

Battelle

The Business of Innovation

**Environmental Technology
Verification Program
Advanced Monitoring
Systems Center**

Quality Management Plan (QMP)
for the
ETV Advanced Monitoring Systems
Center
Version 6.0

ET ✓ ET ✓ ET ✓

QUALITY MANAGEMENT PLAN (QMP)

for the

ETV ADVANCED MONITORING SYSTEMS CENTER Version 6.0

(SIGNATURE ON FILE)

Robert Fuerst	11-21-05
EPA AMS CENTER PROJECT OFFICER	Date
Elizabeth Betz	11-21-05
EPA AMS CENTER QUALITY OFFICER	Date
Karen Riggs	11-15-05
BATTELLE AMS CENTER MANAGER	Date
Zachary Willenberg	11-14-05
BATTELLE QUALITY MANAGER	Date

BATTELLE
505 King Avenue
Columbus, OH 43201

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1.0 GENERAL PROVISIONS

1.1 INTRODUCTION

1.1.1 This document, the Quality Management Plan (QMP) for the Advanced Monitoring Systems (AMS) Center, describes the quality systems that will be employed by Battelle in conducting the AMS Center. These quality systems are designed to be consistent with ANSI/ASQC 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 2.0, dated December 2002, and *EPA Requirements for Quality Management Plans* (QA/R-2, dated March 2001).

1.2 PURPOSE

1.2.1 The purpose of the AMS Center is to verify commercially-available systems for monitoring natural species and contaminants in air, water, and soil. The AMS Center encompasses the full range of environmental monitoring technologies, and as part of the larger Environmental Technology Verification (ETV) program is designed to provide technology users with objective, high quality performance data for air, water, and soil monitoring systems to support technology selection decisions.

1.3 SCOPE AND FIELD OF APPLICATION

1.3.1 This document encompasses activities that Battelle as an EPA verification partner (VP), shall utilize to assure the quality of products and services provided for the AMS Center. The AMS Center is one of six centers operating under the ETV program.

1.3.2 This QMP applies to personnel involved in, and activities conducted for the AMS Center and contains the minimum specifications and guidelines that are applicable to AMS Center quality management functions and activities based upon ANSI/ASQC E4-1994. 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 16,000 scientists, engineers, and support specialists. Each year, thousands of technology projects are in progress at Battelle's various business operations. These programs are performed for nearly 1,000 companies and government agencies. Battelle conducts \$3.4 billion in annual research and development.

Battelle's headquarters are in Columbus, Ohio. Major technology centers are located in Columbus; Richland, Washington; Amarillo, Texas; and Geneva, Switzerland. For the US Department of Energy Battelle manages the Pacific Northwest National Laboratory in Richland, Washington and co-manages Brookhaven National Laboratory in Long Island, New York, Oak Ridge National Laboratory in Oak Ridge, Tennessee, the National Renewable Energy Laboratory in Golden, Colorado, and the Idaho National Laboratory in Idaho Falls, Idaho. Specialized facilities, regional centers, and offices are located in more than 40 other cities in the United States and Europe.

Battelle's organization includes 16 business divisions. The AMS Center is managed within Battelle's Energy and Environment Business Division. The Energy, Transportation, and Environment (ETE) Business Division includes approximately 500 chemists, engineers, statisticians, and support personnel. Staff and facilities will be drawn from the ETE Business and other Battelle Divisions to support the AMS Center. Staff involved in the AMS Center include those with expertise in environmental monitoring, stakeholder involvement, and outreach and communication. Key Battelle facilities that are available for use on the AMS 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 AMS Center is provided in Figure 1.0 and shows key AMS Center staff and their reporting lines. The key AMS Center staff are:

Battelle AMS Center Manager: Ms. Karen Riggs is Battelle's AMS Center manager with responsibility for meeting all technical, budget, and schedule goals for the Center. Ms. Riggs reports directly to Mr. Mark Slonecker, a Vice President in the ETE Business Division. Mr. Slonecker will provide Ms. Riggs and the other key AMS Center staff with direct support in securing and deploying Battelle resources for the AMS Center. Dr. Greg Mack, Assistant Division Manager of Battelle's ETE Business Division, has ultimate responsibility for ensuring that necessary Battelle facility and staff resources are available to support the AMS Center. Ms. Riggs serves as the primary point of contact for EPA's AMS Center Project Officer, Mr. Robert Fuerst. She also directs the activities of the leaders in four technical areas assigned to major tasks on the Center.

Battelle Quality Manager: Mr. Zachary Willenberg is the Battelle Quality Manager for the AMS Center. He is a Quality Assurance Officer in the ETE Business Division and reports directly to Battelle Vice President Mr. Slonecker, and for the AMS Center, to Ms. Riggs. These relationships are illustrated in Figure 1.0.

Verification Testing Leader: Dr. Thomas Kelly and Ms. Amy Dindal are the AMS Center Verification Testing Leaders and have responsibility planning and leading verification tests. Dr. Kelly is a Senior Research Scientist and Ms. Dindal is a Project/Program Manager in Battelle's ETE Business Division. They report directly to Ms. Riggs on their AMS Center activities and can serve in the role as AMS Center Manager for tasks delegate by Ms. Riggs.

