Response – TBD
Technical and Administrative Support -- Jennifer Hubbard

Superfund Site Remediation -- Bhupi Khona
Federal Facility Remediation & Site Assessment -- Dennis Orenshaw
Brownfields and Outreach – Drew Lausch

The Hazardous Site Cleanup Division works with the Quality Assurance Team of the Environmental Assessment and Innovation Division (EAID) to ensure that Agency, Division, and project-specific QA requirements are met. The Quality Assurance Team is located in EAID's Analytical Services and Quality Assurance Branch (ASQAB), in Ft. Meade, Maryland. The QA Team responds to the Hazardous Site Cleanup Division's QA needs by resolving technical problems, reviewing QA/QM documents, answering requests for guidance or assistance, assuring that Quality System requirements are integrated into the overall State/USEPA agreement process and grants, and participating in QA audit reviews of the Division.

In the Remedial and Federal Facilities Branches of the Hazardous Waste Management Division, Remedial Project Managers (RPMs) are responsible for ensuring that Agency and project-specific QA requirements are met on individual projects. RPMs have the authority and responsibility for reviewing project-specific documents and transmitting documents to EAID and to Regional technical experts for review. In the Office of Preparedness and Response, On-Scene Coordinators (OSCs), Site Assessment Managers (SAMs) and Brownfields Project Officers have similar responsibilities to work internally within EPA and with EPA contractors to coordinate laboratory scheduling and data review activities. Throughout the remainder of this Section, RPMs, OSCs, and SAMs will be referred to generally as "Project Managers."

Every removal, remedial and potential remedial site that is inspected by the Division has an individual Project Manager:

i. For Site Assessment activities, the manager is the Site Assessment Manager (SAM). The SAM reviews and approves sampling plans for PA/Ss if there is already an approved "master" QAPP for site assessment work. Each PA/SI report contains a detailed review and discussion of the quality of the data collected.

ii. For Remedial activities (including Federal Facilities), the manager is the Remedial Project Manager (RPM). The RPM reviews and approves the Sampling and Analysis Plan (SAP), which may include the project QA material, or the QAPP document itself. The RPM uses the recommendations of the ASQAB review memo from the QA Team in this approval process. The RPM will sign the cover sheet of the SAP or QAPP, indicating that it has been reviewed and accepted by EPA for site activities. This process is described in the March 6, 1997 memorandum from the HSCD Director, "New Sampling and Analysis Plan Approval Procedures" and the Feb. 12, 2003 memo, "Planning for Successful Sampling and Analysis Activities." RPMs are also responsible for labeling the "final" SAP/QAPP for the site file, insuring that fund and enforcement field work is conducted according to this documentation, and attending appropriate QA training.

iii. For Removal activities, each site is assigned an On-Scene Coordinator (OSC). The OSC has the broad responsibility to insure that the proper sampling and QA

functions are performed during an emergency response. The Office of Preparedness and Response has a designated QA Coordinator to assist the OSC in carrying out these responsibilities.

iv. For Project Managers who also manage contracts and Interagency Agreements, they must also insure that appropriate QA requirements are in place for sampling activities that are supported by EPA funding, including "master" or "generic" QAPPs from state and local governments.

In addition to these traditional Superfund project activities, the Brownfields program has added another group of projects to the Division's list of responsibilities. The project officers for the Brownfields projects report to the Chief of the Brownfields and Site Assessment Section. Brownfields grant recipients are expected to prepare QA Project Plans as a standard condition of their funding agreement and the Project Officers will review site-specific sampling plans before environmental samples are collected. Brownfields grant recipients should use Region 3's QAPP template (March 2001) and SAP template (July 1999). EAID's QA Team will help the Project Officers evaluate the grant recipient's Project Plan but will probably not need to review individual sampling plans.

F. Dispute Resolution

In order to resolve disputes related to quality assurance, the Region will strive to resolve the issue at the lowest administrative level. The dispute resolution process will begin when either disagreeing party declares an issue to be irresolvable and sends written correspondence to the other party, defining the disputed issue. All parties shall make every effort to resolve disputes through discussion and negotiation. Should agreement not be reached at this level, the issue will be directed to the Divisional QA Coordinator. If the issue is not resolved, it will be directed to the Regional QA Manager. If necessary, the Regional QA Manager will work to resolve the problem with the Senior Management Representative to the Regional Quality Council. The resolving officials will document the resolution and provide it to the disputing parties.

