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Environmental Technology Verification Program

Quality Management Plan (QMP) for the ETV Materials Management and Remediation Center Version 1.0

QUALITY MANAGEMENT PLAN (QMP)

for the

ETV MATERIALS MANAGEMENT AND REMEDIATION CENTER
Version 1.0

(SIGNATURE ON FILE)

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LIST OF ACRONYMS AND ABREVIATIONS

ADQ	Audit of Data Quality
CA	Cooperative Agreement
COA	Certificate of Analysis
EPA	U.S. Environmental Protection Agency
ETV	Environmental Technology Verification Program
GVP	Generic Verification Protocol
LRB	Laboratory Record Book
MMR	Materials Management and Remediation Center
NSGB	National Security Global Business (Battelle)
PE	Performance Evaluation
QA	Quality Assurance
QC	Quality Control
QMP	Quality Management Plan
QSA	Quality Systems Audit
SOP	Standard Operating Procedure
TSA	Technical Systems Audit

1.0 GENERAL PROVISIONS

1.1 INTRODUCTION

1.1.1 This document, the Quality Management Plan (QMP) for the Materials Management and Remediation (MMR) Center, describes the quality systems that will be employed by Battelle in conducting the MMR Center. These quality systems are designed to be consistent with ANSI/ASQ E4-1994, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs," the U. S. Environmental Protection Agency (EPA) document "Environmental Technology Verification Program *Quality Management Plan*", Version 3.0, dated January 2008, and *EPA Requirements for Quality Management Plans* (QA/R-2, dated March 2001).

1.2 PURPOSE

1.2.1 The purpose of the MMR Center is to verify materials management technologies, including recycling, beneficial use of waste materials, recovery of useful components of wastes, and treatments to minimize disposal requirements (e.g., containment, volume, cost). The center will also verify technologies to remediate contaminated land and ground water, such as is found at Superfund sites and other properties where industrial or commercial activities resulted in a legacy of hazardous constituents that limits future use of the property. The MMR Center encompasses the full range of materials management and remediation technologies, and as part of the larger Environmental Technology Verification (ETV) program is designed to provide technology users with objective, high quality performance data to support materials management or remediation technology selection decisions.

1.3 SCOPE AND FIELD OF APPLICATION

1.3.1 This document encompasses activities that Battelle, as an ETV verification organization, shall utilize to assure the quality of products and services provided by the MMR Center. The MMR Center is one of six centers operating under the ETV program.

1.3.2 This QMP applies to personnel involved in, and activities conducted by those staff for the MMR Center, and contains the minimum specifications and guidelines that are applicable to MMR Center quality management functions and activities based upon ANSI/ASQ E4-2004 (an update to the ANSI/ASQC E4-1994 document). These include, but are not limited to, personnel qualification and training, procurement of items and services, documents and records, computer hardware and software, planning, implementation for work processes, assessment and response, and quality improvement provisions.

1.4 BACKGROUND

1.4.1 Battelle (Memorial Institute) was established in 1929 by Gordon Battelle and serves as a memorial to his family. Governed by a self-perpetuating Board of Trustees, Battelle is a nonprofit Ohio corporation. Battelle and the laboratories it manages and co-manages has a staff of 20,000 scientists, engineers, and support specialists. Battelle conducts $4 billion in annual research and development.

Battelle's headquarters are in Columbus, Ohio. In addition to headquarters in Columbus, Ohio, Battelle has major technology centers in Richland, Washington, where we manage the Department of Energy's Pacific Northwest National Laboratory; Upton, New York, where we partner with the Research Foundation of the State of New York in managing Brookhaven National Laboratory; Golden, Colorado, where we partner with MRI in managing the National Renewable Energy Laboratory; Oak Ridge, Tennessee, where we partner with the University of Tennessee in managing the Oak Ridge National Laboratory; Idaho Falls, Idaho, where we have formed the Battelle Energy Alliance to manage the Idaho National Laboratory; Frederick, Maryland, location of the National Biodefense Analysis and Countermeasures Center, managed by Battelle National Biodefense Institute; Livermore, California, where we partner with the University of California in managing Lawrence Livermore National Laboratory; and Aberdeen, Maryland, where we manage the Battelle Eastern Science and Technology Center. Specialized facilities, regional centers, and offices are located in 159 other cities in the United States and worldwide.

Battelle's organization includes three global lines of business: National Security, Health and Life Sciences, and Energy Technology. The MMR Center is managed within Battelle's National Security Global Business (NSGB) which includes approximately 3,500 chemists, engineers, statisticians, and support personnel. Staff and facilities will be drawn from NSGB and other Battelle organizations as needed to support the MMR Center. Staff involved in the MMR Center includes those with expertise in materials management and remediation, stakeholder involvement, and outreach and communication. Key Battelle facilities that are available for use on the MMR Center include comprehensive laboratory analysis equipment; field sampling and analysis equipment; source simulators such as pilot plants; environmental chambers; and real-world test sites.

The organization chart for the MMR Center is provided in Figure 1.0 and shows key MMR Center staff and their reporting lines. The key Battelle MMR Center staff are:

Center Manager: Ms. Amy Dindal is Battelle's *MMR Center Manager* with responsibility for meeting all technical, budget, and schedule goals for the Center. Ms. Dindal is organizationally in the Environmental Technologies Product Line within NSGB. Ms. Tracy Stenner, the Environmental Technologies Product Line Manager, has responsibility for ensuring that necessary Battelle facility and staff resources are available to support the MMR Center. Ms. Dindal serves as the primary point of contact for the EPA MMR Center Project Officer, Ms. Teri Richardson. She also directs the activities of the leaders in three organizational areas within the Center: Quality Assurance; Verification Testing; and Stakeholders.

Quality Manager: Mr. Zachary Willenberg is the Battelle *MMR Center Quality Manager*. He is a Quality Assurance Officer in NSGB and reports directly to the Environmental Technologies Product Line Manager, Ms. Stenner, and for the MMR Center, to Ms. Dindal. These relationships are illustrated in Figure 1.0. Mr. Willenberg serves as the primary point of contact for the EPA MMR Center Quality Manager, Mr. Scott Jacobs.

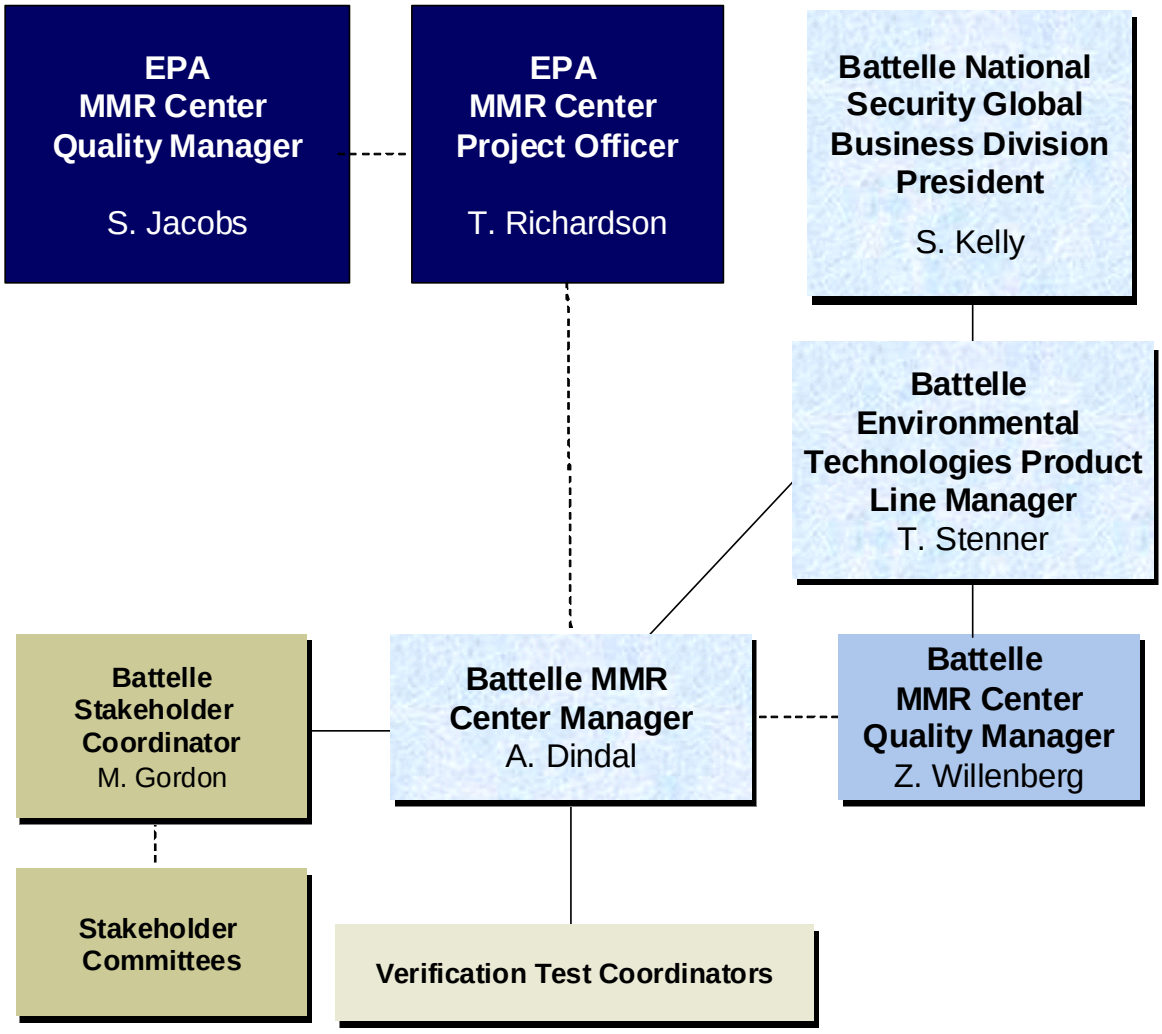

Figure 1.0 MMR Center Organization
(dotted lines indicate indirect reports)