Stakeholder Involvement Leader: Ms. Gretchen Hund is the AMS Center Stakeholder Involvement Leader with primary responsibility for stakeholder recruitment,

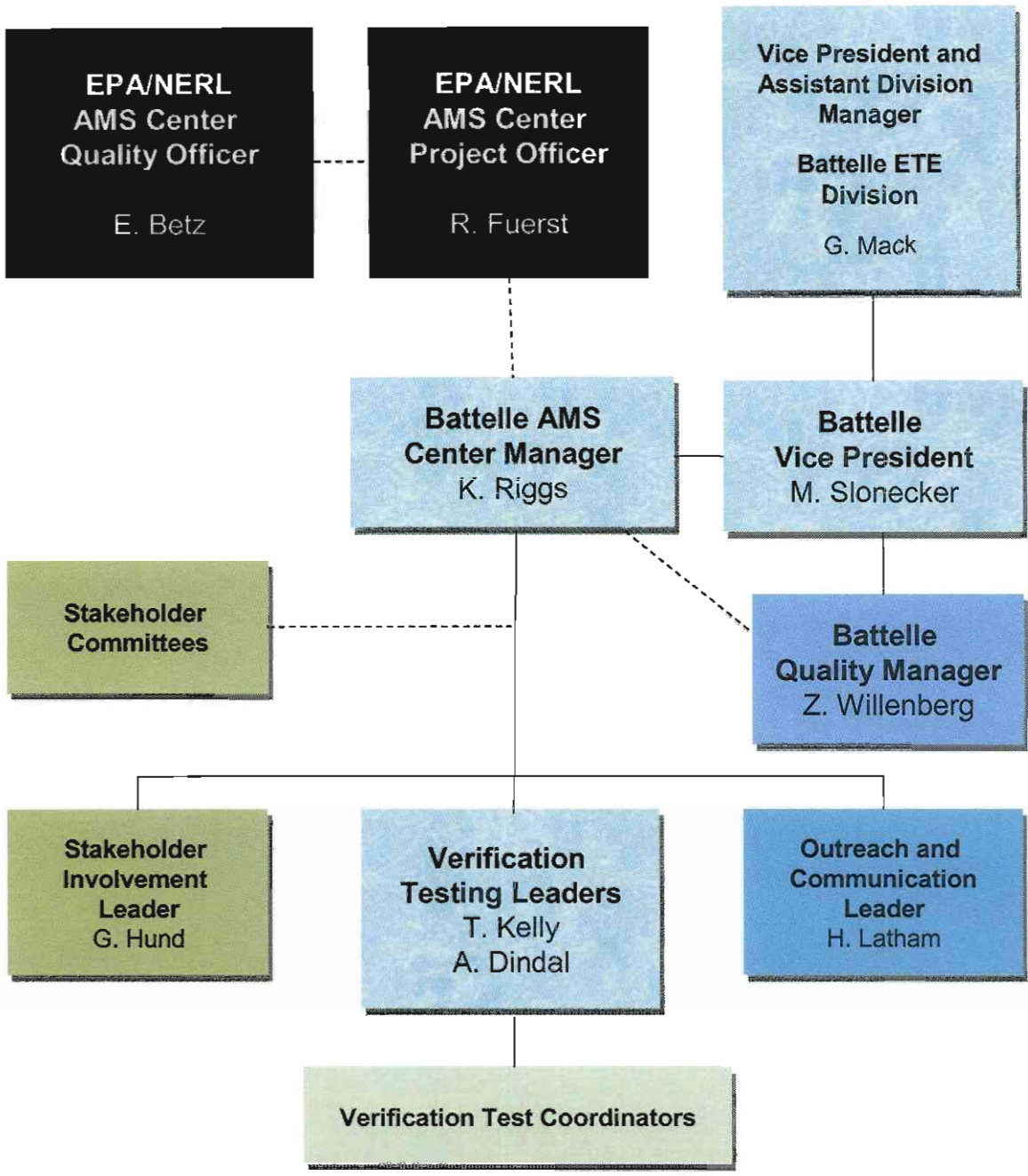


Figure 1.0 AMS Center Organization
(dotted lines indicate indirect reports)

communications, and meetings. Ms. Hund is a Staff Scientist at Battelle and reports directly to Ms. Riggs on the AMS Center.

Outreach and Communication Leader: Ms. Helen Latham leads outreach and communications activities on the AMS Center. Ms. Latham is a Senior Research Scientist at Battelle and reports directly to Ms. Riggs on her AMS Center activities.

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

1.5 DEFINITIONS

1.5.1 Verbs for clarity:

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

Should, will: 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 AMS Center.

Generic Verification Protocol - There are two different types for the AMS Center. First, the protocol developed to define the verification process for the AMS Center, and second, a generisized description of a verification test for a technology category.

Stakeholders - Representatives of verification customer groups including buyers and users of technology, consulting engineers, finance and export communities, and government (local, state, federal) permittees and regulators. Stakeholders are selected based upon their expertise and interest in environmental monitoring and their availability and willingness to participate in the AMS Center. A list of AMS Center Air and Water Stakeholder Committee members, addresses, and phone numbers are 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; this plan may include more than one technology. 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 the AMS Center Generic Verification Protocol and/or standard operating procedures (SOPs).

Vendor - An individual, company, or organization which submits an environmental monitoring technology for verification testing.

Verification Partner - 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 Partner 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 AMS Center, this is the AMS Center Manager.

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

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

Verification Statement - A summary statement developed by Battelle and approved by EPA, which reports quantitatively but **without** endorsement, the performance of a tested technology in a verification test. An example of an ETV verification statement is included in Appendix II.

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 AMS 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 AMS 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 AMS Center.
- That adequate personnel and resources are available to plan, implement, assess, and improve services and products relevant to the AMS Center.
- That staff is (are) clearly designated to stop unsafe work and work of inadequate quality as affects the AMS Center.