II. QUALITY SYSTEM COMPONENTS

The Quality System is designed to implement the goal of obtaining useable, defensible data of known quality. To this end, the major components of the Division's Quality System include:

- Quality Management Plans
- Systematic Planning Process
- Quality Assurance Project Plans
- Data Quality Assessments

- Training Plans
- Technical System Audits
- Standard Operating Procedures
- Quality System Assessments

Each of these components is addressed below.

A. Quality Management Plan (QMP)

This QMP has been prepared for the Hazardous Site Cleanup Division in accordance with Chapter 3 of the US EPA Quality Manual for Environmental Programs (EPA 5360 A1, May 2000). Updates of the QMP are to be made at least annually by the Chief of the Technical Support Branch.

It is also the policy of the Division that all programs, contractors, and agencies that use Division funding to generate environmental data will develop and implement QA programs that are documented in a Quality Management Plan, which conforms to EPA QA/R-2, EPA Requirements for Quality Management Plans (March 2001). This Plan should be reviewed by the ASQAB and approved by the Project Manager before field work is conducted by the funding recipient.

B. Systematic Planning Process

It is the policy of this Division that the intended data uses will be defined before data collection begins, so that appropriate QA measures may be developed in advance. "Data quality" includes establishing the level of data validation and review. DQOs will be established to ensure the utility of environmental data for its intended use. The intended data uses, level of quality, specific QA activities, and data acceptance criteria needed to meet the data quality needs of these uses will be described in each project or activity's QA Project Plan.

For all environmental data collection efforts, Guidance for the Data Quality Objectives Process and QA/G-4HW: Data Quality Objectives Process for Hazardous Waste Site Investigations, are also sources of guidance for implementing the DQO process. The results of the DQO process should be documented in the QAPP.

C. Quality Assurance Project Plan

The QA Project Plan should address records of traceability, adherence to prescribed protocols, descriptions of potential QA problems and corrective actions, the quality of data collection and analyses, deficiencies that may affect quality, and the uncertainty limits for the results. QA Project Plans are expected to conform to the most recent version of "EPA Requirements for Quality Assurance Plans" (EPA QA/R-5).

Each project conducted or overseen by the Division is implemented in accordance with a QA Project Plan, and a Work Plan, a Health and Safety Plan, and a Field Sampling Plan. These plans in turn satisfy the requirements of an enforcement agreement, contract, or other authorization under which the work is performed. It is the responsibility of the Project Manager (SAM, RPM, or OSC) to ensure this compliance through field oversight and document review. The project plans are used as checklists of DQOs, deliverables, activities, etc. Modifications to the Plans that are necessitated by unforeseen circumstances (i.e., field conditions, laboratory problems such as sample container breakage, etc.) are approved by the Project Manager.

For sites in the Office of Preparedness and Response, including emergency removals, enforcement removals, the On-Scene Coordinators (OSCs), EPA's Removal Contractors and the QA Team will work together to evaluate site documentation, as described below:

1. START Contractor "Generic" QAPPs

EPA's START contractors (Tetra Tech EMI and E&E) are used to collect samples as part of CERCLA site assessments, removal assessments, fund-lead removal actions (post-removal confirmation sampling) and targeted Brownfields assessments. Tetra Tech, EMI and E&E have prepared generic QAPPs that are intended to be sufficiently broad-based to address collection/analysis of samples in support of these activities.

These QAPPs were prepared at the onset of the START contract. In order to reflect changes in field/analytical testing methods or QA/QC protocol, the generic QAPPs will be reviewed periodically and revised, as necessary. The current generic QAPPs have been reviewed by the Analytical Services and Quality Assurance Branch's Quality Assurance Team (QAT). These generic QAPPs preclude the need to prepare individual QAPPs for each of the numerous sites addressed in the Office of Preparedness and Response. This also means that the QAT will typically not be performing reviews for individual Removal sites. This process is well suited to the type of work routinely performed in the Branch.

However, the START contractor does prepare Field Sampling Plans (FSPs), which are specific to each of the sites being investigated, prior to initiating field work (exception would be the case of "emergency" removals). The approved, site-specific FSP should incorporate the generic QAPP and appropriate field SOPs by reference. Since a QAPP and FSP are the two components of a Sampling and Analysis Plan (SAP), use of a generic QAPP and development of site-specific FSPs satisfies the need for approved SAPs for environmental investigations.