Stakeholder Coordinator: Ms. Maria Gordon is the *MMR Center Stakeholder Coordinator* with primary responsibility for stakeholder recruitment, communications, and stakeholder meeting facilitation. Ms. Gordon reports directly to Ms. Dindal on the MMR Center.

Names, mailing/email addresses, and phone/facsimile numbers of these Battelle MMR Center key staff are included in Appendix I.

1.5 DEFINITIONS

1.5.1 Verbs for clarity:

Shall, will, must: when the element is required and deviation from the specification will constitute nonconformance with this QMP

Should: when the element is recommended

May: when the element is optional.

1.5.2 **Center Quality Management Plan (QMP)** - Procedures for quality-related activities developed and implemented by Battelle to assure quality in the work processes and services developed for the MMR Center.

Generic Verification Protocol (GVP) - A document that outlines the generic steps to be taken in conducting a verification test for a technology category.

Stakeholders - The representatives of verification customer groups including buyers and users of technology, consulting engineers, finance and export communities, and government (local, state, federal) permitters and regulators. Stakeholders are selected based upon their expertise and interest in materials management and remediation and their availability and willingness to participate in the MMR Center. A list of MMR Center Stakeholder Committee members will be available on the ETV website (http://www.epa.gov/etv).

Test/Quality Assurance (QA) Plan - The plan developed by Battelle, with appropriate input for each individual test of a technology or technology class. The Test/QA Plan provides the experimental approach with clearly stated test objectives and associated quality objectives for the related measurements and may incorporate or reference an MMR Center GVP and/or standard operating procedures (SOPs).

Vendor - An individual, company, or organization which submits a commercially-available remediation technology for verification testing.

Verification Organization - A public or private sector organization selected by EPA to cooperate with the implementation of the ETV program by conducting verification testing and to provide unbiased and objective test performance data on environmental technologies.

Verification Organization Center Manager - The person designated by the verification partner with the responsibility to manage the Center and serve as the chief point of contact with the EPA. For the MMR Center, this is the Battelle MMR Center Manager.

Verification Organization Quality Manager - The person designated by the verification partner with the responsibility to manage quality assurance for the MMR Center on behalf of the verification partner Center manager. For the MMR Center, this is the Battelle MMR Center Quality Manager.

Verification Report - A complete detailed summary of procedures and results for a verification test of a single technology.

Verification Statement - A summary statement developed by Battelle, and signed by EPA and Battelle, which reports quantitatively but without endorsement, the performance of a tested technology in a verification test.

2.0 MANAGEMENT SYSTEMS

Battelle's quality policy is to provide services, products, and data of the highest quality that meet or exceed our client's requirements and expectations. To this end, quality programs such as this MMR Center QMP, and quality achievement, shall be fully supported by Battelle management and staff.

2.1 MANAGEMENT AND ORGANIZATION

2.1.1 Battelle management is responsible for committing to a quality policy and for creating work environments in which all personnel strive for the highest quality of services and products. Management shall also provide the Battelle MMR Center Manager the authority to ensure the following:

- That all applicable elements of the quality system as described in this QMP are understood and are implemented in the MMR Center.
- That adequate personnel and resources are available to plan, implement, assess, and improve services and products relevant to the MMR Center.
- That staff is (are) clearly designated to stop unsafe work and work of inadequate quality as affects the MMR Center.

2.2 QUALITY SYSTEM AND DESCRIPTION

2.2.1 The Battelle quality system to be implemented for the MMR Center according to this QMP is intended to conform with the specifications listed in:

- ANSI/ASQ E4-2004, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs".
- EPA document "Environmental Technology Verification Program *Quality Management Plan*", Version 3.0, January 2008.
- EPA document "EPA QA/R-2, *EPA Requirements for Quality Management Plans*, March 2001.

It should be noted the E4 standard is comparable to the International Standards Organization 9000 series.

2.2.2 The principal quality system document governing general and specific responsibilities for MMR Center management and staff, responsibility and authority for all technical activities, and reporting lines is this document, the "Quality Management Plan for the ETV Materials Management and Remediation Center".

Individual verification tests will conform both to this QMP and to the applicable Test/QA Plan document(s) and applicable SOPs.

The MMR Center QMP and any revisions will be controlled documents identified by a unique Battelle document number (see Section 2.5.1) and will be distributed according to a published list maintained by the Battelle MMR Center Quality Manager.

The QMP review will be documented by the Battelle MMR Center Quality Manager and Battelle MMR Center Manager by signing and dating the copy of the QMP routed for review. Any revisions to the QMP will be compiled by the Battelle MMR Center Quality Manager for review, approval, and distribution. The approved QMP has a scheduled review interval of one (1) year, although this may be adjusted by the EPA MMR Center Quality Manager, depending upon factors such as the revision cycle of the ETV QMP.

The initial approved QMP will serve as Version 1.0, which will be designated, with its effective date, in the upper right corner of each document page. Revisions will be so designated beginning with “2.0” and will subsequently be numbered and dated as applicable. Battelle staff to which controlled copies are issued will be responsible for disposal of outdated QMP versions.

2.2.3 The scope of the MMR Center quality system applies to all Battelle personnel providing products and services for the MMR Center. All MMR Center key staff shall be knowledgeable regarding the QMP requirements.

2.2.4 Quality procedures documentation includes maintenance of all inspection and review/assessment records, listing of all controlled documents (see Section 2.5.1), and retention of records pertaining to personnel training and qualification, instrument maintenance and calibration, and test methods/operating procedures.

2.2.5 Center-specific quality controls are initiated upon approval of Battelle's QMP prior to implementing any verification testing activities. Planning actions documented through approved Test/QA Plans shall also serve as quality control mechanisms for verification testing.

In-process quality controls, through conduct of inspections followed by assessment reports and verification of corrective actions when required, shall also be performed and recorded.

Implementation of a complete and consistent assessment of technical operations provides overall control of Center activities. This will be accomplished by the Battelle MMR Center Quality Manager according to Section 3.0 in this QMP.

2.2.6 An external quality system audit (QSA) of the Battelle quality system will be performed at least once by the EPA MMR Center Quality Manager. In addition, an independent technical systems audit (TSA) will be performed by the EPA MMR Center Quality Manager or designee, at least one time per year for the MMR Center.

2.3 PERSONNEL RESPONSIBILITIES, QUALIFICATIONS, AND TRAINING

2.3.1 Responsibilities

2.3.1.1 Verification Partner Responsibilities. In accordance with EPA's ETV QMP dated January 2008, Battelle's responsibilities for the MMR Center include the following:

- Establish, attend, and/or conduct meetings of stakeholder committees with representation from major customer groups
- Maintain communication with EPA to assure mutual understanding and conformance with EPA quality procedures and expectations and ETV policies and procedures
- Develop, review, and revise Test/QA Plans in cooperation with technology vendors and stakeholders
- Solicit technology vendors and verification test collaborators
- Manage participation of and conduct verification activities
- Assure that quality procedures are incorporated into all aspects of the MMR Center
- Perform ETV activities within the documented quality system
- Prepare ETV verification reports and statements at the completion of each technology verification
- Appoint a quality manager, responsible for ensuring the MMR Center quality systems are in compliance with the E4 standard and the EPA ETV QMP dated January 2008, and MMR Center staff complies with this QMP.
- Submit a written request to the EPA MMR Center Project Officer and EPA MMR Center Quality Manager if desired in specific instances, the responsibility for reviewing and approving Test/QA Plans be delegated to the Battelle MMR Center Quality Manager.

2.3.1.2 Key Staff Responsibilities. Battelle is committed to operate an effective quality system that ensures compliance with all program requirements. The responsibilities of Battelle key staff who will be performing verification testing activities addressed by this MMR Center QMP are listed in Table 1.0.