2.2 QUALITY SYSTEM AND DESCRIPTION

2.2.1 The Battelle quality system to be implemented for the AMS Center according to this QMP (and, historically, previous versions of this QMP) is intended to conform with the specifications listed in:

- ANSI/ASQC E4-1994, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs".
- EPA document "Environmental Technology Verification Program *Quality Management Plan*", Version 2.0, December 2002.
- 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 (ISO) 9000 series.

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

Individual verification tests will conform both to this QMP and to the applicable test/QA plan document(s) and applicable Standard Operating Procedures (SOPs).

The AMS 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 Quality Manager.

The QMP review will be documented by the Battelle Quality Manager and Battelle AMS 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 Quality Manager for review, approval, and distribution. The approved QMP has a scheduled review interval of one (1) year.

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 whom controlled copies are issued will be responsible for disposal of outdated QMP versions.

- 2.2.3 The scope of the AMS quality system applies to all Battelle personnel providing products and services for the AMS Center. All AMS 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 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 AMS Center Quality Officer (Ms. Elizabeth Betz). In addition, an independent technical systems audit will be performed by the EPA AMS Center Quality Officer or designee, at least one time per year for the AMS 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 December 2002, Battelle's responsibilities for the AMS 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 AMS 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 AMS Center quality systems are in compliance with the E4 standard and the EPA ETV QMP dated December 2002, and AMS Center staff complies with this QMP.

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 AMS Center QMP are listed in Table 1.0.

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

- Assist in development of the generic verification protocol
- Assist in prioritizing the types of technologies to be verified, focusing on these technologies with greatest environmental impact
- Review Center-specific procedures and AMS 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 AMS 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)
- Experience in sampling and analysis of air, water, and soil
- Training on standard analytical instrumentation such as gas chromatographs, mass spectrometers, Fourier transform infrared spectrometers, etc.
- Experience in designing experiments to verify the performance of monitoring technologies
- Experience with unique monitoring techniques such as immunoassay, fiber optics, etc.

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

AMS Center Team Member	Responsibilities
Battelle AMS Center Manager Karen Riggs	• Ultimate responsibility for all aspects of the AMS 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 Verification Testing Leaders Thomas Kelly and Amy Dindal	• Coordinate planning, performance, and data reviews of technology verification testing consistent with the AMS Center QMP requirements
	• Coordinate review of applications from technology vendors wanting to have their technology verified
	• Work with stakeholders and EPA to identify and prioritize technologies for verification
	• Schedule verification tests
	• Provide recommendations to the AMS Center Manager for verification teams to perform specific technology verification test/data reviews.
	• Develop and implement test/QA plans
	• Review and approve amendments and deviations to test/QA plans
	• Prepare, review, and/or approve verification reports
	• Prepare, review, and/or approve verification statements
	• Oversee/assist in problem resolution involving verification tests
Battelle Quality Manager Zachary Willenberg	• Ensure that the quality system is compliant with EPA-specified standards
	• Advise the Battelle AMS Center Manager of any QA/QC problems and oversee corrective actions
	• Ensure that the AMS Center QMP includes sufficient and appropriate specifications for QA/QC as required for the AMS Center
	• Interact with AMS Center management and technical personnel to ensure that QA/QC procedures are understood
	• Ensure that Battelle AMS Center QMP and the EPA/ETV QMP are followed for performing system inspections and audits
	• Perform a TSA and ADQ for every verification test
	• Participate in pre-test kick-off meetings to review QA requirements with verification testing staff
	• Review training records of verification testing staff
	• Notify the AMS 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 and returned to the Battelle Quality Manager. Problems that are not addressed will be brought to the attention of management
	• Review test/QA plans, SOPs, verification reports, and verification statements
	• Review and approve amendments and deviations to test/QA plans

Table 1.0 (continued)

AMS Center Team Member	Responsibilities
	<ul style="list-style-type: none"> • 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.
Battelle Verification Test Coordinators	<ul style="list-style-type: none"> • Provide technical support to verification testing as needed, and interact with the Battelle 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 the Verification Testing Leader of potential QC problems • Perform corrective action at the direction of AMS Center management and Battelle 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 • Prepare verification reports • Prepare verification statements

Battelle personnel working on the AMS 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 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 AMS 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 AMS Center
 - Work experience related to the technology category undergoing verification.

This information may be reviewed by the Battelle Quality Manager.

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 shall 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 Verification Testing Leader, Battelle AMS 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 the return of the item to the supplier. 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). 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.

2.5 DOCUMENTS AND RECORDS

2.5.1 Controlled Documents

Document control is the system which ensures that only the latest revision of the defined documents are used by Battelle staff participating in the AMS 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 AMS Center:

- Quality Management Plan for the ETV Advanced Monitoring Systems Center (this document)
- Standard Operating Procedures
- Test/QA plans, including amendments and deviations
- Generic Verification Protocols, for the AMS Center and technology specific.

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

As a controlled document, approved copies of the QMP will be maintained and issued to AMS Center staff by the Battelle 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 Quality Manager is authorized to remove outdated documents observed during inspections and reviews. All controlled documents, including historical revisions, will be retained at least seven years 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. Verification test records specific to the AMS Center shall be retained for at least seven years after final payment of the cooperative agreement. All AMS Center records needed to reconstruct test activities and verify that reported data were collected in a consistent manner with this QMP and AMS Center requirements will be maintained in an appropriate area of limited access, until either transferred to EPA Office of Research and Development (ORD) Records Management or properly destroyed with EPA permission. The Battelle Quality Manager will retain, as a permanent record, documentation of the transfer or destruction of Battelle's AMS Center records.

2.5.3 ETV Program Records

The following program records will be retained, as per ETV directives, for at least seven years after final payment of the cooperative agreement.

- Minutes of stakeholder meetings
- Cooperative agreement 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.