As necessary, any unique activities (use of non-standard analytical methods or planned deviations from field SOPs) not contemplated in the generic QAPP should be incorporated into the appropriate section of the FSP. In these cases, the WAM could elect to consult with the QAT.

2. State-Prepared "Master QAPPs"

EPA R3 has Cooperative Agreements with several States in the Region (currently DE,

MD, VA and WV). Under these Agreements, these states perform the majority of CERCLA site assessment and Brownfields site assessment activities. Similar to the process for the Office of Preparedness and Response, "master QAPPs" are prepared by each of the States to cover the work they are performing. These QAPPs have been reviewed by EPA and they should also be reexamined periodically and revised, as necessary.

3. PRP-Prepared QAPPs

PRPs would prepare QAPPs to address collection/analysis of samples in support of an enforcement-lead CERCLA removal action. The process for preparing, and obtaining regulatory approval of, a QAPP or other deliverable such as an FSP would be covered in the terms and conditions of the enforceable agreement between EPA and the PRP. QAPPs (and FSPs) would be prepared for individual sites (i.e., they would be site-specific). In the case of QAPPs, the OSC should provide this document to the QAT for review.

D. Standard Operating Procedures

Standard Operating Procedures (SOPs) for technical field work and laboratory work are typically established by the organization conducting the field work and sampling (i.e., EPA contractor, Federal Facility, State, etc.) and are referenced in their QA Project Plan, which must be approved by Region III. Tetra Tech EMI and E&E have developed standard operating procedures (SOPs) for various types of field activities, such as soil sampling, water sampling and sample shipping/packaging.

E. Data Quality Assessments

Data validation is conducted by EAID-ASQAB under an ESAT contract in accordance with the National Functional Guidelines for Data Review as modified by the Region III Modifications and Innovative Data Validation Procedures. Data validation is reviewed by ASQAB for compliance to these guidelines with respect to technical and contractual issues. Data collected and validated by PRPs or their contractors may be reviewed by ASQAB at the request of the Project Manager. Project managers have the responsibility and authority to request such reviews. Validation of data performed by States is typically reviewed by ASQAB. For Removal sites, data validation is performed by an EPA TAT contractor, with oversight by the Office of Preparedness and Response QA coordinator and the QA Team, as needed.

A Data Quality Assessment (DQA) is the scientific evaluation of data to determine if data obtained from environmental data operations are of the right type, quality, and quantity to support their intended use. The most recent version of EPA QA/G-9: Guidance for Data Quality Assessment may be used during the DQA. At a minimum, all environmental data shall be reviewed to ensure that the analytical measurement criteria specified in the approved Quality Assurance Project Plan (QAPP) has been achieved. Data shall be qualified in accordance with the data validation criteria specified in the approved QAPP.

After the data has been subjected to this initial data review process, it shall be evaluated to determine if the project's data quality objectives and sampling design criteria have been

achieved. Data validation reports, field and laboratory audit reports, proficiency testing sample results and other quality control information may be used to make this determination. In addition, various statistical tests (i.e., t-tests, quartile tests, etc.) may also be conducted to help draw conclusions about the data.

F. Training Plans

It is the Division's goal to have all personnel aware of their QA/QM responsibilities and to provide on-going training for all Project Managers. HSCD and ASQAB work together to assess and provide training through EPA, its labs and contractors. HSCD supports the training provisions of the Regional Quality Management Plan (June 4, 2003), as described in Section 3.2.

G. Technical Systems Audits

Audits are the principal means to determine compliance with established quality procedures. EAID has the authority and responsibility to conduct State and contractor laboratory audits and provide the Division with a copy of the audit report. Technical systems audits conducted by EAID will include on-site qualitative evaluation of the QA system and physical facilities for sampling and analysis.

III. PERSONNEL QUALIFICATIONS AND TRAINING

Within the Division, specialized QA training is generally provided upon identification of program-specific QA needs. The Hazardous Site Cleanup Division relies on the ASQAB for specialized knowledge with regard to chemistry, laboratory analysis, technical and contractual acceptability of data, and data review and validation. The Division may also seek the assistance of specialists within the Region (i.e., specialists from the Air, Radiation, and Toxics Division for air sampling and monitoring and radiation-related issues) or outside the region (i.e., EMSL for complex statistical questions) to ensure that all types of sampling and data analysis will meet the Division and project-specific goals for data usability. The QA responsibilities of the Division's QA Branch Coordinators are reflected in their performance plans.