2.3.1.3 Stakeholder Responsibilities. The responsibilities of stakeholders for the MMR Center include the following:

- Assist in prioritizing the types of technologies to be verified, focusing on these technologies with greatest environmental and sustainability impacts.
- Review Center-specific procedures and MMR Center documents including Test/QA Plans, verification reports, and verification statements, as requested.
- Participate in verification testing as collaborators, provide funding and/or in-kind support, or recommend collaborators to the MMR Center.
- Assist in the definition and conduct of outreach activities appropriate to the technology area and customer groups.
- Serve as information conduits to the particular constituencies that each member represents.

2.3.2 Qualification and Training

Battelle personnel qualifications and training shall target technical work performed directly in support of verification testing activities. These qualifications and training may include:

- Formal education in physical sciences (e.g., chemistry, physics, engineering).

Table 1.0. Personnel Responsibilities for the MMR Center for Verification Testing Activities

MMR Center Team Member	Responsibilities
Battelle MMR Center Manager Amy Dindal	• Ultimate responsibility for all aspects of the MMR Center
	• Conduct and oversee activities to establish and maintain active stakeholder committees
	• Maintain adequate communication with EPA
	• Manage oversight and conduct of verification activities
	• Assure that quality procedures are incorporated and implemented
	• Review/approve Test/QA Plans
	• Solicit technology vendors
	• Assign Verification Test Coordinators to technology categories
	• Operate ETV activities within the documented quality system
	• Issue stop work orders
	• Review and approve verification reports
	• Review and approve verification statements
Battelle MMR Center Quality Manager Zachary Willenberg	• Ensure that the quality system is compliant with EPA-specified standards
	• Advise the Battelle MMR Center Manager of any QA/quality control(QC) problems and oversee corrective actions
	• Ensure that the MMR Center QMP includes sufficient and appropriate specifications for QA/QC as required for the MMR Center
	• Interact with MMR Center management and technical personnel to ensure that QA/QC procedures are understood
	• Ensure that Battelle MMR Center QMP and the EPA/ETV QMP are followed for performing system inspections and audits
	• Perform a TSA and ADQ for every verification test or ensure that a TSA and Audit of Data Quality (ADQ) are performed by a designee
	• Participate in pre-test kick-off meetings to review QA requirements with verification testing staff
	• Review training records of verification testing staff
	• Notify the Battelle MMR Center Manager to issue a stop work order if assessments indicate health, safety, or quality concerns
	• Review QA documentation of reference laboratories for each verification test, as appropriate
	• Review QC data (including reference laboratories and vendor technologies) generated during verification tests
	• Ensure that inspection reports are prepared and distributed that detail appropriate corrective action and that implementation will be responded to by personnel. Problems that are not addressed will be brought to the attention of the Battelle MMR Center Manager
	• Review Test/QA Plans, SOPs, verification reports, and verification statements
	• Review and approve amendments and deviations to Test/QA Plans
	• Review all quality system documentation, including this document, at intervals necessary to ensure their integrity. Such reviews will be recorded and documents will be revised if necessary. All previous original (i.e., signed) revisions will be retired and archived.
	• Act as a QA resource to respond to quality needs and problems. Answer questions and train laboratory staff in QA/QC requirements and procedures as needed.

MMR Center Team Member	Responsibilities
Battelle Verification Test Coordinators	• Provide technical support to verification testing as needed, and interact with the Battelle MMR Center Quality Manager during inspections and implementation of corrective actions when needed
	• Perform QA/QC activities specified in this document, applicable Test/QA Plans, and in pertinent SOPs
	• Conduct QC measures and activities required for sample analyses
	• Verify 100% of data and evaluate results of QC analyses to determine if quality goals and objectives have been met
	• Inform Battelle MMR Center Manager of potential problems
	• Perform corrective action at the direction of the Battelle MMR Center Manager and Battelle MMR Center Quality Manager in response to TSA and ADQ audit reports
	• Document results of QC analyses and include them with sample results and historical data files
	• Maintain instrumentation (vendor and/or reference instrumentation) in accordance with the QMP, Test/QA Plan, SOPs, and the manufacturer's instructions
	• Prepare Test/QA Plans and amendments and deviations to these plans, as appropriate
	• Perform pre-test kick-off meetings to review technical, project management, and QA aspects of verification testing with verification testing staff
	• Perform performance evaluation (PE) audits of reference laboratories and calibrated equipment for each verification test, as appropriate
	• Maintain verification test records (in bound Laboratory Record Book and/or test binders) that adequately capture the quality of data collected
	• Develop and implement Test/QA Plans
	• Prepare verification reports
	• Prepare verification statements

- Experience materials management or remediation techniques such as recycling, beneficial use of waste materials, recovery of useful components of waste, and treatment to minimize disposal requirements
- Training on remediation technologies
- Experience in designing experiments to verify the performance of materials management and/or remediation technologies.

Battelle personnel working on the MMR Center shall have, at a minimum, documentation maintained by Battelle permanently for each of the following, as applicable:

- Education history which can include formal qualification or certification relevant to technical, quality assurance, or management disciplines.
- Work experience as academic or on-the-job performance in technical and/or management areas.
- Experience in the application of quality assurance/quality control requirements in technical performance or data verification.

2.3.2.1 Formal qualifications and certifications in the form of actual or verified-copy documentation for specific disciplines shall be maintained in the staff member's qualification/training file. Training documents will be reviewed by the Battelle MMR Center Quality Manager, as appropriate.

2.3.2.2 Technical management and training received in-house or offsite shall be recorded and forms, memos, or certificates retained. Performance on either task, project, or program assignments is to be considered as part of training.

2.3.2.3 Retraining needs based on job requirements shall be determined by the staff member and respective management. To maintain staff proficiency, opportunities provided by Battelle or other sources shall be made available, preferably on an annual basis.

2.3.2.4 Personnel job proficiency based on witnessed performance on-the-job by a qualified trainer/staff member designee shall be documented. Specific method requirements for instrument inspection, performance, and maintenance are objective measures that could be considered. Specific performance based on national certification requirements can be recorded with certificates or other documentation. Basic areas of proficiency for verification testing may include, at a minimum:

- Sample management practices, such as chain of custody records
- Sample handling and storage and use of standards and reagents
- Instrument inspection, use, and maintenance
- Data acquisition, analysis, and verification.

2.3.2.5 Training resources should be offered on-site by Battelle for facility requirements, such as general computer software use (E-mail, spreadsheets) or project management. Off-site training, project/program meetings, and technical society membership should be available for specific disciplines contributing to the staff member's overall job proficiency.

2.3.2.6 Verification test collaborators working on behalf of Battelle in support of the MMR Center and/or individual test operations are expected to provide the Verification Test Coordinator, or designee, with:

- Educational background and/or degree(s) relevant to technical areas represented in the MMR Center
- Work experience related to the technology category undergoing verification.

This information may be reviewed by the Battelle MMR Center Quality Manager.

2.3.2.7 Battelle personnel will receive update memorandum with the QMP when the document is revised specifying changes made. In addition, the Battelle MMR Center Quality Manager will provide testing staff with a refresher on QMP requirements with each update.

2.4 PROCUREMENT AND ACCEPTANCE OF ITEMS AND SERVICES

2.4.1 Policy

Procurement technical and quality requirements are generally based upon value (cost, durability, maintainability), performance (specification compliance, operating conditions, calibration capacity), delivery (timeliness, ease of ordering), customer support (responsiveness, technical ability), past experience with a particular vendor, and completeness and coherence of instructions (clarity, accuracy).

2.4.2 Procurement

Technical and quality requirements for items and services procured for a specific verification test may be included in the Test/QA Plan. These requirements will typically be specified under materials and/or measurement system equipment (Test/QA Plan Section B8, Inspection/Acceptance Requirements for Supplies and Consumables). The request for items or services will initiate from the Verification Test Coordinator or designee with approval for purchase from the Battelle MMR Center Manager, line manager, or designee.

2.4.3 Acceptance

2.4.3.1 Testing equipment procured for activities affecting quality shall be calibrated to ensure accuracy with required specifications listed in the Test/QA Plan and may be verified prior to use in the verification test (e.g. PE audits), as appropriate. Any discrepancies shall result in a recalibration of the equipment, or if the equipment is unusable, then a return of the item to the supplier for repair/replacement as necessary. Verification, storage, and maintenance records will be included in individual verification test records.

2.4.3.2 Testing materials procured for activities affecting quality (e.g. reference standards or gases) shall be accompanied with a Certificate of Analysis (COA) where appropriate. The COA will be examined to ensure that the listed specifications are within the required limits. The COA will be retained and included in the verification test records.

2.4.3.3 Methods to accept procurement of services (i.e. subcontractors; installation, repair, or maintenance work; etc.) includes technical verification of the data produced, surveillance and/or audit of the activity being performed, or review of objective evidence for conformance to procurement document requirements.