Table 2.0 Records Management Responsibilities for the AMS Center

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

NA = 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.

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

- ANSI/ASQC E4-1994, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs".
- EPA document "Environmental Technology Verification Program *Quality Management Plan*", Version 2.0, December 2002.
- 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 AMS Center Manager, Quality Manager, Verification Testing Leader, 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.

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

- AMS Center QMP
- Verification Protocols (both Center and technology-specific)
- 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 ensure 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.

2.6.1 Hardware

All computer hardware at Battelle contains Intel based Pentium processors running a Microsoft operating system. Each personal computer (PC) 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.

2.6.2 Software

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 AMS 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.

2.6.3 Validation Policy

Since all hardware and software used on the ETV AMS 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 XP, 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 the EPA AMS Center Project and Battelle. Individual stakeholders shall be selected for these committee(s) based on their expertise and interest in environmental monitoring and their availability and willingness to participate.

A joint meeting of the EPA AMS 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 AMS Center Project Officer, Battelle, and the ETV Webmaster.

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 AMS 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 for the Data Quality Objectives Process, August 2000). 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
- 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 which include revisions based on actual test experience.
- Prepare amendments and deviations to the test/QA plan, as necessary

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

- The ETV Program Policy Compendium

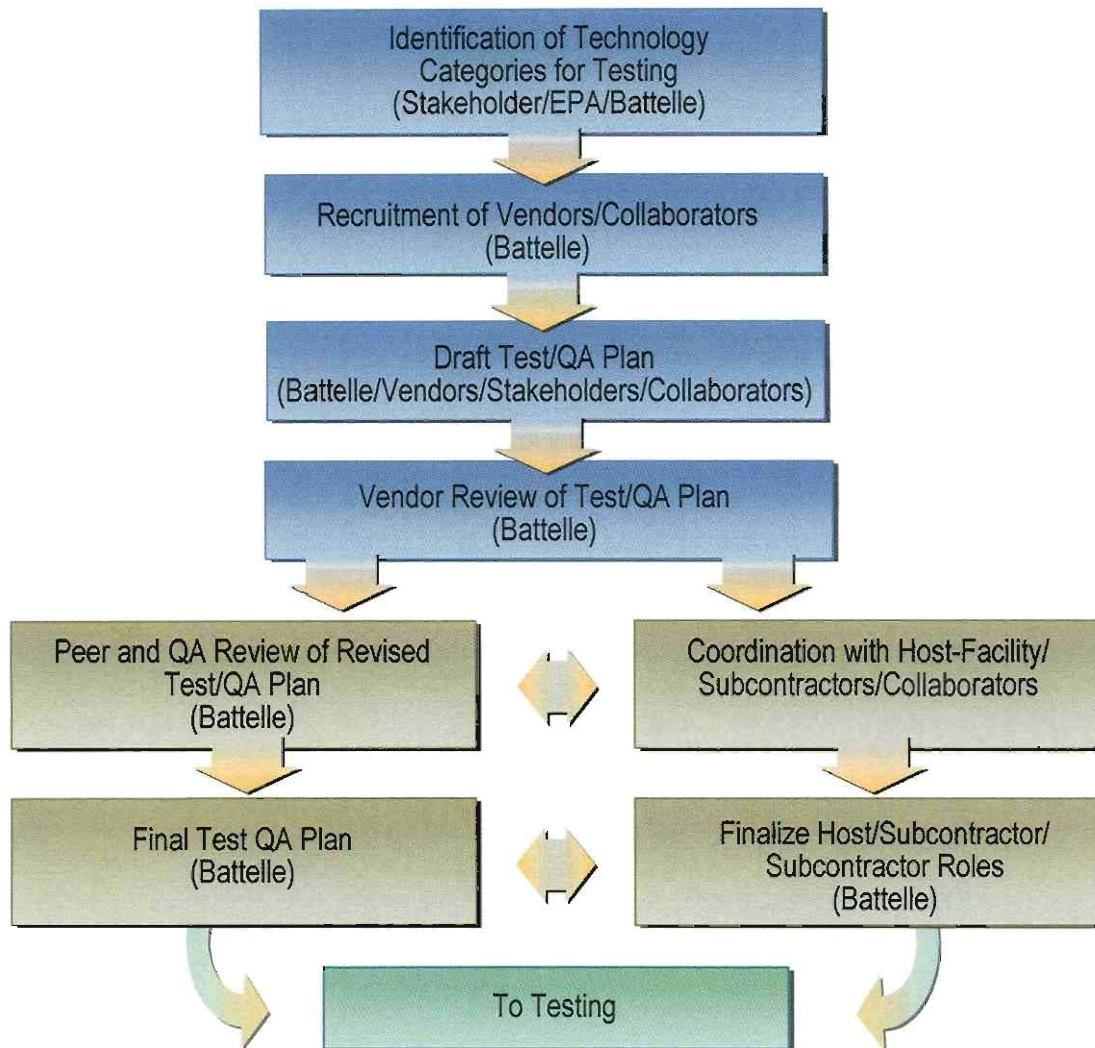


Figure 2 Systematic Planning of Verification Tests

- 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 AMS Center Manager, shall identify the planning roles of the participants, and shall conduct planning activities by shared communication via e-mail, teleconference, video conference, 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.