IV. PROCUREMENT OF ITEMS AND SERVICES

Implementation of contracts and interagency agreement (IAG) QA procedures in accordance with EPA regulations is assured by the Contracts, ADP and State Support Section. Program QA requirements are included in contracts and IAGs to ensure that data quality is part of the work process. For procurements, requests for proposals will contain a description of QA requirements prior to advertisement and will be part of the criteria on which contractors are selected and their performance is rated.

Procurement actions or suppliers who provide services or items that directly affect the quality of results or products (i.e., sample collection, sampling plan preparation, analytical laboratory services) are monitored by the Project Managers involved in specific projects and by the Project Officers in the Contract, ADP and State Support Section. The responsible personnel must ensure that all procured items and services meet program and project goals, and that

deliverables are timely and as specified.

V. DOCUMENTS AND RECORDS

Documents such as Work Plans, QA Project Plans, and other project-related reports are submitted to the Project Manager. The Project Manager has the responsibility and authority of requesting reviews from the appropriate technical project team members, such as the QA Team at ASQAB. The flow of document review relative to the collection of environmental data is also discussed in Section II and VIII of this QMP. It is Agency policy that QA Plans are valid for five years and must be updated for projects lasting longer than that.

Project managers also have the responsibility of updating the site file for each project. These files are kept in the HSCD file room. The file room is managed by the Office of Brownfields and Outreach, with contractor support, and access to the files is limited to the file room contractor, EPA personnel, and those authorized by EPA. Any item that is removed from the file must be signed for by the recipient and materials are checked for completeness when returned.

HSCD also supports the Regional document handling goals discussed in Chapter 5 of the Regional QMP.

VI. COMPUTER HARDWARE AND SOFTWARE

Currently, data collection, transfer, validation, and other processes are not conducted solely by electronic means within the Division. Any electronic submissions are accompanied by paper submissions, for which objectives and relevant guidance apply. If such electronic procedures are established in the future, a defensible system of QA would be needed to ensured the same quality as paper copies.

VII. PLANNING

The originating Project Manager coordinates with EAID all work assignments and interagency agreements during the planning phase. The Hazardous Site Cleanup Division ensures that all requests for proposals will contain an acceptable description of the QA requirements prior to advertisement. All QA/QM Plans must be acceptable prior to awarding of a contract. Interagency Agreements include standard language requiring QA Plans before environmental samples are collected. The QA/QM Plans will be reviewed and evaluated by EAID. Upon completion of the monitoring activities, the Project Manager and EAID will assess the actual performance of the planned activity and subsequent results.

For remedial Superfund sites, the originating Project Manager notifies EAID and specifically the QA Team of projects requiring data collection during the planning phase. A contact within the QA Team will review QA Project Plans upon request. The Remedial Project Manager (RPM) will approve or revise the project-specific QAPPs based on the review and

recommendations of the QA Team.

The Region negotiates Record of Decision (ROD) goals with Headquarters for each fiscal year and Headquarters tracks the ROD completions. These goals and time frames for project completion influence the number of documents and the amount of data collection that will be handled by the Division in a given year. ASQAB, which supports the Division with respect to QA activities, annually prepares a Work Plan outlining its activities, services, and FTE for the Hazardous Site Cleanup Division.

VIII. IMPLEMENTATION OF WORK PROCESSES

As sites are discovered and evaluated in the Hazardous Site Cleanup Division, they move through different parts of the organization. For instance, an initial site discovery would be handled by the CEPP and Site Assessment Section in the Office of Preparedness and Response. If an emergency response were necessary, the Office of Preparedness and Response would handle that activity and then the site would be examined as a potential candidate for the National Priorities List (NPL). Once a site is proposed to the NPL, it ordinarily is assigned to the Remedial or Federal Facilities Branch.

As a site moves through this evaluation and response process, the data generated for site evaluation are handled by the Branch QA/QM procedures. All remedial site sampling data are subjected to QA reviews administered by EAID (i.e., the QA Team at ASQAB). Site Inspection reports, RI/FS's, etc., are reviewed by the Technical Support Section toxicologist and geologist and by the Site Assessment Manager (SAM) or RPM for technical and scientific validity and accuracy.

