EPA Report No: 600/R-08/009
January 2008

# ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM QUALITY MANAGEMENT PLAN

National Risk Management Research Laboratory
National Exposure Research Laboratory
Office of Research and Development
U.S. Environmental Protection Agency
Cincinnati, Ohio 45268

**US Environmental Protection Agency**
**Environmental Technology Verification Program**
**QUALITY MANAGEMENT PLAN**

**Approvals***

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## ACKNOWLEDGMENTS

The first draft of the ETV QMP was developed for the pilot period (1995–2000) by a team of writers consisting of the following quality assurance staff members from the U.S. Environmental Protection Agency Office of Research and Development National Risk Management Research Laboratory and National Exposure Research Laboratory: Sam Hayes, Lora Johnson, Ann Vega, and Jeff Worthington. Subsequent revisions included significant input in the form of comments from members of the Environmental Technology Verification Team. Verification organizations also provided comments. The team of writers was joined by the following EPA staff in development of the final document: Nancy Adams, Penelope Hansen, Linda Porter, and Shirley Wasson.

The first revision was completed in 2002 and reflected the conversion of the pilot projects to ETV centers targeted to broader classes of technologies was developed by Shirley Wasson, Teresa Harten, and Nancy Adams with input from the team.

The second revision was completed in 2007 and addressed the inclusion of ESTE projects in the ETV program, delegation of QA review responsibilities to verification organizations, and revision of the existing data policy. It was prepared by Robert Wright, Evelyn Hartzell, and Teresa Harten with input from the ETV team and the verification organizations

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# DOCUMENTS AND GENERAL TERMS

**Annual ETV progress report**

The report developed on an annual basis to report implementation of the ETV program.

**ANSI/ASQC E4-1994**

*American National Standard: Specifications and Guidance for Quality Systems for Environmental Data Collection and Environmental Technology Programs* is the national consensus standard for quality management systems for environmental programs, is the Agency standard, and is applicable to extramural agreements.

**ANSI/ASQC E4-2004**,

*Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.* Replaces the ANSI/ASQC E4-1994. More compatible with ISO 9000

**Assessment**

The evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: quality systems audit, technical systems audit, and audit of data quality. Guidance may be found at www.epa.gov/quality/qa_docs.html.

**Audit of data quality**

An examination of a set of data after it has been collected and 100% verified by project personnel, consisting of tracing at least 10% of the test data from original recording through transferring, calculating, summarizing and reporting. (Note: "10% of the test data" means a random selection of 10% of the data from all of the measured parameters.) It is documented in a data audit report. The goal is to determine the usability of test results, as defined during the design process. Guidance may be found at www.epa.gov/quality/qa_docs.html.

**Certify**

To guarantee a technology as meeting a standard or performance criteria into the future. Synonyms are ensure, warrant, and guarantee. ETV does not certify technologies.

**Data quality indicators**

Quantitative and qualitative measures of principal quality attributes including precision, accuracy, representativeness, comparability, completeness and sensitivity. One way to employ DQIs is as a means of specifying quality goals or criteria which, if achieved, will provide an indication that the resulting data are expected to meet DQOs. Used in this way, DQIs provide a metric against which the performance of a program can be measured during the implementation and/or assessment phases of a verification test.

**Data quality objectives**

The qualitative and quantitative statements derived from the DQO process that clarify a study's technical and quality objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions. Guidance may be found at www.epa.gov/quality/qa_docs.html.

**Document**

An instruction, specification, or plan containing information on how the ETV program functions, how specific tasks are to be performed, or how specific products or services are to be provided. Examples of documents include the ETV QMP, the center/project QMPs, GVPs, and test/QA plans.

**DQO process**

A systematic planning process that clarifies test objectives and establishes a basis for the types, quality, and quantity of data required to support customers' decisions for use of a technology. It provides a method for establishing DQOs for an individual technology verification test. Guidance may be found at www.epa.gov/quality/qa_docs.html.

**Environmental and Sustainable Technology Evaluations**

An ETV program element that expands ETV's ability to respond directly to EPA's need for credible performance information on innovative and commercial-ready technologies with potential to address high-risk environmental problems. It continues to maintain the quality assurance, cost-sharing, and stakeholder involvement that are fundamental operating principles of ETV. Under ESTE, the prioritized categories for verification are chosen by the EPA Office of Research and Development (ORD) with program office and/or regional office support. Project managers from ORD will direct the verifications using contractor support. All environmental technology categories are considered under ESTE, with the exception of remediation technologies which are covered under the EPA Superfund Innovative Technology Evaluation (SITE) Program.

**Environmental data**

Any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

**Environmental technology**

An all-inclusive term that is used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be used to remove pollutants or contaminants from, or to prevent them from entering, the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term applies

to hardware-based systems; however, it can also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

**Environmental Technology Verification**
This EPA program develops generic verification protocols and verifies the performance of innovative environmental technologies that have the potential to improve protection of human health and the environment. It was created to accelerate the entrance of new environmental technologies into the domestic and international marketplace. It also verifies monitoring and treatment technologies relevant for water security.

**EPA directors of quality assurance**
QA directors for the EPA ORD laboratories, the National Exposure Research Laboratory and the National Risk Management Research Laboratory

**EPA quality managers**
The EPA QA employees who are designated by EPA line management to manage QA efforts on behalf of the ETV center project officer or ESTE project manager. This is usually the Division's QA Manager.

**EPA line management**
The management structure (i.e., branch chief, division director, and laboratory director) to whom each ETV center project officer or ESTE project manager reports.

**EPA review/audit reports**
The quality records that are developed by EPA as a result of conducting assessments during ETV implementation.

**ESTE project**
An environmental technology verification that is initiated by an ORD researcher, collaborating with program office or regional office partners under the ESTE effort.

**ESTE project manager**
The EPA employee who is designated by EPA line management to serve as the lead for an individual ESTE project.

**ETV centers**
The different organizations that falls under the Environmental Technology Verification (ETV) Program which are in charge of verifying the performance of innovative technologies that have the potential to improve protection of human health and the environment. The centers, under the lead of an ETV center project officer from EPA, work with the verification organizations. ETV currently operates five ETV centers that test and evaluate the performance of environmental technology in all environmental media—air, water, and land

**ETV center project officer**
The EPA employee who is designated by EPA line management to serve as the lead for an individual ETV center.

**ETV coordination staff**
The EPA employees who work directly with the ETV director to coordinate and implement outreach and evaluation activities at the program level.

**ETV extramural agreement**
The contractual record that is developed by the EPA and signed by the verification organization.

**ETV director**
The EPA employee who is designated by EPA ORD to lead the ETV team.

**ETV team**
EPA employees actively working on the ETV program; the ETV director, ETV coordination staff, ETV center project officers, ESTE project managers, EPA directors of quality assurance (currently these are the NRMRL and NERL Directors of Quality Assurance), and the EPA quality managers are core members.

**ETV test objective**
The stated objective(s) of each test. Verification organizations use the DQO process or systematic planning to establish test objectives and test measurement quality criteria.

**ETV verification**
A verification test that is performed only by the EPA ETV program.

**ETV verification report**
The report of the result of an individual verification test and/or accepted existing data.

**ETV verification statement**
A summary statement, developed by the verification organization and approved by the EPA laboratory director, which reports individual technology performance.