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 should 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 Protocol (Center and verification test specific), Test/QA Plans, and Standard Operating Procedures

Three types of planning documents have been identified for operation of an ETV Center: the generic verification protocol, the test/QA plan, and Standard Operating Procedures (SOPs). The generic verification protocol is meant to promote uniform testing for a single center, 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 AMS Center Manager will be responsible for assuring that the generic verification protocol is prepared and transferred to the EPA AMS Center Quality Officer and stakeholders for review. This addresses both the Center Generic Protocol as well as technology specific protocols. The issues that may be addressed in the generic verification protocol 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 AMS Center Manager and are reviewed by the Battelle Quality Manager and EPA AMS Center Quality Officer. The generic verification protocol 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 III. Elements of the test/QA plan may include the following. Elements listed that are not appropriate for the test will be listed as such:

- Group A: Project Management - This group of elements covers the general areas of project management, project history and objectives, and roles and responsibilities of the participants. The following nine elements ensure that the project's goals are clearly stated, that all participants understand the goals and the approach to be used, and that project planning is documented:
 - A1 Title and Approval Sheet
 - A2 Table of Contents and Document Control Format
 - A3 Distribution List
 - A4 Project/Task Organization and Schedule
 - A5 Problem Definition/Background
 - A6 Project/Task 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 project 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 project's objectives. This group of elements covers the QA activities that occur after the data collection phase of the project 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 follow topics, from EPA QA/G-6, *Guidance for Development of Standard Operating Procedures (SOPs)*, may be included (or a reference provided) in the standard operating procedure:

- 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. The kick-off meeting checklist is provided in Appendix IV. 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. 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 test/QA plan before the proposed change will be made. Amendments must be approved internally by the Battelle Verification Testing Leader, Battelle Quality Manager, and AMS Center Manager. Following approval, the amendment will be distributed to all internal personnel holding a copy of the parent test/QA plan and the EPA AMS Center Quality Officer. A deviation report is produced for any changes to the 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 III.

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 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 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 Quality Manager records. The EPA AMS Center Project Officer will be included in the routing of the inspection results and a written copy provided to both the EPA AMS Center Project Officer and EPA AMS Center Quality Officer.

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 AMS 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 AMS Center Manager, Verification Testing Leader, Battelle 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).
- 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 Routine monitoring (e.g. 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 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 AMS Center as shown in Table 3.0, and are defined as follows:

Quality Systems Audit, an on-site review of the implementation of the AMS Center quality system as documented in the AMS Center QMP. This review is used to verify the existence of, and evaluate the adequacy of, the internal quality system. A Quality Systems Audit (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 Quality Manager, or designee, conducts a TSA at least once during each verification test. The EPA AMS Center Quality Officer conducts an independent TSA once per year, as applicable, for the AMS Center.

Performance Evaluation Audits, a quantitative evaluation of a measurement system. The type and frequency of performance evaluation self-audits to be performed by the Battelle Verification Testing Leader or designee (and assessment of results by the Battelle Quality Manager) are 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 Quality Manager will review results of PE audits. The need for independent performance evaluation audits will be determined by the EPA AMS Center Quality Officer.

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

Table 3.0 Assessments for the AMS Center

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

3.2 GENERAL REQUIREMENTS

3.2.1 Each assessment must be fully documented. The Battelle Quality Manager will archive all internal assessment reports generated on the AMS 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 Verification Testing Leader and the Battelle AMS Center Manager. The assessment reporting forms are provided in Appendix V.

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 Verification Testing Leader and Battelle AMS Center Manager.

3.2.3 Implementation of corrective actions must be verified by the Battelle 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 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 AMS 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 will be discussed:

- Assessment plan format,
- 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),
- Assessment checklist consistent with requirements,
- Assessment report format,
- 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.

The kick-off meeting checklist is included in Appendix IV.

3.3.2 Personnel Qualifications for Assessment

The principal Battelle inspector shall be the Battelle 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 AMS Center assessment requirements. Should the need arise, the Battelle 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 Quality Manager is responsible for immediately notifying the Battelle Center Manager of the need to consider a stop work order. The Battelle AMS Center Manager shall then direct the AMS Center staff accordingly.

Should any AMS Center staff suspect compromise to personal health or test objectives during the conduct of verification testing, that staff member shall immediately contact the Battelle Verification Testing Leader, who shall through vested authority from the Battelle AMS Center Manager, issue the stop work order and subsequently notify the Battelle AMS Center Manager.

The EPA AMS Center Quality Officer is delegated to notify the EPA AMS Center Project Officer who will notify the Battelle AMS 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 AMS Center Project Officer and Quality Officer.

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 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 Quality Manager or designee. Once all corrective action associated with an assessment report has been taken, the Battelle 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 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.

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 AMS Center shall be conducted by the Battelle Quality Manager and technical and management staff in order to incorporate improvements to the quality system process.

Any revisions to the QMP will be compiled by the Battelle Quality Manager for review, approval, and distribution. The QMP review will be documented by the Battelle Quality Manager and Battelle AMS 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 AMS 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 Quality Manager. When problems are reported to the Battelle 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.

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 AMS 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 AMS Center Quality Officer, for example, may indicate trends or common and recurring problems for an entire technology evaluation. In this case, the situation is immediately communicated to the ETV Program Director, who then provides information and any corrective actions to the EPA AMS Center Project Officer.

Root cause determination is immediately reported by Battelle to the EPA AMS 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 AMS 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 monthly program reviews.