Remedial Investigations, whether federal or State lead projects, are conducted in accordance with Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA (Interim Final) (USEPA/540/G-89/004). This guidance manual has specific requirements for sampling plans, QA plans, and data evaluation which implement the requirements of the NCP. USEPA Publication 9285.7-09, PB92-963356, Guidance for Data Useability in Risk Assessment, is another source of guidance when scoping, performing, and reviewing such project activities.

All site-specific sampling and QA plans developed by contractors or grant recipients are reviewed and approved by the Region III site Project Manager in accordance with the recommendations of the QA section of the ASQAB. Data collection activities during remedial cleanup actions are also supported by site-specific sampling and QA plans and are reviewed by the Project Manager.

IX. ASSESSMENT AND RESPONSE

Facilities, equipment, and services which, directly or indirectly, impact data quality or integrity shall be routinely inspected by EAID. To ensure that a satisfactory level of QA capability is maintained in the Division, technical assistance may also be requested from technical specialists within EAID. The EAID technical specialists will assist the Division with

technical aspects of QA related to their expertise in air, water, toxic substances, hazardous waste, chemistry, field operations, and data operations. They will conduct field and laboratory performance audits, inform the Division of the need for new methods, and conduct compliance monitoring inspections.

The Contract Laboratory Program (CLP) Technical Project Officer (TPO) in ASQAB manages and oversees the CLP laboratories within Region III, including the laboratory and field audits conducted by EPA's oversight contractor.

In June 1994, special analytical services (SAS) through the CLP were terminated. The Division and EAID currently coordinate the procurement of these laboratory services and the placement of individual task orders. HSCD and ASQAB's Client Services Team coordinate the procurement of non-CLP laboratory services using the Delivery of Analytical Services (DAS) process, as described in "EPA Region III Users' Guide for Acquiring Analytical Services." In order to control and evaluate labs generating DAS data for the Superfund Program, ASQAB may perform on-site lab audit inspections and provide blanks and other QC materials to verify a laboratory's credentials, assess method performance, etc.

Field audits are used to determine whether all the planning steps have occurred and are actually being implemented as per the approved QA Project Plan. ASQAB staff may perform field audits on EPA contractors, IAG agencies, and private parties to determine whether field sampling is being properly conducted and the appropriate QA plans are being implemented. A checklist is used to document findings of the audit and is provided to the Project Manager when completed. Sites are coordinated through Hazardous Site Cleanup Division Programs or recommended by the QA Team as a result of documentation review.

Corrective actions taken in response to internal Quality System Assessments (QSAs) and external audits and assessments are verified as follows:

- Final response reports to internal QSAs and external audits and assessments are placed in Divisional files and held by the QA team at Fort Meade. Corrective actions taken are verified at the next scheduled internal QSAs.

- Corrective actions resulting from a major nonconformity will be subject to a limited internal re-audit. This type of corrective action usually results in significant changes to the system. The re-audit will focus not just on the corrective action taken, but may also be concerned with any consequential changes to other parts of the system.

- Corrective actions that only require change in documentation are verified by a paper review. The Divisional QA Coordinator forwards the revised document to the RQAM or designee for review.

X. QUALITY IMPROVEMENT

The Hazardous Site Cleanup Division and the QA Team in ASQAB meet regularly to

discuss common issues and plan work activities. These meetings are used to review contractor performance, discuss data review issues, and address other items relevant to QA for the Superfund Program. The team also discusses, helps plan, and disseminates information with respect to new technologies, new directives, and new work processes. HSCD and the QA Team constantly look for innovative ideas to improve QA activities in the Region's Superfund programs.

APPENDICES

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

FEB 12 2003

SUBJECT: Planning For Successful Sampling and Analysis Activities

FROM: Abraham Ferdas, Director
Hazardous Site Cleanup Division

TO: Division Staff and Managers

Every year, our Division collects over a thousand environmental samples at our sites. These samples are needed for many reasons, such as characterizing site conditions, assessing potential health and environmental problems, and confirming that cleanup activities are proceeding successfully. In an effort to make these sampling events more efficient and effective, I would like to summarize the Division's expectations for planning sampling activities and acquiring the laboratory services. As discussed below, a critical part of this process is to see that the data objectives, the number and type of samples, and the analytical procedures are all clearly specified before laboratory services are requested.

I expect the project managers in our Division, including RPMs, OSCs and SAMs, to take an active role in planning the field sampling and laboratory work for their sites. For remedial sites, the best way to make sure that this work is properly organized is to have an approved, up-to-date quality assurance plan in place before field work is scheduled and laboratory services are requested. For emergency response and site assessment work, OSCs and SAMs should make arrangements that are consistent with their program requirements and contract procedures.