2.5 DOCUMENTS AND RECORDS

2.5.1 Controlled Documents

Document control is the system which ensures that only the latest revision(s) of the defined documents are used by Battelle staff participating in the MMR Center. The system includes retention of the document with original signed page(s) in a limited access storage area, a unique numbering system for all documents (typically identified by revision number

and/or date), and a distribution list for each document. Such documents are defined as "controlled documents" and can be revised only by the personnel listed within each document or this QMP. The following is a list of the controlled documents within the MMR Center:

- Quality Management Plan for the ETV Materials Management and Remediation Center (this document)
- Standard Operating Procedures
- Test/QA Plans, including amendments and deviations
- Generic Verification Protocols

Controlled document identification will consist of a number (if applicable), date, and version, if applicable, assigned to the document by the Battelle MMR Center Quality Manager or designee. A current Master List of Controlled Documents and Distribution shall be maintained by the Battelle MMR Center Quality Manager.

As a controlled document, approved copies of the QMP will be maintained and issued to MMR Center staff by the Battelle MMR Center Quality Manager or designee.

Obsolete or superseded documents shall be removed from operations when new documents are provided. Notification will accompany new document versions that the previous version is to be removed from use and destroyed. Staff members are responsible for destroying outdated versions of documents assigned to their person. The Battelle MMR Center Quality Manager is authorized to remove outdated documents observed during inspections and reviews. All controlled documents, including historical revisions, will be retained at least 10 years or six years and three months after final payment of the cooperative agreement, with the exception of the Standard Operating Procedures which will be permanently archived.

2.5.2 Verification Test Records

2.5.2.1 Active Verification Test Records. All verification test records shall carry minimum identification pertaining to title, responsible person or author, and date. All manual entries shall be entered using ink and initial and dated by the individual recording the entry. No changes to entries, manual or electronic, shall obscure the original record during the correction process, and corrections shall be initialed and dated by the individual recording the correction. A short explanation will be added to non-obvious corrections.

2.5.2.2 Storage of Verification Test Records. Per the ETV QMP, verification test records specific to the MMR Center shall be retained for at least 10 years or six years and three months after final payment of the cooperative agreement. All MMR Center records needed to reconstruct test activities and verify that reported data were collected in a consistent manner with this QMP and MMR Center requirements will be maintained in an appropriate area of limited access, until either transferred to EPA Office of Research and Development Records Management or properly destroyed with EPA permission. The Battelle MMR Center Quality Manager will

retain, as a permanent record, documentation of the transfer or destruction of Battelle's MMR Center records.

2.5.3 MMR Center Program Records

The following program records will be retained, as per the ETV QMP, for at least 10 years or six years and three months after final payment of the cooperative agreement.

- Minutes of stakeholder meetings
- Cooperative agreement (CA) records
- Test/QA Plans
- Verification reports
- Verification statements
- Battelle quality assessment reports.

2.5.4 Record Preparation, Review, Approval, and Distribution

Responsibilities for these activities are summarized in Table 2.0 and are detailed below.

2.5.4.1 Preparation. Individual case requirements and this QMP shall guide document and record content and/or format. For the MMR Center, guidance for content and/or format are derived by EPA/ETV directive and the following documents:

- ANSI/ASQ E4-2004, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs".
- EPA document "Environmental Technology Verification Program *Quality Management Plan*", Version 3.0, January, 2008.
- EPA document "EPA QA/R-2, *EPA Requirements for Quality Management Plans*, March 2001.

2.5.4.2 Review/Approval. Record review/approval shall be performed by qualified technical and/or management personnel as deemed appropriate. The individual reviewer shall have access to all needed references.

All Battelle prepared documents in QMP Sections 2.5.1 through 2.5.3 shall require at least one review by a Battelle staff member prior to external distribution by Battelle. Document and record reviews are performed at the request of the Battelle MMR Center Manager, Quality Manager, or other staff personnel.

In addition, ETV record review assigned to Battelle extends to the following documents, at a minimum:

- EPA/ETV strategy
- EPA/ETV QMP
- Annual Center progress reports.

Table 2.0 Records Management Responsibilities for the MMR Center

Record Type	Preparation/ Updating	Review	Approval	Finals Distributed to:
ETV Verification Strategy	N/A	Battelle MMR Center Manager	N/A	N/A
ETV Quality Management Plan	N/A	Battelle MMR Center Manager	N/A	N/A
CA Records	Battelle MMR Center Manager	EPA MMR Center Project Officer	N/A	N/A
MMR Center Quality Management Plan	Battelle MMR Center Quality Manager	EPA MMR Center Quality Manager	EPA MMR Center Project Officer EPA MMR Center Quality Manager Battelle MMR Center Manager Battelle MMR Center Quality Manager	Testing Staff ETV Webmaster EPA MMR Center Quality Manager EPA MMR Center Project Officer
Minutes of Stakeholder Meetings	Battelle	EPA MMR Center Project Officer Stakeholders	N/A	Stakeholders ETV Webmaster EPA MMR Center Project Officer
Test/QA Plan (including SOPs, amendments and deviations*)	Battelle	Battelle MMR Center Manager Battelle MMR Center Quality Manager EPA MMR Center Quality Manager EPA MMR Center Project Officer Assigned Stakeholders Peer Reviewers	Vendors EPA MMR Center Project Officer EPA MMR Center Quality Manager	Testing Staff Vendors EPA MMR Center Project Officer EPA MMR Center Quality Manager
Generic Verification Protocol	Battelle	EPA MMR Center Project Officer Battelle MMR Center Quality Manager Assigned Stakeholders	EPA MMR Center Project Officer EPA MMR Center Quality Manager	ETV Webmaster EPA MMR Center Project Officer
Raw data	Battelle	Internal Technical Peer Review	N/A	EPA can request copies
ETV Verification Report	Battelle	Battelle MMR Center Manager Battelle MMR Center Quality Manager EPA MMR Center Quality Manager Vendor Peer Reviewers	EPA MMR Center Project Officer EPA MMR Center Quality Manager	ETV Program Director EPA MMR Center Project Officer ETV Webmaster Vendors
ETV Verification Statement	Battelle	Battelle MMR Center Manager Battelle MMR Center Quality Manager EPA MMR Center Project Officer EPA MMR Center Quality Manager Vendor ETV Program Director Peer Reviewers	EPA Laboratory Director Battelle Management EPA MMR Center Project Officer EPA MMR Center Quality Manager	ETV Program Director EPA MMR Center Project Officer ETV Webmaster Vendors
Annual ETV Progress Report	N/A	Battelle MMR Center Manager	N/A	N/A
Quarterly ETV Progress Report	N/A	Battelle MMR Center Manager	Battelle MMR Center Manager	EPA MMR Center Project Officer EPA MMR Center Quality Manager ETV Program Director
EPA Reviews/Audit Reports	N/A	N/A	N/A	EPA Laboratory Directors Battelle MMR Center Manager Battelle MMR Center Quality Manager
Battelle Reviews/Audit Reports	Battelle MMR Center Quality Manager	Battelle MMR Center Manager	N/A	EPA MMR Center Project Officer EPA MMR Center Quality Manager

N/A = Indicates Battelle does not have responsibility for preparing/updating record; conducting or obtaining review; providing or obtaining approval; or distributing and/or receiving final record.

* = Amendments and deviations are not reviewed or approved by EPA. Only amendments are distributed.

2.5.4.3 Distribution. Once records have been reviewed and approved as required, distribution will be made as listed in Table 2.0. MMR Center documents specifically requiring EPA approval before release include:

- MMR Center QMP
- Generic Verification Protocols
- Test/QA Plans
- ETV verification reports
- ETV verification statements

2.6 COMPUTER HARDWARE AND SOFTWARE

This QMP requires that Battelle staff understand the necessity for all computer hardware and software specifications. Staff shall attempt to utilize computer hardware and software within the acceptance criteria specified, and ensures that hardware and software are installed, maintained, and used according to specifications. Any time a change in hardware components or configuration or a software modification is needed, retesting and recalibration must be performed and documentation included with facility records.

2.6.1Hardware

All computer hardware at Battelle contains Intel based Pentium processors running a Microsoft operating system. Each personal computer primarily consists of a standard complement of Microsoft software (e.g., Word, Excel, Access, PowerPoint, and Outlook) with capabilities of running other commercial software (e.g., WordPerfect, Quattro, Lotus, SAS) and delivery of data in various standard formats. These computers are replaced approximately once every three years to ensure staff have access to the most updated, state-of-the-art equipment, especially those staff with the heaviest computational needs.

Computer hardware is upgraded to improve performance and provide complete compatibility with current standards. The decision to upgrade computer hardware is made when a project that requires specific computer capabilities is received. Next, an assessment of impact is completed. This assessment includes a review of current computer programs and the impact or upgrading hardware on data accessibility.