APPENDIX I

**NAMES, ADDRESSES, AND PHONE NUMBERS OF
BATTELLE AMS CENTER KEY STAFF**

KEY BATTELLE AMS CENTER STAFF

Battelle Center Manager:

Ms. Karen Riggs
505 King Avenue
Columbus, OH 43201
Phone: 614-424-7379
Fax: 614-424-3638
email: riggsk@battelle.org

Battelle Quality Manager:

Mr. Zachary J. Willenberg
505 King Avenue
Columbus, OH 43201
Phone: 614-424-5795
Fax: 614-424-3638
email: willenbergz@battelle.org

Verification Testing Leaders:

Dr. Thomas J. Kelly
505 King Avenue
Columbus, OH 43201
Phone: 614-424-3495
Fax: 614-424-3638
email: kellyt@battelle.org

Ms. Amy Dindal
1801 Waldorf Dr.
Royal Palm Beach, FL 33411
Phone: 561-422-0113
Fax: 561-258-0777
email: dindala@battelle.org

Stakeholder Involvement Leader:

Ms. Gretchen Hund
Battelle
P.O. Box 5395 S-1-48
Seattle, WA 98105-5428
Phone: 206-528-3338
Fax: 206-528-3552
email: hund@battelle.org

Outreach and Communication Leader:

Ms. Helen Latham
505 King Avenue
Columbus, OH 43201
Phone: 614-424-4062
Fax: 614-424-5601
email: lathamh@battelle.org

APPENDIX II

ETV VERIFICATION STATEMENT

THE ENVIRONMENTAL TECHNOLOGY VERIFICATION
PROGRAM



ETV Joint Verification Statement

TECHNOLOGY TYPE: Atrazine Test Kit

APPLICATION: ANALYSIS OF ATRAZINE IN WATER

TECHNOLOGY NAME: Atrazine ELISA Kit

COMPANY: Abraxis LLC

ADDRESS: 54 Steamwhistle Drive **PHONE:** (215) 357-3911
Warminster, PA 18974 **FAX:** (215) 357-5232

WEB SITE: www.abraxiskits.com

EMAIL: info@abraxiskits.com

The U.S. Environmental Protection Agency (EPA) has created the Environmental Technology Verification (ETV) Program to facilitate the deployment of innovative or improved environmental technologies through performance verification and dissemination of information. The goal of the ETV Program is to further environmental protection by accelerating the acceptance and use of improved and cost-effective technologies. ETV seeks to achieve this goal by providing high-quality, peer-reviewed data on technology performance to those involved in the design, distribution, financing, permitting, purchase, and use of environmental technologies. Information and ETV documents are available at www.epa.gov/etv.

ETV works in partnership with recognized standards and testing organizations; with stakeholder groups that consist of buyers, vendor organizations, and permittees; and with the full participation of individual technology developers. The program evaluates the performance of innovative technologies by developing test plans that are responsive to the needs of stakeholders, conducting field or laboratory tests (as appropriate), collecting and analyzing data, and preparing peer-reviewed reports. All evaluations are conducted in accordance with rigorous quality assurance (QA) protocols to ensure that data of known and adequate quality are generated and that the results are defensible.

The Advanced Monitoring Systems (AMS) Center, one of seven technology areas under ETV, is operated by Battelle in cooperation with EPA's National Exposure Research Laboratory. The AMS Center recently evaluated the performance of test kits for the analysis of atrazine in water. This verification statement provides a summary of the test results for the Abraxis LLC Atrazine ELISA Kit for measuring atrazine.

VERIFICATION TEST DESCRIPTION

The Atrazine ELISA Kit was verified in terms of its performance on the following parameters: accuracy, precision, linearity, method detection limit (MDL), cross-reactivity of hydroxylatrazine and desethyl atrazine, matrix interference effects, and rate of false positives/false negatives. Qualitative factors including ease of use, reliability, and sample throughput were also evaluated. All preparation and analyses were performed according to the manufacturer's recommended procedures. The verification test involved challenging the Atrazine ELISA Kit with seven performance test (PT) samples and four types of environmental samples. The PT samples consisted of ASTM

Type I water samples fortified with atrazine or an atrazine degradation product. Five of the PT samples contained atrazine at concentrations ranging from 0.1 to 5 parts per billion (ppb), and two of the PT samples contained 3 ppb of a cross-reactive compound, but no atrazine. Four types of environmental samples also were analyzed: fresh pond water, brackish pond water, groundwater, and chlorinated drinking water. Environmental samples were filtered prior to test kit analysis. The background atrazine concentration in each environmental sample was less than 0.062 ppb. Each environmental sample was fortified in the laboratory at concentrations of 1 ppb and 3 ppb atrazine. All laboratory-fortified samples were prepared using certified, commercially available standards. All samples were analyzed by the Atrazine ELISA Kit and by gas chromatography/mass spectrometry (GC/MS) according to modified EPA Method 525.2. Each sample was analyzed in triplicate using the test kit (seven replicates of the MDL sample were analyzed). Samples were given to the analyst blind and in random order.

The verification test was conducted in September 2003 at the Battelle laboratory in Duxbury, Massachusetts. Environmental samples were provided by the National Oceanic and Atmospheric Administration, National Ocean Service's Center for Coastal Environmental Health and Biomolecular Research Center at Charleston, and the University of Missouri - Rolla. Reference laboratory analyses were provided by the EPA's Office of Pesticide Programs, Environmental Chemistry Branch at the John C. Stennis Space Center. Test kit analyses were conducted by the Texas Commission on Environmental Quality.

The Atrazine ELISA Kit and reference method results were used to assess accuracy and linearity. Replicate sample results were used to assess precision. Results for replicates of a low-level spiked sample were used to evaluate the MDL. Cross-reactivity of hydroxyatrazine and desethyl atrazine were assessed by evaluating the Atrazine ELISA Kit results for samples that contained only one degradation compound, but not atrazine. Potential matrix effects were assessed by comparing accuracy and precision results for environmental samples (i.e., chlorinated drinking water, fresh surface water, brackish surface water, and groundwater) to those for ASTM Type I water samples. Performance parameters, such as ease of use and reliability, were based on documented observations of the analyst. Sample throughput was estimated based on the time required to analyze a sample set. QA oversight of verification testing was provided by Battelle and EPA. Battelle QA staff conducted a data quality audit of 10% of the test data, a performance evaluation audit, and a technical systems audit of the procedures used in this verification. This verification statement, the full report on which it is based, and the test/QA plan for this verification are all available at www.epa.gov/etv/centers/center1.html.