**ETV webmaster**
The person designated by EPA line management with responsibility for establishing and maintaining the ETV website.

**Evaluate**
To carefully examine and judge the efficacy of a technology; to submit technologies for testing under conditions of observation and analysis. Synonyms are measure, estimate, and classify, test. ETV does evaluate technologies.

**Existing data**

Existing data are data or information that you plan to use that have not been newly generated by your project. They may also be known as secondary data or non-direct measurement.

**Generic verification protocol**

(Also known as guideline document, generic test protocol, or protocol). This document is developed, modified, or selected to promote uniform testing procedures by the verification organization for a single class of technologies. Adequate documentation of a robust GVP may allow the development of abbreviated individual test/QA plans which incorporate the GVP by reference. GVPs may retain draft status until verification testing is performed, then finalized, building upon the testing experience.

**Independent assessment**

An assessment performed by a qualified individual, group, or organization that is not part of the organization directly performing and accountable for the work being assessed.

**Internal assessment**

An assessment of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

**Laboratory director**

The directors of EPA ORD laboratories, the National Exposure Research Laboratory and the National Risk Management Research Laboratory.

**Metadata**

A type of data that describes and defines other data, but what makes it different from ordinary data is how it is used. It refers to data that are used to describe a data set, such as the content, quality, and condition of data. It is the information that answers questions like: Who owns the data? How was the data collected? How current is the data? It is a set of facts about data and other information elements. It is everything except for the data itself.

**Office of Research and Development Assistant Administrator**

The administrative employee who directs EPA's Office of Research & Development.

**Peer review**

A documented critical review, which is conducted by qualified individuals (or organizations) who are independent of those who performed the work but who are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. A peer review is conducted to ensure that activities are technically adequate, competently performed, and properly documented and that they satisfy established quality requirements. It is an in-depth assessment of the assumptions, calculations, extrapolations, alternative interpretations, methodology, acceptance criteria, and conclusions pertaining to the specific major scientific and/or technical work product and of the documentation that supports them.

**Performance evaluation audit**
A quantitative evaluation of a measurement system, usually involves the measurement or analysis of a reference material of known value or composition.

**Program support contractor**
The contractor selected to assist with the generation of the annual report.

**Quality assurance**
An integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality that is needed and expected.

**Quality control**
The system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet stated requirements; operational techniques and activities that are used to fulfill requirements for quality.

**Quality management plan**
The specific policies and procedures that have been established for managing quality-related activities in the ETV program. It is the "blueprint" that defines an organization's QA policies and procedures; the criteria for and areas of QA application; and the different QA-related roles, responsibilities, and authorities of personnel.

**Quality system**
A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. It provides the framework for planning, implementing, documenting, and assessing work performed by the organization and for carrying out required QA and QC activities.

**Quality system audit**
An on-site review of the implementation of a verification organization's quality system as documented in the approved QMP. This review is used to verify the existence of, and evaluate the adequacy of, the internal quality system. It is the qualitative assessment of data collection operations and/or organization(s) to evaluate the adequacy of the prevailing quality management structure, policies, practices, and procedures for obtaining the type and quality of data needed. Guidance may be found at www.epa.gov/quality/qa_docs.html.

**Raw data**
All data and information recorded in support of analytical and process measurements made during planning, testing, and assessing environmental technology including records such as: computer printouts, instrument run charts, standards preparation records, field log records, technology operation logs, and monitoring records. ETV test files (all records including raw data) and technical data and associated quality control data which support the data that are summarized and the conclusions that are made in each ETV verification report.

**Record**

A statement of data and facts pertaining to a specific event, process, or product, that provides objective evidence that an activity has occurred. All books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by the EPA or a verification organization or their designated representative for the ETV program are records. Examples include verification statements and reports, raw and summary data tables, data notebooks, audit reports, and stakeholder meeting minutes.

**Stakeholder groups**

Groups set up for each ETV center and ESTE project consisting of representatives of any or all of the following groups: buyers and users of technology, technology developers/vendors, the consulting engineers, the finance and export communities, government permitters, regulators, first responders, emergency response, disaster planners, public interest groups, and other groups interested in the performance of innovative environmental technologies.

**Standard operating procedures**

Procedures describing routine verification activities including sample collection, analytical testing, and associated verification processes.

**Technical systems audit**

A qualitative on-site evaluation of sampling and/or measurement systems. The objective of the TSA is to assess and document acceptability of all facilities, maintenance, calibration procedures, reporting requirements, sampling and analytical activities, and quality control procedures. An approved test/QA plan provides the basis for the TSA. Guidance may be found at www.epa.gov/quality/qa_docs.html.

**Test measurement**

Those critical measurements that must be made during the course of a verification test to evaluate achievement of the ETV test objective.

**Test/QA plan**

The plan developed by a verification organization for each individual test of a technology *or technology class*. Therefore, the test/QA 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. The test/QA plan may incorporate or reference existing GVPs or provide the basis for refining draft GVPs. Guidance may be found at www.epa.gov/quality/qa_docs.html.

**Verification (data verification)**

The process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual requirements. Guidance may be found at www.epa.gov/quality/qa_docs.html.

**Verification (ETV verification)**
Establishing or proving the truth of the performance of a technology under specific, predetermined criteria, test/QA plans or GVPs, and adequate data QA procedures.

**Verification organizations**
The public and private sector organizations holding cooperative or interagency agreements or contracts to assist EPA in implementing the ETV program.

**Verification organization manager**
The person designated by the verification organization to manage the ETV center and ESTE project and serve as the chief point of contact with the EPA.

**Verification organization quality manager**
The person designated by the verification organization to manage QA for the ETV center and ESTE project on behalf of the verification organization manager.

**Verification organization quality management plan**
The documented procedures for quality-related activities developed and implemented by the verification organization to assure quality in the work processes and services developed for ETV. If the verification organization has a current quality system that conforms to EPA quality requirements, additional quality system elements do not need to be developed.

**Verification report**
Contains the technology description, how the tests were conducted, performance verification test results, statistics and summary. The report is developed for each verified technology.

**Verification statement**
A statement signed by the EPA laboratory director and the VO manager. The statement contains the summary (2 to 7 pages) of the test results for a given environmental technology.

**Verification test**
The simultaneous performance evaluation of one or more similar environmental technologies that is documented in a single test/QA plan and in one or more verification statements and verification reports. Multiple verification tests, each with its own test/QA plan, may be conducted at different times under a single GVP.

**Verify**
To establish or prove the truth of the performance of a technology under specific, predetermined criteria or protocols and adequate data quality assurance procedures. Synonyms are confirm, corroborate, substantiate, and validate. ETV does verify technologies.

# ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| ACE | any credible evidence |
| ADQ | audit of data quality |
| ANSI | American National Standards Institute |
| ASQ | American Society for Quality |
| CA | cooperative agreements |
| CMD | Contracts Management Division |
| DEP | data evaluation panel |
| DQO | data quality objective |
| EPA | U. S. Environmental Protection Agency |
| ESTE | Environmental and Sustainable Technologies Evaluation |
| ETV | environmental technology verification |
| FBO | FedBizOpps (formerly Commerce Business Daily) |
| FRC | Federal Records Center |
| FTE | full time equivalent |
| GAD | Grants Administration Division |
| GVP | generic verification protocol |
| IAG | interagency agreement |
| IGE | independent government estimate |
| IQGs | Information Quality Guidelines |
| ISO | International Organization for Standardization |
| NERL | ORD's National Exposure Research Laboratory |
| NRMP | National Records Management Program |
| NRMRL | ORD's National Risk Management Research Laboratory |
| OAQPS | EPA's Office of Air Quality Planning and Standards |
| OMIS | ORD's Management Information System |
| ORD | EPA's Office of Research and Development |
| OSHA | Occupational Safety and Health Administration |
| PEA | performance evaluation audit |
| PARS | EPA’s Performance Appraisal and Recognition System |
| PO | project officer |
| QA | quality assurance |
| QAPP | quality assurance project plan |
| QSA | quality systems audit |
| QC | quality control |
| QMP | quality management plan |
| SOP | standard operating procedure |
| SOW | statement of work |
| TSA | technical systems audi**t** |

# INTRODUCTION

Background

The Environmental Technology Verification Program (ETV) was established by the U.S. Environmental Protection Agency (EPA) to evaluate the performance characteristics of innovative environmental technologies across all media and to report objective performance information to the permitters, buyers, and users of environmental technology. ETV evolved in response to the following mandates:

- a 1995 Presidential directive to EPA in B*ridge to a Sustainable Future - National Environmental Technology Strategy*, to "work with the private sector to establish a market-based verification process . . . which will be available nationally for all environmental technologies within three years."
- goals articulated in the Administration's *Reinventing Government; A Performance Review* which directed EPA to begin a comprehensive environmental technology verification program no later than October 1995.
- Congressional appropriation language, contained in the FY96 and FY97 budgets, that the Agency fund technology verification activities at the $10 million level in each year.

To comply with these directives, EPA's Office of Research and Development (ORD) established a five-year pilot program to evaluate alternative operating parameters and determine the overall feasibility of a technology verification program. ETV began the five-year pilot period in October 1995. At the conclusion of the pilot period, the Agency prepared a Report to Congress containing an evaluation of the results of the pilot program and recommendations for its future operation.

Credible, high-quality performance information is one of the tenets of ETV. Therefore, the highest appropriate level of QA is used throughout the program. The EPA's Office of Research and Development, under which ETV operates, has implemented an Agency-wide quality system to assure that activities conducted in EPA research laboratories and other facilities or at facilities being operated on behalf of or in cooperation with the EPA are supported by data of known and acceptable quality for their intended use. Each of the ORD laboratories involved in ETV, the National Risk Management Research Laboratory (NRMRL) and the National Exposure Research Laboratory (NERL), operate under laboratory-specific quality management plans (QMPs). The ETV QMP is consistent with the policies expressed in the individual laboratory QMPs and is intended to provide an overarching, uniform quality system for all aspects of the ETV program.

Program Description

Developers of innovative environmental technology report numerous impediments to commercialization. Among those most frequently mentioned is the lack of acceptance of technology developer/vendor performance claims. The success of the pilot program shows that objective, independently acquired, high-quality performance data and operational information on new technologies significantly facilitates the use, permitting, financing, export, purchase, and general marketplace acceptance of such technologies. ETV provides these data and information

to the customer groups that require them to accelerate the real world implementation of improved technology. Improved technology more thoroughly, rapidly, and efficiently protects human health and the environment. It is important to stress that the product of ETV is high-quality data and information, not technology approval or endorsement. Although there is substantial EPA involvement in guiding and administering this program, ETV does not provide EPA endorsement or certification of commercial products.

At the conclusion of the pilot period the Agency internally reviewed the performance and operation of the program to assess its future direction and scope. The ETV Director recommended consolidation of the program into six technology centers:

- Advanced Monitoring Systems Center (AMS)
- Air Pollution Control Technology Center (APCT)
- Greenhouse Gas Technology Center (GHG)
- Drinking Water Systems Center (DWS)
- Water Quality Protection Center (WQP)
- Pollution Prevention, Recycling and Waste Treatment Center (P2,R,WT)

During 2000 and 2001 the first five centers above were established. The sixth center was not put in place due to a lack of adequate funding to support it. However the Coatings and Coating Equipment Pilot Program, which was part of the P2,R,WT, continues to operate.

Environmental and Sustainable Technology Evaluations (ESTE)

In 2005, the program introduced a new way of operating to expand ETV's ability to respond immediately and directly to high priority Agency problems. Under the new ETV program element, Environmental and Sustainable Technologies Evaluations (ESTE), the verifications are initiated by ORD researchers, collaborating with program office or regional office partners. ESTE maintains the quality assurance, cost sharing and stakeholder involvement of the original ETV program, with the categories for verification chosen by the Agency. Office of Research and Development (ORD) project managers direct the verifications using contractor support. A three-step process is followed.

In Step One, technology categories for verification are chosen through an ORD competitive process. All environmental technology categories, except remediation technologies, are considered. A review committee recommends prioritized categories for verification.

In Step Two, funding is provided to the ESTE project manager to conduct a scoping study which identifies the commercial-ready technologies and their vendors within the category, confirms collaborative partners and identifies others, develops a multi-interest stakeholder group to assist in developing and reviewing a GVP and/or test/QA plan, develops and approves the GVP and/or test/QA plan, and develops the budget for actual verification.

In Step Three, the ESTE project manager with contractor assistance conducts testing and finalizes peer-reviewed and quality-assured verification reports and statements. ESTE projects may also involve technology transfer of verification results, and follow-up with the technology user and permitting community to determine usefulness of the verification information in

decision-making. Projections to document policy-making and pollutant reduction outcomes of the research may also be conducted under ESTE.

Operation of the ETV Centers and ESTE Projects

The verification organizations work with or for EPA through an extramural agreement (a cooperative agreement (CA), an interagency agreement (IAG), or an existing contract). Each agreement has oversight by an EPA project officer who may also be the ETV center project officer or ESTE project manager. EPA provides substantial oversight through an active QA program. Each verification organization is contractually required to fully implement EPA QA requirements for planning, auditing, and documenting the testing and reporting activities. If the verification organization intends to perform verifications by contracting or sub-contracting with other organizations, EPA quality requirements and all of the controls incumbent upon the verification organization that are specified in Section 4.1 pass through to the contractor or sub-contractor and the verification organization is responsible for ensuring that these controls are in place. Qualified reviewers review the technical aspects of the test/QA plans and final reports.

Program and Quality Management Document

The ETV QMP is the program and quality management document being used by ETV to guide its operation. It uses the structure, policies, and standards established in the *American National Standard Specification and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ANSI/ASQC E4-1994). This latter document, ". . . describes a basic set of mandatory specifications and non-mandatory guidelines by which a quality system for programs involving environmental data collection and environmental technology can be planned, implemented, and assessed". Based on the structure and standards of ANSI/ASQC E4-1994, the ETV QMP contains the definitions, procedures, processes, inter-organizational relationships, and outputs that assure the quality of both the data and the programmatic elements of ETV. Part A of the ETV QMP contains the specifications and guidelines that are applicable to common or routine quality management functions and activities necessary to support the ETV program. Part B contains the specifications and guidelines that apply to test-specific activities involving the generation, collection, analysis, evaluation, and reporting of environmental data.