2.6.2Software

Specific software required for a verification test will be identified in the Test/QA Plan. Most software used at Battelle is acquired commercially, loaded, and tested as specified by the publisher. Independently-developed software is not used within the ETV MMR Center; only commercial products are used. Software used for data management activities may include Microsoft Excel or Access. Standard word processing software (e.g. Word) is used to create reports. Currently, Battelle does not use nor are the systems currently compatible with Windows Vista.

2.6.3Validation Policy

Since all hardware and software used on the ETV MMR Center is commercially available and wide public use and continued market viability is considered proof of software dependability, validation is not considered necessary. However, verification of data analysis techniques within each program (e.g. the use of formulas and macros) is required. For each defined spreadsheet a performance test document will be prepared which will contain the following:

- An overview of the application. The overview will describe what the application is required to do and specify the methods used to meet the predetermined requirements.
- References to the productivity software used (e.g., Excel 2003, SigmaPlot V8.0, etc), and the operating system (e.g., Windows 2000, Windows XP, etc.).
- A description of important equations used to derive data.
- A description of what test(s) were conducted to confirm the accuracy of the application.

2.7 PLANNING

This QMP addresses the purpose and scope of systematic, timely, and effective planning necessary to assure services and products of the highest quality.

2.7.1 Stakeholder committee(s) containing representatives of appropriate technology interest groups shall be jointly established by Battelle with input from the EPA MMR Center Project Officer. Individual stakeholders shall be selected for these committee(s) based on their expertise and interest in materials management and remediation and their availability and willingness to participate.

A joint meeting of the EPA MMR Center Project Officer, Battelle, and each stakeholder committee will be held at least once annually, with minutes of such meetings recorded, reviewed, and circulated to the stakeholders, the EPA MMR Center Project Officer, Battelle, and subsequently posted on the ETV Website. The meeting can be conducted in person or by teleconference.

The planned quality-related purposes of this meeting are to:

- Identify, revise, and/or clarify the technical and quality goals of the work to be accomplished
- Determine testing priorities and evaluate customer satisfaction
- Define and review verification plans, and identify verification test collaborators.

2.7.2 Systematic Planning of Verification Tests

An overall view of the EPA ETV verification process is shown in Figure 2.0. Battelle, in cooperation with the EPA MMR Center Project Officer, begins a systematic process to plan the individual verification tests. Systematic planning may be accomplished through any demonstrated technique such as the data quality objectives process (EPA QA/G-4,

Guidance on Systematic Planning Using the Data Quality Objectives Process, February 2006). The planners perform the following actions:

- Convene stakeholder committees of representatives of verification customer groups who advise during the planning process
- Mediate and facilitate the selection of prioritized technologies
- Refine the scope of respective technology areas
- Determine interest in verification from the vendors of commercial-ready technologies within the defined scope of these areas and other collaborators that could contribute funding or in-kind support

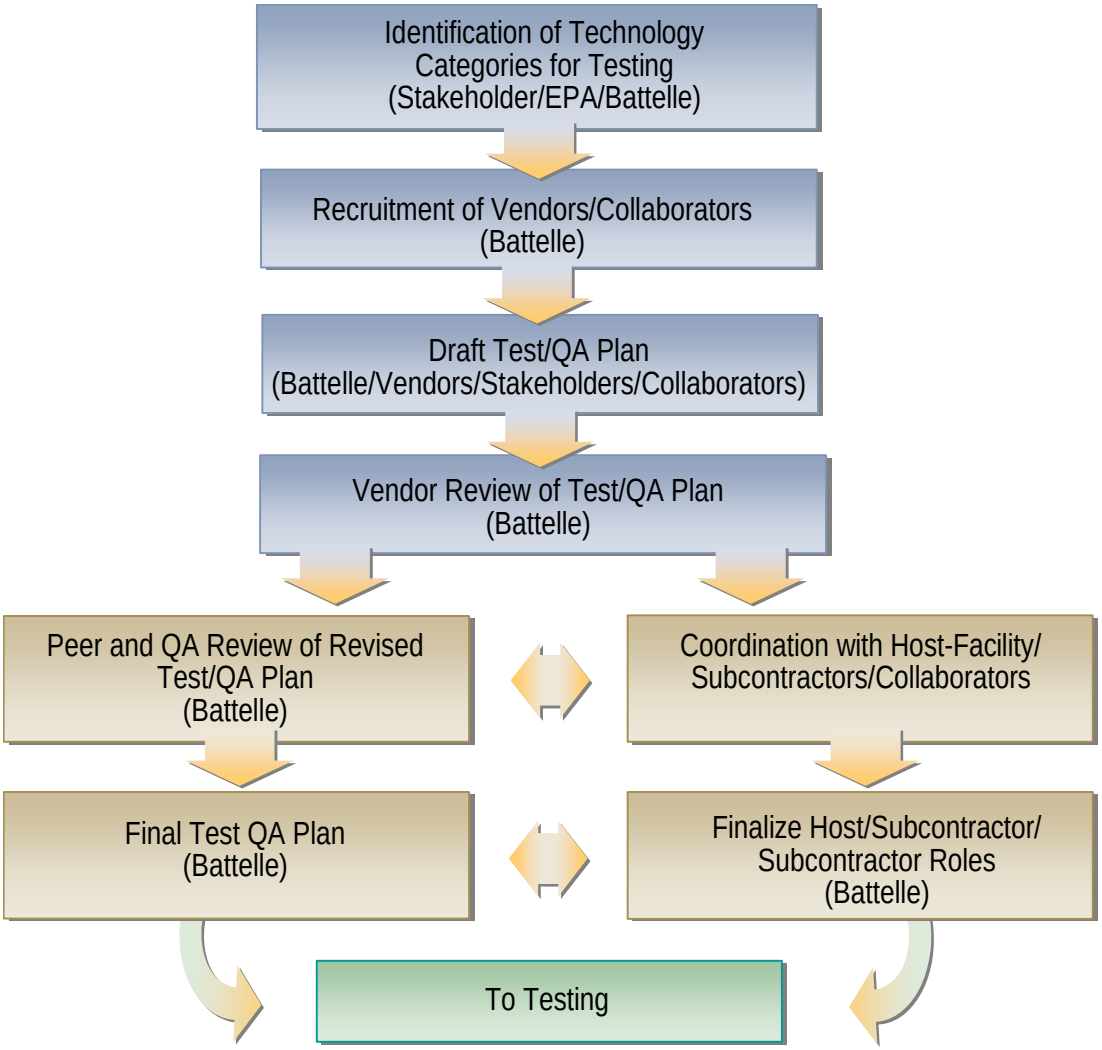

Figure 2 Systematic Planning of Verification Tests

- Solicit vendor and prepare vendor agreements to participate in verification of their products based on the Test/QA Plan
- Prepare Test/QA Plan(s) which are developed to promote uniform testing for a given type of technology
- Involve host facilities, collaborator organizations, and any subcontracted laboratories in the planning process
- Coordinate the review and revision of the Test/QA Plan(s) (by vendors, EPA, and peer reviewers) keeping in mind both the customer and EPA objectives for verification as defined in the ETV Strategy
- Prepare final Test/QA Plans after testing a given type of technology
- Prepare amendments and deviations to the Test/QA Plan, as necessary, to include revisions based on actual test experience.

Systematic planning process-control documents for the MMR Center include:

- The ETV Program Policy Compendium
- The ETV Program QMP
- This QMP which defines the operational quality system necessary to provide acceptable products and services.
- Written quality procedures specific to the technology and verification test including Test/QA Plans and Standard Operating Procedures.
- Outputs from stakeholder committee meetings in the form of reviewed and distributed minutes.
- Quarterly financial and progress reports to the EPA ETV program.

2.7.3 Planning Personnel

Verification test planning shall be coordinated by Battelle among the participating organizations including EPA, the stakeholders, the vendors, and any testing organizations and laboratories participating in the test. Battelle, with the concurrence and oversight of the EPA MMR Center Project Officer, shall identify the planning roles of the participants, and shall conduct planning activities by shared communication via e-mail, teleconference, web meetings, and in-person meetings, as appropriate, and within the constraints of budget.

2.7.4 Existing Data

Existing data may be used according to the procedures described in the Test/QA Plan for each verification test and in accordance with the ETV QMP.

2.8 DESIGN OF TECHNOLOGY VERIFICATION OPERATIONS

2.8.1 Design Process

The design process produces a Test/QA Plan based upon the data quality objectives for the verification.

2.8.1.1 Design Technique. In designing verification tests, Battelle staff use consensus-accepted test design including statistical methods, as appropriate. The design takes into account constraints of time, scheduling, and resources. All relevant activities pertaining to environmental data operations shall be identified, as well as performance specifications and the appropriate controls.