TECHNOLOGY DESCRIPTION

The following description of the Atrazine ELISA Kit is based on information provided by the vendor. This information was not verified in this test. The Atrazine ELISA Kit applies the principle of enzyme-linked immunosorbent assay (ELISA) to determine atrazine in water samples. The Atrazine ELISA Kit uses a colorimetric procedure to detect atrazine. A sample and an enzyme conjugate are added to a disposable test tube, followed by atrazine antibodies attached covalently to paramagnetic particles. Any atrazine that may be in the sample competes with the atrazine enzyme label conjugate for a finite number of antibody binding sites. At the end of a 15-minute incubation period, a magnetic field is applied; and atrazine and labeled-atrazine bind to the antibodies on the paramagnetic particles in proportion to their original concentration. Unbound reagents are decanted. After decanting, the particles are washed with a washing solution. A substrate is added and enzymatically converted from a colorless to a blue solution until terminated by acidification. The atrazine concentration is determined by measuring the absorbance of the sample solution with a photometer and comparing it to the absorbance of the standards. The calibration range of the test kit is 0.1 ppb to 5 ppb atrazine. The vendor-stated detection limit of the test kit is 0.05 ppb atrazine.

The Atrazine ELISA Kit contains a vial of atrazine antibody (rabbit anti-atrazine covalently bound to paramagnetic particles suspended in a buffered solution with preservative and stabilizers), a vial of horseradish peroxidase-labeled atrazine analog diluted in a buffered solution with preservative and stabilizers, three vials of atrazine standard concentrations with preservative and stabilizers, a vial of concentrated atrazine (3 ± 0.6 parts per billion [ppb]) with preservative and stabilizers, a vial of an atrazine-free solution with preservative and stabilizers for use as a zero standard, a vial of a hydrogen peroxide and 3,3',5,5'-tetramethylbenzidine solution in an organic base, a vial of diluted acid, a vial of preserved deionized water,

and five bags of 22 polystyrene tubes. The Atrazine ELISA Kit is 14 by 6-¼ by 3-½ inches. Final results and calibration curves are printed out on the photometric analyzer or sent directly to a lab computer. List price is \$350 for a 100-test kit. Other materials that are required but are not provided with the Atrazine ELISA Kit are pipettes, a vortex mixer, a magnetic separation system, and a photometer capable of readings at 450 nanometers (nm). These materials can be purchased separately or rented.

VERIFICATION OF PERFORMANCE

Quantitative performance results for all parameters except ease of use, reliability, and sample throughput are summarized in the following table:

Parameter	Performance Results	Comments
Accuracy (percent recovery) PT samples, 0.1 – 5 ppb atrazine Environmental samples: 1 ppb and 3 ppb atrazine-fortified, respectively: Fresh pond water Brackish pond water Groundwater Chlorinated drinking water	102% to 127%; average 120% 130% and 102% 110% and 107% 111% and 100% 140% and 122%	Background atrazine concentrations in all environmental samples were <0.062 ppb.
Precision (relative standard deviation) PT samples, 0.1 – 5 ppb atrazine and cross-reactivity samples Environmental samples: 1 ppb and 3 ppb atrazine-fortified, respectively: Fresh pond water Brackish pond water Groundwater Chlorinated drinking water	6.9% to 24.1%; average 13% 3.5% and 10.6% 15.2% and 7.1% 7.7% and 8.3% 3.7% and 11.1%	
Linearity Slope of regression equation y-intercept Correlation coefficient (r)	1.23 -0.025 0.9937	Results for PT samples from 0.1 ppb to 5 ppb atrazine used to assess linearity.
MDL	0.06 ppb atrazine	Based on analysis of 0.1 ppb atrazine spiked into ASTM Type I water sample (seven replicates).
Cross-reactivity 3 ppb hydroxyatrazine 3 ppb desethyl atrazine	Average result 0.06 ppb atrazine Average result 0.25 ppb atrazine	Cross-reactivity samples did not contain atrazine.
Matrix interference effects	No apparent interferences from matrices tested	
False positive results	4 out of 38 results	Evaluated relative to 0.1 ppb atrazine (lowest calibration standard). Three of the four false positive results associated with a sample containing an atrazine degradation product.
False negative results	None	Evaluated relative to 0.1 ppb atrazine (lowest calibration standard). Three of these results associated with a sample containing an atrazine degradation product.

APPENDIX III
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 Verification Testing Leader

Battelle Quality Manager

DATE

DATE

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

- Battelle AMS Center Management**
- Battelle AMS Center Testing Staff**
- Battelle AMS Center Quality Manager**
- Subcontractors (if any)**
- Verification Test Collaborators (if any)**
- EPA/ETV AMS Center Project Officer**
- EPA/ETV Quality Staff**
- 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 Verification Testing Leader

Battelle Quality Manager

DATE

DATE

Required Distribution - All individuals/organizations listed below:

Battelle AMS Center Management

Battelle AMS Center Quality Manager

Distribution must be documented

APPENDIX IV

ETV KICK-OFF MEETING CHECKLIST

ETV VERIFICATION TEST KICK-OFF MEETING

PURPOSE

To prepare verification testing staff for an upcoming test and review critical logistical, technical, and administrative aspects of the test.