The ETV QMP is designed to play a major role in clearly delineating the roles and responsibilities of all the diverse and important participants. The ETV program is organizationally complex. Within EPA, the program is coordinated through ORD's ETV Team, consisting of staff from ten branches located in five divisions in two laboratories, NRMRL and NERL including the QA staff assigned to each organizational element. There are also numerous outside organizations involved through the extensive stakeholder process, the verification organizations who bear most of the QA responsibilities, and testing and consulting companies hired by verification organizations to conduct field and laboratory work. Finally, EPA program offices and regions are increasingly involved in outreach activities, as are other Federal agencies and states.

Each verification organization uses the ETV QMP and ANSI/ASQC E4-1994 to create ETV center-specific or ESTE project-specific QMPs that assure that the testing and evaluation efforts

carry the appropriate level of QA to meet the needs of the users of the performance information. These QMPs are submitted to EPA for review and approval at the outset of the operation and are reviewed annually with the review of the ETV QMP. The annual reviews incorporate lessons learned from the experiences of the ETV centers and ESTE projects, the feedback from the program's customers, and to accommodate any policy or programmatic changes.

Note: If a verification organization already has a QMP for an ETV center that conforms to the ETV QMP (this document) and ANSI/ASQC E4-1994, it need not prepare another QMP specifically for an ESTE project. Some modifications may be needed, however, to address differences that may be introduced by using a different extramural mechanism (e.g., contracts) to perform an ESTE project. In general these modifications may be handled using an addendum to the QMP or within an ESTE joint QMP/test/QA plan.

# PART A: MANAGEMENT SYSTEMS

Part A of the ETV QMP contains the specifications and guidelines that are applicable to common or routine quality management functions and activities necessary to support the ETV program.

Part B of the ETV QMP contains the specifications and guidelines that apply to test-specific environmental activities involving the generation, collection, analysis, evaluation, and reporting of test data.

Note: The italicized text following the section headings refer to requirements of the ANSI/ASQC E4-1994 and the *Environmental Technology Verification Program Policy Compendium*.

## 1.0 MANAGEMENT AND ORGANIZATION

### *1.1 ETV quality policy*

*The Office of Research and Development shall establish and implement a quality policy to ensure that the Environmental Technology Verification (ETV) program produces the type and quality of program outputs needed and expected by ETV clients.*

The EPA Office of Research and Development's (ORD) quality policy for the Environmental Technology Verification (ETV) program is established as follows:

> *The quality system for the overall ETV program seeks to be consistent with industry consensus standards. Each verification organization shall implement a valid and approved quality system. The Agency's required quality system for cooperative agreements and contracts is ANSI/ASQC E4-1994. Each verification test will be performed according to planned and documented, pre-approved test/QA plans. All technical statements in ETV verification reports shall be supported by the appropriate data.*

### *1.2 Organization structure*

*The relevant organizations, functional responsibilities, levels of accountability and authority, and lines of communication shall be formally defined in the quality system and approved by the EPA laboratory directors responsible for the quality of work performed by or in cooperation with each EPA laboratory.*

The overall organizational structure of the ETV program graphically presents lines of accountability, authority, and communication. The general functional responsibilities for the major organizational units are specified in the structure. See the organization chart for ETV verifications in Figure 1. Note: the relationship of the stakeholder group to the rest of the ETV organization may vary from that depicted in Figure 1 for different ESTE projects.

1.2.1 Assistant administrator for ORD and the EPA administrator responsibilities:

- provide overall program direction
- serve in a program leadership role with Congress, other agencies of the Executive Branch, and the general public

1.2.2 ORD laboratory directors' responsibilities:

- approve and implement annual program budgets and resource allocations
- allocate laboratory personnel and other resources to accomplish ETV's goals,

Currently the following responsibilities are assumed by the NRMRL lab director

- appoints the ETV director
- select ESTE verification projects, unless delegated to the ETV director
- approve all ETV verification reports and statements
- approve ETV QMP
- ensure that appropriate program quality system assessments (see Table 9.1) are implemented

1.2.3 EPA line management's responsibilities:

- allocate appropriate personnel and other necessary resources to support the ETV centers and ESTE projects associated with the division
- appoint an EPA quality manager for each ETV center and ESTE project
- approve ETV QMP
- provide oversight via administrative and technical review of ETV center and ESTE project outputs and products prior to public release
- review and approve verification reports and statements

1.2.4 ETV director responsibilities:

- leads the ETV team by providing communication opportunities, e.g., periodic conference calls, meetings, and training to both the team and the verification organizations
- coordinates the overall ETV program, including design of multi-year strategies, operating principles, implementation activities, and annual budgets
- communicates ETV team and program activities, progress, outputs, and recommendations to EPA, Congress, agencies in the Executive Branch, customer groups, and the general public
- reviews and approves the annual report
- maintains an up-to-date ETV website containing materials relevant to the program and to each ETV center and ESTE project
- manages overall ETV program outreach activities to ensure that stakeholder and customer groups are knowledgeable about the existence and use of ETV generated data
- collects data on operational parameters and program outputs to continuously evaluate the ETV program and make recommendations to management and the Congress on its present and future operation.
- reviews, approves, and assists in revision of ETV QMP
- ensures ETV QMP is implemented in the ETV program
- reviews CA, IAG, and contracting packages (e.g., statements of work [SOWs], independent government estimates [IGEs], and approval packages), including ESTE task orders and work assignments
- reviews ETV verification reports and statements and GVPs