2.8.1.2 Field and Laboratory Equipment and Methods. During the design process, the appropriate field and laboratory equipment which were identified during planning for the testing of the technology verification performance are incorporated. Appropriate test methods and operating parameters are specified.

2.8.1.3 Sampling and Analysis. If samples for analysis are taken in the field, they are handled according to procedures specified in the Test/QA Plan. The oversight responsibility of Battelle is to determine that the approved systems and plans contain adequate procedures for handling, storage, cleaning, packaging, shipping, and preservation of field and laboratory samples to prevent damage, loss, deterioration, artifacts, or interferences. Battelle will provide adequate chain of custody procedures, if they are required. The following sampling and analysis design parameters will be addressed in the Test/QA Plan.

- Experiments to be conducted, the baseline parameters, the number of replicate tests, and the controls.
- Sampling methods, sample types, numbers, quantities, handling, packaging, shipping, and custody (if sampling is performed).
- Sample locations, storage conditions, and holding times.
- Analysis methods, quantitative measures of performance, calibration standards, calibration check standards, and performance evaluation samples, as appropriate, and as identified in the planning process.
- Methods and procedures to ensure the test produces traceable data of known and acceptable quality.
- Field and/or laboratory QA/QC activities.
- Requirements for qualifications of technical staff responsible for obtaining, analyzing, and evaluating the data.
- Protection of the health and safety of testing personnel and the public.
- Procedures for the minimization and disposal of waste generated.

2.8.1.4 Assessments. Assessments incorporated into the design include self-assessments (internal audits) by Battelle and independent assessments by EPA. The assessments identified in the planning process are incorporated into the design. The type and minimum number of assessments are identified in Section 3.0.

2.8.2 Generic Verification Protocols, Test/QA Plans, and Standard Operating Procedures

Three types of planning documents have been identified for operation of an ETV Center: the GVP, the Test/QA Plan, and Standard Operating Procedures (SOPs). The GVP is meant to promote uniform testing for a technology category, and therefore, is a more general document. The Test/QA Plan gives the specific information needed to conduct a

verification test. If another level of detail is required for describing test activities, for example operation of an instrument, an SOP will be written and attached to the Test/QA Plan.

2.8.2.1 Generic Verification Protocol. The Battelle MMR Center Manager will be responsible for assuring that the GVPs are prepared and transferred to the EPA MMR Center Quality Manager and stakeholders for review. The issues that may be addressed in the GVP are the following:

- General description of the Center
- Responsibilities of all involved organizations
- Experimental design
- Equipment capabilities and description
- Description and use of field test sites
- Description and use of laboratory test sites
- QA/QC
- Data handling
- Requirements for other documents
- Health and safety
- References.

2.8.2.2 Test/QA Plans. Test/QA Plans are the responsibility of the Battelle MMR Center Manager and are reviewed by the Battelle MMR Center Quality Manager and EPA MMR Center Quality Manager. The appropriate GVP is incorporated by reference. Appropriate guidance for writing Test/QA Plans is available in EPA/QA G-5, *Guidance for Quality Assurance Project Plans*, December 2002. Planned changes to the Test/QA Plan are made by amendment. Deviations from the plan must be fully documented including, date and description of deviation, and impact on the verification test. Amendment and deviation forms are in Appendix II. Elements of the Test/QA Plan will include the following. Elements listed that are not appropriate for the test will be listed as such:

- Group A: Verification Management - This group of elements covers the general areas of verification management, verification history and objectives, and roles and responsibilities of the participants. The following nine elements ensure that the verification's goals are clearly stated, that all participants understand the goals and the approach to be used, and that verification planning is documented:

  - A1 Title and Approval Sheet
  - A2 Table of Contents and Document Control Format
  - A3 Distribution List
  - A4 Verification Organization and Schedule
  - A5 Problem Definition/Background
  - A6 Verification Description
  - A7 Quality Objectives and Criteria for Measurement Data
  - A8 Special Training Requirements/Certification

- A9 Documentation and Records

- Group B: Measurement/Data Acquisition - This group of elements covers all of the aspects of measurement system design and implementation, ensuring that appropriate methods for sampling, analysis, data handling, and QC are employed and will be thoroughly documented:

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

- Group C: Assessment/Oversight - The purpose of assessment is to ensure that the Test/QA Plan is implemented as prescribed. This group of elements addresses the activities for assessing the effectiveness of the implementation of the verification and the associated QA/QC activities:

  - C1 Assessments and Response Actions
  - C2 Reports to Management

- Group D: Data Validation and Usability - Implementation of Group D elements ensures that the individual data elements conform to the specified criteria, thus enabling reconciliation with the verification's objectives. This group of elements covers the QA activities that occur after the data collection phase of the verification has been completed:

  - D1 Data Review, Validation, and Verification Requirements
  - D2 Validation and Verification Methods
  - D3 Reconciliation with Data Quality Objectives

2.8.2.3 Standard Operating Procedures. The following topics, from EPA QA/G-6, *Guidance for Development of Standard Operating Procedures (SOPs)*, April 2007, will be included (or a reference provided), as appropriate, in standard operating procedure that are prepared for MMR Center verification tests:

- Title Page
- Table of Contents
- Procedures - The following are topics that may be appropriate for inclusion in technical SOPs. Not all will apply to every procedure or work process detailed.

  - Scope & Applicability
  - Summary of Method
  - Definitions
  - Health & Safety Warnings (indicating operations that could result in personal injury or loss of life)
    - Cautions (indicating activities that could result in equipment damage, degradation of sample, or possible invalidation of results)
    - Interferences (describing any component of the process that may interfere with the accuracy of the final product)
  - Personnel Qualifications
  - Equipment and Supplies
  - Procedure (identifying all pertinent steps, in order, and materials needed to accomplish the procedure such as:
    - Instrument or method calibration and standardization
    - Sample Collection
    - Sample Handling and Preservation
    - Sample Preparation and Analysis
    - Troubleshooting
    - Data Acquisition, Calculations & Reduction
    - Requirements for Computer Hardware & Software used in Data Reduction and reporting
  - Data and Records Management
- Quality Control and Quality Assurance Section
- References

2.9 IMPLEMENTATION

2.9.1 General

Technology performance verifications are implemented according to the Test/QA Plans and technical documents (e.g., Standard Operating Procedures) prepared during planning. A kick-off meeting will be held prior to the start of each verification test to review procedures for the test with all verification testing staff. Test personnel have access to the approved planning documents, approved changes to planning documents, and all referenced documents. When a prescribed sequence for the work is defined during the planning stages, work performed shall follow that sequence. Changes to that sequence need to be documented by either amendment (planned changes) or deviation (unplanned changes). All implementation activities are documented. Suitable documents are bound notebooks (e.g. laboratory record books, or LRBs), field and laboratory data sheets, spreadsheets, computer records, and output from instruments (both electronic and hardcopy). All documentation is implemented as described in the planning documents. All implementation activities are traceable to the planning documents and traceable to test personnel.

2.9.1.1 Conformance of implementation to planning is accomplished by following approved documents for the Battelle quality system implementation, verification testing, and for any field and laboratory technical operations.

Generation of verification test data will not be initiated until the approved Test/QA Plan is in place.

When work cannot be implemented according to the approved planning and test document, Battelle shall be responsible for providing a written amendment to the Test/QA Plan or a deviation report for the test records. Amendments are produced for changes that are made to the approved Test/QA Plan before the proposed change will be made. Amendments must be approved internally by the Battelle MMR Center Quality Manager and the Battelle MMR Center Quality Manager. Following approval, the amendment will be distributed to all internal personnel holding a copy of the approved Test/QA Plan and the EPA MMR Center Quality Manager. A deviation report is produced for any changes to the approved Test/QA Plan that occurred during the test. Deviation reports must be retained in the verification test records and summarized in the verification test report. Frequent deviations from established procedures should result in a retrospective review of the written document and possible revision. Amendments and deviations will include all the information displayed on the forms shown in Appendix II.

All persons responsible for performing verification testing and those participating vendors shall receive copies of the current revision of the Test/QA Plan and associated documentation provided by Battelle.

Current versions of Test/QA Plans and any applicable methods and SOPs are required to be physically in place at each technology verification testing site.

2.9.1.2 Battelle oversight and inspection of a verification test shall be provided by the Battelle MMR Center Quality Manager or designee at intervals prescribed in each Test/QA Plan. This frequency, at a minimum, will be once for each verification test of a technology category. To verify full implementation of the Test/QA Plan, the inspection will include the testing process and any documentation associated with the process, such as sample tracking records; instrument maintenance and calibration; sample preparation and actual analysis; and data records. The Battelle MMR Center Quality Manager will provide a written report, verify the completion of any corrective actions needed, and retain a copy of the report with permanent Battelle MMR Center Quality Manager records. The EPA MMR Center Project Officer will be included in the routing of the inspection results and a written copy provided to both the EPA MMR Center Project Officer and EPA MMR Center Quality Manager.