Please use these steps as a basic approach to planning sampling and analysis activities at your sites:

- For all sampling activities, clearly identify the objectives, data needs and the most efficient way to acquire the needed site data.

- For remedial sites, make sure that the quality assurance project plan (QAPP) has been approved and is "current" (for some older sites, this may take some digging through the files and talking with former site managers). Make sure that the new sampling activities are consistent with the existing QAPP. Forward a copy of the QAPP to the Office of Analytical Services and Quality Assurance (OASQA) at Ft. Meade before requesting analytical services; they will use it when they review the sampling and analytical requests for the site.

- In the Removal Branch, generic QAPPs have been developed to expedite emergency response activities and preremedial investigations. OSCs and SAMs should plan their site

work according to these Branch procedures. The Brownfields program has also developed guidance of its own for quality assurance activities. If a request for laboratory services will be made through Ft. Meade for these kinds of projects, please make sure that OASQA understands the nature and objectives of the sampling activity before the laboratory request is made.

- If you have any questions about these issues, please contact your Branch QA coordinator (Jennifer Hubbard, Drew Lausch, Bhupi Khona or Dennis Orenshaw), or Eric Johnson, our Division coordinator. They can help resolve your questions with input from OASQA.

These steps are intended to make our sampling activities more successful by eliminating the delays and additional costs that arise from last minute questions and changes in sampling activities and laboratory procurement. This approach should also help improve our documentation of QA issues in our project files.

I would like to see these steps implemented as quickly as possible. *I have also arranged with OASQA that beginning April 14th, no new laboratory procurement will be processed unless a current, approved QAPP is on file at Ft. Meade.* Thank you for your cooperation in taking these steps to improve our sampling and analytical procedures.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
841 Chestnut Building
Philadelphia, Pennsylvania 19107

SUBJECT: New Sampling and Analysis Plan Approval Procedures

DATE: MAR 0 6 1997

FROM: Abe Ferdas, Associate Director
Office of Superfund Programs

TO: All Remedial Project Managers

The Superfund Program received a position paper on November 27, 1996, from the Inspector General's Office outlining audit findings and recommendations on our process for reviewing and approving Sampling and Analysis Plans (SAPs). The primary change that the Inspector General (IG) recommended in the position paper was that RPMs and the regional quality assurance reviewer both sign and date SAPs when approved. RPMs interviewed by the auditors were not able to produce copies of SAP approval letters for seven out of 21 SAPs reviewed. In addition, the auditors were not able to determine whether the SAPs in the site file were final or draft documents in most instances. We provided comments on the position paper stating that we have not experienced any data quality problems resulting from our current process of sending approval letters. We further commented that the program had received advice from legal staff indicating that use of an approval letter was the preferred approach. Upon further inquiry into the legal aspects of the issue, ORC stated that there is no legal basis for preferring one approach over the other. Therefore, the IG retained the recommendation to sign and date SAPs in the Draft Audit Report issued on January 23, 1997. The IG did, however, change the recommendation to require that *only RPMs* need to sign and date the SAPs.

The specific SAP review and approval process recommendations included in the Draft Audit Report are:

1) RPMs, as well as the preparing organization's project manager and quality assurance officer, should sign and date both components of approved SAPs (*i.e.*, field sampling plans and quality assurance project plans) before the collection of site samples.

2) RPMs should label approved SAPs as "Final" versions.

3) On enforcement-lead sites where Agency contractors perform direct oversight of sampling and analysis activities, RPMs should ensure that oversight contractors verify that the field personnel are following the final approved SAPs.

4) On fund-lead sites or on any site where the RPM is directly overseeing the sampling and analysis activities, the RPM should verify that the field personnel are following the final approved SAPs.

RPMs should begin to implement the above recommendations immediately. For all new SAPs received, RPMs should indicate approval by signing and dating the final documents and labeling these documents as "Final". For previously approved SAPs, RPMs should ensure that approval letters and final SAPs are in the site files.

If you have any questions concerning these new procedures or believe these procedures will present a problem on any of your sites, please discuss the matter with your Section Chief.

cc: Peter Schaul (3HW20)
Hank Sokolowski (3HW50)
Anthony Dappolone (3HW21)
Gregg Crystall (3HW22)
Peter Ludzia (3HW23)
Kim Hummel (3HW20)
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