STAFF TO ATTEND

- Verification test coordinator
- Verification testing leader
- ETV program manager
- QA manager(s)
- All testing staff involved in all phases of test (need to have kick-off meeting on-site with staff from partnering organizations/subcontractor if necessary)

TIMING AND LENGTH

- The kick-off meeting should be scheduled prior to the start of testing. It should be near the start of the test but allow time for the test coordinator to address any lingering issues.
- A tentative date/time should be set for the kick-off meeting a month in advance of the start of the test, if possible, to allow the meeting to be scheduled when the critical staff mentioned above are all available.
- It may be necessary to schedule a second kick-off meeting for tests that are conducted at multiple locations if all staff cannot attend the original meeting.

PROJECT MANAGEMENT

- Review roles/responsibilities of all staff attending meeting
- Work authorization distributed to all staff?
- All staff have project number and subaccount number(s)?
- All testing staff have budget for their time on each subaccount involved?
- Stakeholders, EPA/ETV program manager, and EPA/QA staff pre-notified of testing schedule and start date?
- Review test schedule
- Formal distribution of final, signed hard-copy test/QA plan made to all Battelle staff, subcontractor (if any), vendors, and EPA?
- Documentation: All pertinent forms should be signed, copied for Karen, and brought to the meeting.
 - Peer review forms on test/QA plan. Must include one EPA reviewer/two non-EPA peer reviewers.
 - Final test/QA plan signed by all vendors? Where are original signature pages stored? All staff attending meeting should be told to bring their copy of test/QA plan to kick-off meeting prior to meeting or final test/QA plan should be distributed at meeting.

- All vendor agreements signed/checks received/copies sent to Karen for project files?
- If Battelle, partner, or subcontractor staff is operating technology, has vendor trained those staff in operating the technology and signed formal training form certifying training and vendor's acceptance of Battelle generated results? Where is original signed form located/filed?
- Subcontractors (if used)
 - Subcontract fully signed? Provide copy to Karen for project files.
 - Due dates well defined in subcontract?
 - Get test data from subcontractor/partner real time or at close of test
- Has a pdf file been generated of the final test/QA plan and has it been sent to the ETV web master?

QUALITY ASSURANCE

- Are annual training records of all testing staff on file and up-to-date? Training memo in place for temporary staff? Do the training records adequately reflect the abilities of the staff involved for the tasks involved with this verification testing (e.g., reference sampling or reference sample analysis)?
- Copies of all standard methods cited in test/QA plan available to testing staff and in laboratory where test will be performed?
- EPA QA staff pre-notified of test start date and external technical systems audit planned/coordinated? When is external TSA scheduled? Who will perform? Who has been coordinating with EPA/QA staff? Remind testing staff to not offer information during external TSA.
- When is internal TSA scheduled? Who will perform?
- Remind testing staff to sign and date everything
- If samples are to be transported between labs, or between Battelle/partner/subcontractor, bring chain-of-custody form to meeting, review how to complete, and where to obtain form
- Review deviation/amendment procedures at meeting – what to do in the middle of a test if test/QA plan cannot be followed – who to notify/what forms to file
- Review test/QA plan at meeting – identify key testing procedures and critical steps to ensure no ambiguity or questions
- Are or will there be copies of the certificates of analysis in the verification test binder?
- When will PE audit be performed? Who will perform? Has materials/equipment been purchased or obtained for the PE audit? What are QC limits? What to do if QC limits are not met? Who to contact?
- If testing is being performed off-site, will regular communication with the staff at the test site be maintained? If so, how?

TECHNICAL

- Emphasize to testing staff to document anything and everything that is observed about the technologies, particularly if there are unusual sample results (e.g., sample color).
- Will the samples be blind and randomly distributed to the operators?
- Are provisions made to handle daily preparation of solutions/standards, if necessary?
- Take digital photos of all test activities.

DATA/REPORTING

- Review data recording forms or sheets at meeting or discuss how/where will data be recorded for each testing activity
- How are data going to be converted electronically? Are data saved in technology undergoing verification and then exported to Excel? Or will data be recorded manually by the operators? If so, how will transcription errors be avoided?
- Data review – who will be doing two week review for each data set collected? If Battelle staff not on-site, how will data be transmitted to Battelle for two-week review?
- Who is Battelle verification report author? Distribute and review report schedule. Reporting should begin at the same time as testing.
- Has the test/QA plan been sent to Bea/PMP for report template generation?

APPENDIX V

ETV ASSESSMENT REPORTING FORMS

Quality Assurance Routing Sheet

ETV Program

Verification Test:

Audit Type:

Test Coordinator:

Vendor:

Auditor: Battelle Quality Manager

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 Quality Manager no later than _____.

<i>Route To</i>	<i>Signature</i>	<i>Date</i>
<u>Test Coordinator</u>	_____	_____
<u>Battelle Quality Manager</u>	_____	_____
 <i>Approval</i>		
<u>Testing Leader</u>	_____	_____
<u>AMS Center Manager</u>	_____	_____
<u>Battelle Quality Manager</u>	_____	_____
_____	_____	_____

Verification Test Designation:

Page ___ of ___

QA Auditor: Z. Willenberg

Audit Type:

Audit Date:

Audit Comment Sheet

Instructions: The Battelle Quality Manager will fill out the first column for the audit indicated above. The Verification Testing Leader (or assigned responder such as the Verification Testing Coordinator) will respond to the comments and initial and date the response in column three. The Battelle Quality Manager will verify and document that the response/corrective action has been completed by initialing and dating the final column.

QA Comment	Testing Leader/Coordinator Response/Corrective Actions	Responder Initials/ Date	QA Initials/ Date