2.9.2 Implementation Procedures

2.9.2.1 Testing procedures shall be documented in approved Test/QA Plans and SOPs. Testing personnel, by virtue of training requirements described in this QMP, shall demonstrate proficiency of performance and knowledge of QA and MMR Center requirements for the verification test operations.

2.9.2.2 Content requirements for testing procedures may include those of existing Battelle SOPs or other referenced documents.

2.9.2.3 Before the initiation of testing, a test kickoff meeting will be held by the Verification Test Coordinator. The Battelle MMR Center Manager, Battelle MMR Center Quality Manager, and all Battelle technical staff who will be utilized for the verification test will attend the kickoff meeting. Subjects to be discussed at the meeting will include, but not be limited to, a general overview of the Test/QA Plan, staff assignments, schedules, and assessments (see Section 3.0). A separate meeting may also be held with external staff (e.g. collaborators, external personnel, vendors, etc…) prior to the test.

2.9.2.4 Review of technical Center-specific procedures shall be done by personnel technically competent with respect to the procedure. Time must be allowed for the composition, review, and approval of technical procedures to be completed in advance of the actual performance.

2.9.3 Implementation Monitoring

2.9.3.1 Quality assessments during implementation of individual verification tests will be prescribed at a minimum frequency/interval in the Test/QA Plan. Specifically, the Test/QA Plan will address:

- A routine monitoring schedule and,
- The required specifications of performance, or particular aspects of the process, that are determined to be critical for monitoring

2.9.3.2 Monitoring of the work process is conducted by the Battelle MMR Center Quality Manager or designee and is done to:

- Ensure satisfactory performance based on requirements,
- Ensure required actions (as specified in implementation documents) are performed so that routine measurements meet specifications,
- Ensure preventive maintenance is performed and documented as specified in facility and study records,
- Ensure calibrations are performed as planned and prescribed,
- Ensure corrective actions are implemented and documented as planned in response to items of nonconformance.

3.0 ASSESSMENT AND RESPONSE

3.1 SCOPE

3.1.1 Assessments shall be planned, scheduled, conducted, and reported in order to measure the efficacy of the Battelle quality system.

3.1.2 Assessment and response elements shall include assigning appropriate, qualified persons to conduct assessments at planned, scheduled intervals; having provisions for timely responses and implementation of corrective actions if needed; and completing the evaluation process with written reports to technical and management staff.

3.1.3 Assessment types, responsibility, and schedule for the MMR Center as shown in Table 3.0, and are defined as follows:

Quality Systems Audit, an on-site review of the implementation of the MMR Center quality system as documented in the MMR Center QMP. This review is used to verify the existence of, and evaluate the adequacy of, the internal quality system. A QSA may be a self-assessment or an independent assessment by EPA.

Technical Systems Audit, a qualitative on-site evaluation of sampling and/or measurement systems associated with a particular verification test. The objective of the Technical Systems Audit (TSA) is to assess and document the acceptability of all facilities, maintenance, calibration procedures, reporting requirements, sampling, and analytical activities, and quality control procedures in the test. Conformance with the Test/QA Plan and associated methods and/or Standard Operating Procedures is the basis for this assessment. The Battelle MMR Center Quality Manager, or designee, conducts a TSA at least once during each verification test. The EPA MMR Center Quality Manager conducts an independent TSA once per year, as applicable, for the MMR Center.

Performance Evaluation Audits, a quantitative evaluation of a measurement system. The type and frequency of performance evaluation (PE) self-audits to be performed will be specified in the Test/QA Plan for each verification test. The value or composition of reference materials must be certified or verified prior to use, and the certification or verification must be adequately documented. The Battelle MMR Center Quality Manager, or designee, will review results of PE audits. The need for independent PE audits will be determined by the EPA MMR Center Quality Manager.

Audits of Data Quality, an examination of the verification data after they have been collected and 100% verified by project personnel. The Battelle MMR Center Quality Manager, or designee, will audit at least 10% of all verification data, including equations and calculations. The need for independent audits of data quality (ADQ) will be determined by the EPA MMR Center Quality Manager.

Table 3.0 Assessments for the MMR Center

Level	Assessment Tool	Assessors	Responders	Subject of Assessment	Minimum Frequency	Reason for Assessment	Report Reviewed by
Center	Quality Systems Audit	Self Battelle MMR Center Quality Manager Independent EPA MMR Center Quality Manager	Battelle	center QMP	once; thereafter, as requested	assess quality management practices of verification partner	EPA directors of quality assurance EPA MMR Center Project Officer Battelle MMR Center Manager ETV Program Director
Center	Technical Systems Audits	Self Battelle MMR Center Quality Manager Independent EPA MMR Center Quality Manager	Battelle	Test/QA Plans	Self Once per verification test Independent once per year, as applicable	assess technical quality of verification tests	EPA MMR Center Project Officer EPA MMR Center Quality Manager Battelle MMR Center Manager
Center	Performance Evaluation Audits	Self Battelle MMR Center Quality Manager Independent EPA MMR Center Quality Manager	Battelle	Test/QA Plans	Self each test, as applicable Independent for each center, as applicable	assess measurements performance	Self Battelle MMR Center Manager Independent EPA MMR Center Project Officer EPA MMR Center Quality Manager
Center	Audits of Data Quality	Self Battelle MMR Center Quality Manager Independent EPA MMR Center Quality Manager	Battelle	raw data and summary data	Self At least 10% of the verification data Independent for each center, as applicable	assess data calculations and reporting	Self Battelle MMR Center Manager Independent EPA MMR Center Project Officer EPA MMR Center Quality Manager

3.2 GENERAL REQUIREMENTS

3.2.1 Each assessment must be fully documented. The Battelle MMR Center Quality Manager will archive all internal assessment reports generated on the MMR Center.

Each assessment must be responded to by the appropriate level of management. The Battelle quality assessment reports shall require a written response by the person performing the inspected activity, and acknowledgment of the assessment by the Battelle MMR Center Manager and the Battelle MMR Center Manager. The assessment reporting forms are provided in Appendix III.

3.2.2 Corrective action must be documented and approved on the original assessment report, with detailed narrative in response to the assessor's finding. Initials and date are required for

each corrective action response. Acknowledgment of the response will be provided by the Battelle MMR Center Manager.

3.2.3 Implementation of corrective actions must be verified by the Battelle MMR Center Quality Manager or designee to ensure that corrective actions are adequate and have been completed. This will be done in real-time if corrective actions can be immediately performed and signed off on the assessment report. Alternatively, should the corrective action require additional approvals not immediately available on-site, the Battelle MMR Center Quality Manager or designee may need to repeat the inspection in order to corroborate the implementation and effectiveness of the corrective action.

3.3 PLANNING AND PROCEDURES

3.3.1 Assessment Planning

Assessment planning is performed by Battelle's Quality and MMR Center Managers prior to the actual performance of any assessments. Planning the assessment scope helps provide the type of evaluation information needed to determine whether procedural compliance and technical requirements are being met during verification testing.

Assessment planning by Battelle shall include a kickoff meeting with the verification testing team where at least the following information may be discussed:

- Schedule of assessment(s),
- Proper completion of data records
- Notification to affected parties,
- Specific assessment requirements (personnel lists, equipment lists, and availability of Test/QA Plans),
- Follow-up procedures for corrective action, including debriefing and discussion of possible resolutions,
- Corrective action guidelines to facilitate completion of the reported assessment,
- Appropriate management signature approval of the reviewed assessment report.

3.3.2 Personnel Qualifications for Assessment

The principal Battelle inspector shall be the Battelle MMR Center Quality Manager, who will have an extensive quality assurance laboratory and field inspection background, and technical and management experience, and who will be directly familiar with the MMR Center assessment requirements. Should the need arise, the Battelle MMR Center Quality Manager will designate an individual to perform scheduled assessments, based upon that person's technical skill and knowledge of QMP compliance requirements and Test/QA Plan specifications. Battelle personnel conducting assessments shall have the responsibility and authority to:

- identify and document problems affecting the quality of verification results,
- propose recommendations for resolving these problems,
- independently confirm implementation and effectiveness of solutions.

3.3.3 Stop Work

Assessor responsibility and authority to stop work during a verification test for safety and quality considerations is delegated to Battelle, who must ensure compliance with all applicable federal, state, and local safety policies during the performance of verification testing.

Should it be determined during an assessment that adverse health effects could result, or that test objectives of acceptable quality cannot be achieved during performance of verification testing, the Battelle MMR Center Quality Manager is responsible for immediately notifying the Battelle Center Manager of the need to consider a stop work order. The Battelle MMR Center Manager shall then direct the MMR Center staff accordingly.

Should any MMR Center staff suspect compromise to personal health or test objectives during the conduct of verification testing, that staff member shall immediately contact the Battelle MMR Center Manager who will issue the stop work order.