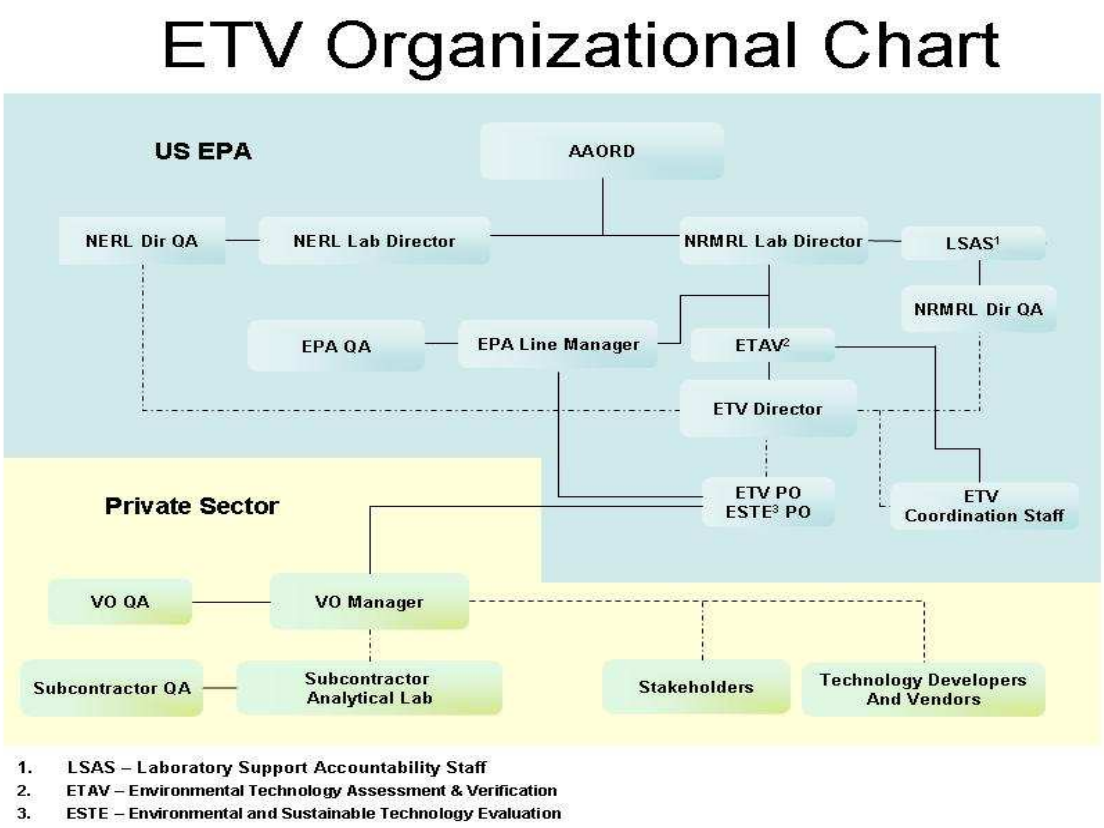


**Figure 1. ETV Program Organizational Chart ***

(* Organizational Chart does not necessarily reflect the line of responsibilities. The above chart is a summary. A detailed explanation of the roles and responsibilities is provided in Section 1.2 )

1.2.5 ETV team responsibilities:

- establishes mutually acceptable program-level strategies and protocols
- participates in development of overarching ETV outreach and outcomes strategies
- communicates ETV center-specific and ESTE project-specific progress, issues, difficulties, and lessons learned
- meets to discuss program objectives, seek collegial guidance, and evaluate success
- reviews ETV QMP
- prepares annual report

1.2.6 ETV coordination staff responsibilities:

- oversee and perform programmatic outreach, including web site development, conference exhibitions, publications (journal articles, fact sheets, brochures, etc.), and workshops/outreach events
- compile and document ETV outcomes, in coordination with ETV centers and ESTE project staff
- evaluate and communicate programmatic progress, issues, difficulties, and lessons learned

- document and interpret ETV policies and procedures
- host team training events, meetings, and conference calls
- review ETV QMP and track implementation
- prepare annual report

1.2.7 ETV center project officer responsibilities:
- oversees verification organizations
- has overall responsibility for the quality of verification tests conducted by the ETV center verification organization
- reviews and approves verification organization QMP, ETV verification reports and statements, and generic verification protocols (GVPs)
- reviews and approves test/QA plans. The responsibility for reviewing and approving certain test/QA plans may be delegated to the verification organization quality manager. Section 2.2.2.1, Part B discusses the delegation process of test/QA plans.
- communicates requirements for and oversee the verification organization quality system, and ETV policies and procedures
- arrange for peer review of verification organization proposals and ETV verification reports, and statements.
- attend and/or conduct regular meetings with stakeholders
- reviews minutes from stakeholder meetings
- oversee production and approval process of GVPs, test/QA plans, ETV verification reports and statements
- assist with ETV outreach activities for the assigned ETV center
- participate in ETV team activities, including the development of the annual report and input to the ETV online database
- ensure that appropriate center-specific assessments (see Table 9.1) are implemented
- reviews independent QA document reviews and assessment reports by EPA quality manager
- reviews verification organization internal QA reviews and assessment reports (e.g., test/QA plan reviews, internal assessment reports, audits of data quality)
- assists in verification outcomes projection at start of verification process and helps to track outcomes
- communicates ETV results and outcomes to EPA line management, EPA program offices, states, local government, and the public.

1.2.8 ESTE project manager responsibilities
- attends and/or conduct regular meetings with stakeholders
- reviews minutes from stakeholder meetings
- manages the oversight and conduct of verification activities
- oversees verification organizations
- has overall responsibility for the quality of verification tests conducted by the ESTE project
- selects technologies for verification based on input from EPA labs, regions, and program offices, technology developers/vendors, and other stakeholders
- communicates requirements for and oversees the verification organization quality system,

and ETV policies and procedures
- arranges for peer review of verification organization proposals and ETV verification reports and statements
- reviews and approves verification organization QMP
- oversee production and approval process of test/QA plans, GVPs, and ETV verification reports and statements
- reviews and approves test/QA plans, GVPs, and verification reports and statements
- reviews independent QA document reviews and assessment reports by EPA quality manager
- review verification organization internal QA reviews and assessment reports (e.g., test/QA plan reviews, internal assessment reports, audits of data quality) and initiates corrective actions
- reviews and approves existing data submitted by third-party testing organizations or technology developers/vendors
- conducts outreach activities for the ESTE project
- participates in ETV team activities, including the development of the annual report and input to the ETV online database
- ensure that project-specific assessments (see Table 9.1) are implemented
- projects outcomes at start of verification process and tracks actual outcomes after completion of verification tests
- communicates ETV results and outcomes to EPA line management, EPA program offices, states, local government, and the public.

1.2.9 ETV center verification organization responsibilities:
- establishes, attends, and/or conducts meetings of stakeholders
- mediates and facilitates the stakeholders' selection of technology focus areas
- documents stakeholder meetings with minutes to reflect discussions and decisions
- maintains communication with EPA to assure mutual understanding and conformance with EPA quality procedures and ETV policies and procedures
- manages the oversight and conduct of verification activities
- assures that QA/QC procedures are incorporated into all aspects of each verification test
- develops DQOs based on input from stakeholders and ETV center project officer
- develops a center QMP, test/QA plans, and GVPs based on input from stakeholders, ETV center project officer, and developers/vendors
- ensures that all subcontractors and analytical labs conform to the requirements of the GVP and/or test/QA plan
- solicits technology developer/vendor proposals or developer/vendor products
- selects technologies for verification based on input from stakeholders and technology developers/vendors
- develops agreements for verification tests with technology developers/vendors and other collaborators, including cost-sharing agreements
- conducts ETV verification tests and other ETV activities within their documented and approved QMP, GVPs, and test/QA plans
- reviews internal QA reviews and assessment reports (e.g., test/QA plan reviews, internal assessment reports, audits of data quality) and initiates corrective actions

- reviews independent QA document reviews and assessment reports by EPA quality manager
- prepares ETV verification reports on verification tests
- prepares a three-to-five page ETV verification statement at the completion of each verification test
- appoints a verification organization quality manager who is independent of those generating project information
- reviews and internally approves existing data submitted by third-party testing organization and technology developers/vendors
- provides input for quarterly and annual reports
- assists with ETV outreach activities for the assigned ETV center
- participates in meetings, conference calls and other activities with the ETV team
- projects and tracks verification outcomes
- submits a written request to the EPA center project officer and the EPA quality manager, who then forwards it to the EPA director of quality assurance, that the responsibility for reviewing and approving test/QA plans be delegated to verification organization quality manager.

1.2.10 ESTE project verification organization responsibilities:

- communicates with EPA to assure mutual understanding and conformance with EPA quality procedures and expectations and ETV policies and procedures
- establishes, attends, and/or conducts meetings of stakeholders
- mediates and facilitates the stakeholders' input on technology focus areas
- documents stakeholder meetings with minutes to reflect discussions and decisions
- assures that QA procedures are incorporated into all aspects of each ETV project
- solicits technology developer/vendor proposals or developer/vendor products
- develops agreements for verification tests with technology developers/vendors and other collaborators
- develops DQOs based on input from stakeholders and ESTE project manager
- develops, conducts, and/or oversees test/QA plans in cooperation with technology developer/vendors
- develops GVPs based on input from stakeholders, ESTE project manager, and developers/vendors
- ensures that all subcontractors and analytical labs conform to the requirements of the GVP and test/QA plan
- conducts ETV verification tests and other ETV activities within their documented and approved QMP
- prepares ETV verification reports on verification tests
- prepares a three-to-five page ETV verification statement at the completion of each technology verification
- appoints a verification organization quality manager who is independent of those generating project information
- projects outcomes at start of verification process and tracks actual outcomes of verification tests
- reviews and approves internal QA reviews and assessment reports (e.g., test/QA plan

reviews, internal assessment reports, audits of data quality)
- reviews independent QA document reviews and assessment reports by EPA quality manager
- reviews and internally approves existing data submitted by third-party testing organization and technology developers/vendors

1.2.11 Subcontractor or Analytical Laboratory
- maintain communication with ETV center/ESTE project verification organization to assure mutual understanding and conformance with requirements of GVP and test/QA plan
- performs QA/QC procedures during technical or analytical activities
- conducts technical or analytical procedures in support of ETV center/ESTE project verification tests under technical oversight of ETV center/ESTE project verification organization
- reports technical or analytical results with associated QC check results to ETV center/ESTE project verification organization

1.2.12 Stakeholders' group responsibilities may include the following:
- attends stakeholder meetings
- reviews minutes from stakeholder meetings
- assists in development of GVPs, test/QA plans, and DQOs
- assists in prioritizing the types of technologies to be verified
- reviews project-specific procedures, test/QA plans, GVPs, and ETV verification reports emerging from the ETV center or ESTE project
- assists in the definition and conduct of outreach activities appropriate to the technology area and customer groups
- serves as information conduits to the particular constituencies that each member represents
- assists in verification outcomes projection at start of verification process and help track outcomes, especially regulatory outcomes following verification process

1.2.13 Developers/vendors responsibilities:
- review GVPs and test/QA plans
- review verification reports and verification statements
- provide comment section input to verification reports and verification statements
- direct third-party testing organization to submit existing data to verification organization

1.2.14 EPA directors of quality assurance responsibilities:
- develop and implement the ETV quality system at the direction of the ETV director and in coordination with EPA quality managers and the ETV team
- document the ETV quality system in the ETV QMP with input from the ETV director and EPA quality managers
- review, and update, if necessary, the ETV QMP annually in cooperation with the ETV director and EPA quality managers
- work with EPA quality managers to ensure implementation of ETV QMP

- provide current copies of the ETV QMP to the appropriate participants in the ETV program
- communicate quality issues and information to the ETV team in a timely manner
- conduct internal quality systems audits (QSAs) of the ETV program
- work with the EPA QA manager the delegation of responsibility for the approval of test/QA plans to a verification organization's quality manager when a written request for delegation has been requested by the VO.
- may approve or reject the delegation of the test/QA plan review and approval responsibilities, after discussion with the EPA QA Manager**,** to a verification organization's quality manager provided that EPA has reviewed and approved previously a test/QA plan for a very similar technology, that the verification organization demonstrates it has a functioning quality system in place that has the same rigor and integrity as the EPA quality system, and that the verification organization quality manager is independent of the environmental data collection process. EPA retains the right to review and approve any QAPP prepared by verification organizations under this delegated responsibility.

1.2.15 EPA quality manager responsibilities:

- assists EPA directors of quality assurance in documenting the ETV quality system in the ETV QMP
- communicates ETV quality system requirements, quality procedures, and quality issues to the assigned ETV center project officer or ESTE project manager and verification organization
- oversees verification organization QA activities to verify conformance to the QA requirements of the ETV QMP (this document)
- reviews and approves verification organization QMP.
- performs and documents independent QSAs for each ETV center and ESTE project to verify conformance to the quality requirements of this document
- reviews and approves verification organization GVPs, test/QA plans, and verification statements and reports (see Table 5.1 for details).
- may review, on a routine basis, verification organization internal quality records (e.g., test/QA plan reviews, internal assessment reports, audits of data quality)
- performs and documents independent technical systems audits (TSAs) and performance evaluation audits (PEAs) of verification tests, as appropriate, to verify conformance to the QA requirements of the applicable GVP and/or test/QA plan
- provides assistance to ETV center and ESTE project personnel in resolving QA issues
- reviews existing data submitted by third-party testing organization and technology developers/vendors and approves its use in a ETV verification report or statement as part of the review of the verification package.
- discuss with the EPA Director of QA, the delegation of the approval of certain routine TQAP.

1.2.16 Verification Organization Quality Manager

- is independent of the environmental data collection process.
- is responsible for ensuring that the verification organization and its subcontractors and

analytical labs have quality systems in compliance with the ETV QMP (this document), and that the verification organization complies with its own documented quality system and the applicable test/QA plan
- communicates ETV quality system requirements, quality procedures, and quality issues to the assigned ETV center project officer or ESTE project manager, to verification organization, and to subcontractor or analytical laboratory
- oversees verification organization QA activities to verify conformance to the quality provisions of this document, QA oversight of the implementation of test/QA plans
- oversees subcontractor and analytical lab QA activities to verify conformance to the QA requirements of the GVP and/or test/QA plan
- prepares the verification organization QMP , which conforms to the QA requirements of this document
- review, and update, if necessary, the VO QMP annually
- performs and documents internal reviews of GVPs, test/QA plans, verification statements and reports and internally approves their release
- if responsibility has been delegated by the ETV director for QA, provides the final QA approval of test/QA plans prior to the start of testing
- performs and documents internal QSAs to verify conformance to the quality requirements of the verification organization QMP
- performs and documents internal TSAs and PEAs of verification tests, as appropriate, to verify conformance to the quality requirements of the applicable test/QA plan
- performs and documents audits of data quality (ADQs) on 10% of test data
- reviews and internally approves existing data submitted by third-party testing organization and technology developers/vendors

1.2.17 Subcontractor or Analytical Laboratory Quality Manager
- oversees internal QA activities to verify conformance with verification organization GVP and/or test/QA plan
- reviews internal QA check results to ensure that verification organization quality acceptance criteria are attained

Information available on the ETV website presents a current listing of the ETV centers and ESTE projects, including the ETV center project officer, ESTE project managers, and verification organization managers' names, company affiliations, and phone numbers.

## *1.3 ETV customer identification and ETV customer needs and expectations*

The ETV director, ETV center project officers, ESTE project managers, and verification organizations are responsible for coordinating the identification of customers and communicating the needs of the internal and external customers to ensure that ETV work products satisfy their needs.