The EPA MMR Center Quality Manager is delegated to notify the EPA MMR Center Project Officer who will notify the Battelle MMR Center Manager to facilitate a stop work order if work of inadequate quality is discovered.

Documentation is required of any stop work order and the corrective action implemented and shall be maintained as part of the Battelle quality records, with a copy provided to the EPA MMR Center Project Officer and EPA MMR Center Quality Manager.

3.3.4 Internal Assessment Reporting

Authority to effectively report internal technical system audits, performance evaluation audits, and audits of data quality is assigned to the Battelle MMR Center Quality Manager or designee. These reports should:

- Identify and document problems that affect quality and the achievement of objectives required by the QMP, Test/QA Plan, and any associated Standard Operating Procedures,
- Identify and cite noteworthy practices that may be shared with others to improve the quality of their operations and products,
- Propose recommendations (if requested) for resolving problems that affect quality,
- Independently confirm implementation and effectiveness of solutions,
- Provide documented assurance (if requested) to line management that, when problems are identified, further work performed is monitored carefully until the problems are suitably resolved.

3.3.5 Response

Responses to TSA adverse findings should be addressed within 10 working days after the TSA report is completed. However, it is expected that findings that have a direct impact on

the conduct of a verification test will be corrected immediately following notification of the finding.

Responses to each adverse finding shall be documented in the assessment report (QMP Section 3.3.4). Ideally, assessment reports will provide space after each adverse finding for a response to be recorded. The response will indicate the corrective action taken or planned to address the adverse finding. The response should be signed and dated by the staff responsible for implementing the corrective action.

Any corrective action that cannot be immediately implemented should be verified following completion by the Battelle MMR Center Quality Manager or designee. Once all corrective action associated with an assessment report has been taken, the Battelle MMR Center Quality Manager or designee will initial the corrective action in the assessment report thus documenting verification of the corrective action. Any impact that an adverse finding had on the quality of verification test data should be addressed in the verification test report.

The TSA report, with responses to adverse findings recorded within, will be sent to EPA within 10 working days after the Battelle MMR Center Quality Manager has verified all corrective actions.

3.4 DATA VALIDATION

Validation is based on the performance measures for the test specified during the design process. The usability of a verification report and statement is determined relative to how well it determines the performance of the tested technology under the conditions of testing. Any limitations on the data and recommendations for limitations on data usability are documented in the data audit report and the ETV verification report. All validation procedures are performed by the Verification Test Coordinator and then reviewed by the Battelle MMR Center Quality Manager.

3.5 REPORT REVIEW

Review and approval procedures for verification reports and statements are given in Table 2.0. Verification reports are peer-reviewed by external reviewers and verification statements are signed by an EPA laboratory director and Battelle management.

3.6 QUALITY IMPROVEMENT

3.6.1 Policy

A continuous quality improvement process is considered essential for Battelle staff to develop a more responsive quality system in all aspects of technical and management activities.

3.6.2 Annual QMP Review

An annual review of the QMP for the MMR Center shall be conducted by the Battelle MMR Center Quality Manager and technical and management staff in order to incorporate improvements to the quality system process. MMR Center QMP revisions may be delayed beyond one year such as when an update to the ETV QMP is pending. Approval for any delay to the annual review will be obtained from the EPA MMR Center Quality Manager.

Any revisions to the QMP will be compiled by the Battelle MMR Center Quality Manager for review, approval, and distribution. The QMP review will be documented by the Battelle MMR Center Quality Manager and Battelle MMR Center Manager by signing and dating the revised QMP routed for review and approval.

3.6.3 Problem Identification and Resolution

Detecting and correcting quality system problems is a result of qualified MMR Center technical and management staff implementing not only this QMP, but also the Test/QA Plan and other procedures. All staff are encouraged to identify problems and offer solutions to problems in the following quality areas:

- Adequacy of the quality system, as defined in the QMP,
- Consistency of the quality system,
- Implementation of the quality system to specific verification tests,
- Correction of quality system procedures,
- Completeness of documented information,
- Quality of data,
- Quality of planning documents, such as the Test/QA Plans,
- Implementation of the work process.

Cause and effect relationships of significant problems shall be documented by the Battelle MMR Center Quality Manager. When problems are reported to the Battelle MMR Center Quality Manager, attempts to determine the root cause based on cause and effect during performance of planned and documented procedures will be made, through intensified observations of testing activities and audits of test data. When problems are identified for the quality system, the Battelle MMR Center Manager will contact the EPA MMR Center Project Officer of the problem(s) and corrective action(s).

Collaboration with trained technical/management staff associated with or performing the activity can provide insight and determine whether any of the following is required:

- A Test/QA Plan change,
- A management system change, or
- A quality system change within the MMR Center.

Assessment reports can also serve as tools to determine cause and effect relations of significant problems that might require testing protocol, management system, or quality system changes. Continual monitoring and evaluation by the EPA MMR Center Quality

Manager, for example, may indicate trends or common and recurring problems for an entire technology evaluation. If recurring problems are identified, Battelle will immediately communicate this situation to the EPA MMR Center Project Officer.

Root cause determination is immediately reported by Battelle to the EPA MMR Center Project Officer prior to any planned implementation of preventative measure. Once the root cause determination is verified, appropriate actions can be planned, documented, and implemented by the MMR Center staff.

3.6.4 Ongoing Quality Improvement

Quality improvement action is ongoing in the Battelle quality system, where quality issue action items can be reviewed by all levels of line management at periodic continuous improvement meetings. Quality processes are continually monitored and both short-term and long-term quality issues are identified through customer feedback and client involvement, peer review and internal lessons learned, and program reviews.

APPENDIX I

NAMES, ADDRESSES, AND PHONE NUMBERS OF BATTELLE MMR CENTER KEY STAFF

KEY BATTELLE MMR CENTER STAFF

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Fax: 614-458-5795
e-mail: willenbergz@battelle.org

Stakeholder Coordinator:

Ms. Maria Gordon
505 King Avenue
Columbus, OH 43201
Phone: 614-424-5278
Fax: 614-458-5278
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APPENDIX II

AMENDMENT AND DEVIATION FORMS

TEST/QA PLAN AMENDMENT

TEST/QA PLAN TITLE AND DATE:

AMENDMENT NUMBER: _____

EFFECTIVE DATE: _____

PART TO BE CHANGED/REVISED:

CHANGE/REVISION:

REASON FOR CHANGE:

ORIGINATED BY:

_____
Battelle Verification Test Coordinator

_____
DATE

APPROVED BY:

_____ _____
Battelle MMR Center Manager Battelle MMR Center Quality Manager

_____ _____
DATE DATE

Required Distribution - All individuals/organizations listed on distribution for the applicable Test/QA Plan, including but not limited to:

Battelle MMR Center Manager
Battelle MMR Center Testing Staff
Battelle MMR Center Quality Manager
Subcontractors (if any)
Verification Test Collaborators (if any)
EPA/ETV MMR Center Project Officer
EPA/ETV MMR Center Quality Manager
Vendors
Distribution must be documented

TEST/QA PLAN DEVIATION REPORT

TEST/QA PLAN TITLE AND DATE:

DEVIATION NUMBER: _____

DATE OF DEVIATION: _____

DESCRIPTION OF DEVIATION:

CAUSE OF DEVIATION:

IMPACT OF DEVIATION ON THE TEST:

CORRECTIVE ACTION:

ORIGINATED BY:

_____
Battelle Verification Test Coordinator

_____
DATE

ACKNOWLEDGED BY:

_____ _____
Battelle MMR Center Manager Battelle MMR Center Quality Manager

_____ _____
DATE DATE

Required Distribution - All individuals/organizations listed below:
Battelle MMR Center Manager
Battelle MMR Center Quality Manager

Distribution must be documented

APPENDIX III

ETV ASSESSMENT REPORTING FORMS

Quality Assurance Routing Sheet
ETV MMR Center

Verification Test:

Audit Type:

Test Coordinator:

Vendor:

Auditor: **Date**:

Test Coordinator, please complete the attached form indicating CORRECTIVE ACTION TAKEN (IF NEEDED), sign and date this Routing Sheet in the space provided beside your name, and return the entire set when completed to the Battelle MMR Center Quality Manager no later than _____.

Route To	***Signature***	***Date***
Test Coordinator		
Battelle MMR Center Quality Manager		
Approval		
Battelle MMR Center Manager		
Battelle MMR Center Quality Manager		

Audit Comment Sheet

Instructions: The Battelle MMR Center Quality Manager will fill out the first column for the audit indicated above. The Verification Test Coordinator will respond to the comments and initial and date the response in column three. The Battelle MMR Center Quality Manager will verify and document that the response/corrective action has been completed by initialing and dating the final column.

QA Comment	Test Coordinator Response/Corrective Actions	Responder Initials/Date	QA Initials/ Date