1.3.1 External customers (i.e., outside EPA) include, but are not limited to:
- federal, state and local government permitting/regulatory agencies
- public and private sector buyers and users of technology
- developers/vendors of technology
- the consulting engineering community that recommends technologies to buyers

- international marketers and the financial and insurer communities
- Congress

In a general sense, needs and expectations of external customers include:

- ETV verification reports and ETV verification statements supported by objective and reliable data, provided in a timely manner
- a justifiable documented approach to selecting technologies for testing
- characterization by stakeholders of the quality/uncertainty of the verification test results
- a practical approach in testing which provides efficient, timely, well-documented, and cost-effective verification tests
- full disclosure of all testing results, including those which do not verify the technology manufacturer's claims
- user-friendly documents (e.g., easy to read and to implement)
- technology operation consistent with statements in the ETV verification report

For each ETV center and ESTE project, needs and expectations of external customers are defined and documented in the minutes of stakeholders meetings. The process to define these needs and expectations includes:

- discussions between the ETV center project officers or ESTE project managers, verification organizations, and stakeholders
- development by ETV center project officer or ESTE project managers, verification organizations, and stakeholders of verification test objectives and data quality objectives (DQOs) prior to testing

1.3.2 Internal customers of the ETV program are EPA staff who are responsible for execution of the ETV program in accordance with the expectations of Congress and the Administration. These customers include EPA and ORD senior managers who expect conformance with management and quality policies of the Agency.

Other EPA staff in the regions and headquarters benefit from the program in the following areas:

- data of known and useful quality
- expedited use of improved environmental technologies
- ETV testing accomplished on a wide variety of technologies
- user-friendly documents (e.g., easy to read and to implement)
- development of appropriate GVPs and test/QA plans

## *1.4 Management negotiation with verification organizations on constraints*

*When necessary, appropriate EPA management shall negotiate acceptable measures of quality and success when constraints of time, costs, or other problems affect the verification organization capability to fully satisfy customer needs and expectations.*

When constraints of time, costs, or other problems significantly affect the verification organization capability to fully satisfy the ETV quality system needs and expectations, or when problems are identified through the EPA QA function, the verification organization will notify the project officer and negotiations will proceed according to agreement terms.

## *1.5 Resources*

*The laboratory directors shall provide adequate resources to the ETV directors of quality assurance, ETV center project officer, ESTE project managers, and EPA quality managers to enable them to plan, implement, assess, and improve the overall ETV program and quality system effectively.*

Laboratory directors take the following actions to achieve the above policy:

- provide full-time equivalent (FTE) allotment of ETV center project officer or ESTE project managers
- provide FTE allotment of QA and other support personnel at each laboratory's geographical location
- provide sufficient travel funds for each ETV center and ESTE project for an appropriate level of oversight and independent assessments, which should be determined based on the needs of the ETV center and ESTE project. Needs may include attendance at ETV team meetings, verification tests, and meetings with technology developers/vendors and stakeholder. Travel for assessments is based on the requirements of Part A, Table 9.1.
- provide for maintenance of communication lines between ORD laboratory directors, the ETV team, and the ETV director.

## *1.6 Authority to stop work for safety and quality consideration*

*The verification organization shall stop unsafe work and work of inadequate quality, or shall delegate the authority to do so to others.*

The following procedures are necessary to stop unsafe work and work of inadequate quality:

- the verification organizations shall ensure compliance with all federal, state, and local health and safety policies during the performance of the verification tests. This includes obtaining appropriate permits.
- the verification organization quality system shall identify one or more individuals who may issue a stop work order in the event that unsafe work or work of inadequate quality is identified.
- ETV center project officers, ESTE project managers or EPA quality managers shall contact the authorized individual(s) in the event that work of inadequate quality is discovered.
- in extreme instances, ETV center project officers or ESTE project managers may ask the Grants Administration Division (GAD) or the Contracts Management Division (CMD) to intervene if the verification organization does not implement their approved QMP.

# 2.0 QUALITY SYSTEM AND DESCRIPTION

*A quality system shall be planned, established, documented, implemented, and assessed as an integral part of an ETV management system for environmental technology verification programs defined by ETV quality policy.*

Development and subsequent endorsement of this plan by the ETV director and EPA line management are evidence that the ETV quality system is planned, established, documented, implemented, and assessed as an integral part of an EPA ETV management system.

## *2.1 Authorities and conformance to ANSI/ASQC E4-1994 quality standard*

*The ETV quality system shall address applicable parts of ANSI/ASQC E4-1994 and shall include the organizational structure, policies and procedures, responsibilities, authorities, resources, and guidance documents.*

The authorities for developing appropriate quality systems for ETV are EPA Order 5360.1 A2 (*Policy and Program Requirements for the Mandatory Agency-wide Quality System* ), *Federal Register*, 40 CFR Parts 30 and 33, and *Higher-level Contract Quality Requirements*.

This plan complies with ANSI/ ASQC E4-1994, *Specifications and Guidance for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, the Agency standard. ANSI/ASQC E4-1994 is comparable to the International Organization for Standardization (ISO) 9000 standards series, as shown in the comparison table provided in Annex B-5 to ANSI/ASQC E4-1994. Another acceptable quality system model is ISO 17025, *General Requirements for the Competence of Calibration and Testing Laboratories*.

The ETV quality system addresses each applicable individual "specification" provided in the published quality standard, ANSI/ASQC E4-1994, using the policies and procedures in this plan, as appropriate.

Verification organizations develop QMPs that are consistent with both ANSI/ASQC E4-1994 (and/or ISO 9001:2000) and the ETV QMP (this document). Joint QMP/test/QA plans can be prepared for ESTE projects.

Note: If a verification organization already has a QMP for an ETV center that conforms to this document and ANSI/ASQC E4-1994, it need not prepare another QMP specifically for an ESTE project. Some modifications may be needed, however, to address differences that may be introduced by using a different extramural mechanism (e.g., contracts) to perform an ESTE project. In general these modifications may be handled using an addendum to the verification QMP or within an ESTE joint QMP/test/QA plan.

## *2.2 Quality system documents*

*The ETV quality system shall be described in a QMP that is reviewed and approved by the ETV director and EPA line management.*

The ETV quality system is described in this QMP. The ETV team develops and implements the quality system, both internally and through oversight of the verification organizations. The ETV

director, ORD laboratory directors, and appropriate ORD line management review and approve the ETV QMP and subsequent revisions to the plan, as policy for the ETV program. Verification organization quality systems (which are consistent with ANSI/ASQC E4-1994) are described in a written ETV center QMP or ESTE project joint QMP/test/QA plan, and are reviewed and approved by verification organization management, the ETV center project officer, ESTE project manager, and EPA quality manager. Subsequent revisions are reviewed in a similar manner. These documents conform to EPA Requirements for Quality Management Plans (EPA QA/R-2).

## *2.3 Quality system scope*

*The ETV quality system description shall identify in general terms those items, programs, or activities to which it applies.*

This quality system description applies to the following:

- the EPA ETV program
- selection and oversight of verification organizations
- review and approval of verification organization QMPs
- ETV products (e.g., test/QA plans, reports, ETV verification statements)
- planning, implementation, and assessment activities supporting ETV verification activities

## *2.4 Quality expectation for products and services*

*The ETV quality system shall include provisions to ensure that products or results of the environmental programs defined by the ETV program are of the type and quality needed and expected by ETV clients.*

The preeminent products of the ETV program are the environmental technology verification reports and statements issued by EPA and the verification organization. Provisions to ensure that these products and other results of the ETV program are of the quality expected include:

- products are reviewed as described in Part A, Section 5.0.
- QSAs and technical assessments are conducted as described in Part A, Section 9.0. technical assessments may include field and laboratory audits, performance evaluation audits, and audits of data quality.

## *2.5 Quality procedures documentation*

*Following approval of the ETV QMP, management elements of the quality system shall be implemented as described.*

Verification organizations must operate the ETV centers and ESTE projects under a written and EPA-approved QMP that is based on ANSI/ASQC E4-1994 and/or the provisions of this plan. Verification organizations provide evidence of compliance before verification activities begin, as required by the extramural agreement signed by the verification organization. The ETV center project officer or ESTE project manager is responsible for obtaining a copy of the verification organization QMP for his own review and forwarding the document to the EPA quality manager for review and approval prior to planning verification tests.

## *2.6 Quality controls*

*The ETV quality system description shall define when and how controls are to be applied to specific technical or technology testing efforts and shall outline how these efforts are planned, implemented, and assessed.*

2.6.1 ETV program controls include:

- existing EPA policies and procedures for selection and administration of verification organization efforts in ETV
- an approved ETV QMP
- quality management, quality assurance, and quality control procedures as part of the extramural agreement

Specifically, the data produced by ETV centers and ESTE projects are controlled such that verified data will be published in verification reports, regardless of the outcome of the testing.

2.6.2 ETV center-specific and ESTE project-specific controls include:

- GVPs and specific test/QA plans developed and approved prior to testing
- oversight by the EPA quality managers of the implementation process and follow-up to any finding of nonconformance
- technical assessments and QSAs
- specified quality control requirements in the extramural agreement

ETV center-specific and ESTE project-specific procedures for planning, implementation, and assessment are described in the verification organization quality system. Procedures for planning, implementing, and assessing the overall ETV quality system are detailed in Sections 7.0 , 8.0 , and 9.0 in Part A and in Part B .

## *2.7 Quality system audits (QSAs)*

*At regular intervals (at least annually) the ETV quality system shall be reviewed and its description updated, if appropriate, to reflect changes in the organization as well as changes in ETV quality policy.*

The EPA directors of quality assurance perform an internal QSA of the ETV program every 3 – 5 years in accordance with the process as outlined in Part A, Section 9.0. The assessment report provides input into any update of the QMP. The EPA quality managers shall perform a QSA of each center/project preferably in the first year after the start of the center/project but no later than the second year. Subsequent QSAs of each center/project shall be performed at a frequency of every three years or as needed.

# 3.0 PERSONNEL QUALIFICATION AND TRAINING

## *3.1 Personnel training and qualification procedures*

*Personnel performing work shall be trained and qualified based on appropriate requirements prior to the start of the work or activity.*

3.1.1 ETV center project officers and ESTE project managers are selected based on:

- educational background and/or a degree that is directly relevant to the technology area for the ETV center or ESTE project
- work experience specific to the technology area
- experience in program management
- participation in required training for project officer responsibilities on extramural agreements, as documented in training records

3.1.2 EPA quality managers are selected based on:

- educational background and/or a degree relevant to the verification tests and programs
- familiarity with the ETV quality management system and quality requirements, as demonstrated by work experience with the ETV program or on the job training on the ETV program, ETV QMP and center QMP
- experience in quality management.
- freedom from personal and external barriers to independence and from bias and influences that could affect objectivity, organizational independence, and ability to maintain an independent attitude and appearance

3.1.3 Verification organization personnel

Key participants working directly for or on behalf of the verification organization in support of the center/project and/or individual verification tests are selected by the verification organization and evaluated by the EPA. Evaluation criteria for key personnel will vary, but typically include a consideration of the following:

- educational background and/or a degree(s) relevant to technical areas represented in the center/project
- work experience related to the technology areas represented in the center/project
- experience in quality management systems

The verification organization quality manager is independent of the environmental data collection process.

The verification organization QMP will document training and qualification procedures for verification organization personnel.

## *3.2 Formal qualifications and certifications*

*The need to require formal qualification or certification of personnel performing certain specialized activities shall be evaluated and implemented where necessary.*

ETV program management, quality management, and center/project management require no formal qualification or certification other than where applicable:

- EPA project officer training and extramural agreement training (or work assignment manager training as appropriate)
- appropriate Occupational Safety and Health Administration (OSHA) courses

Formal qualification or certification of personnel performing specialized activities for each center/project or for specific test/QA plans is addressed on a center/project-specific or test/QA plan-specific basis. Verification organizations maintain records of the qualification or certification of such personnel.

NOTE: Requirements for formal qualifications or certification may be based on applicable federal, state, or local requirements associated with a particular test. Examples of possible certifications include but are not limited to drinking water plant operator certification, professional engineering registration, and certification of industrial hygienists.

## *3.3 Technical management and training*

*Appropriate technical and management training, which may include classroom and on-the-job, shall be performed and documented.*

EPA line management is responsible for appropriate technical and management training for staff working on the ETV program. Such training will be documented in each individual's training file.

Verification organizations are responsible for personnel training and qualification procedures for each ETV center and ESTE project or for specific test/QA plans. Verification organizations maintain the training records (available for review by EPA).

The ETV team and verification organizations will be trained at meetings which occur approximately once a year. At these meetings, the team develops policy, and shares information and lessons learned. The directors of quality assurance provide training on the requirements of the ETV QMP during the periodic workshops organized by the ETV director.

## *3.4 Retraining*

*When job requirements change, the need for retraining to ensure continued satisfactory job proficiency shall be evaluated.*

The need for retraining EPA ETV staff is evaluated on an annual basis by the appropriate EPA line management. Evaluating the need for and performing retraining of verification organization staff is the responsibility of the verification organization management.

## *3.5 Personnel job proficiency*

*Evidence of personnel job proficiency shall be documented and maintained for the duration of the technology test or activity affected, or longer if required.*

3.5.1 ETV center project officers and ESTE project managers - The existing performance

standards of the ETV center project officer and ESTE project managers may already include tasks consistent with the following items. These items should be considered for specific identification in the performance standards:

- active participation in the ETV team; communicating center/project issues, lessons learned, required reports, and appropriate assistance to members of the ETV team and management
- developing solicitations and/or management of CAs, IAGs), and contracts
- facilitating stakeholders group activities
- ensuring development of and contributing to GVPs and test/QA plans
- providing a leadership role to ensure technologies are selected consistently with the ETV QMP (this document)
- serving as a communication link between EPA and the verification organization, in particular, providing information and documents to support the ETV website
- reviewing draft and final ETV verification reports and other center/project documents
- reporting to program management on the completeness and validity of the ETV verification statement prior to report issuance
- ensuring the timely delivery of complete and consistent ETV products and services

Evidence of personnel job proficiency is found in the human resources module in ORD's Management Information System (OMIS) for tracking training, and in EPA's Performance Appraisal and Recognition System (PARS) for satisfactory job performance.

Note: Evaluations are the responsibility of the appropriate supervisor and are not a record of the ETV program.

3.5.2 EPA quality managers -The existing performance standards of the EPA quality managers may already include tasks consistent with the following items. These items should be considered for specific identification in the performance standards:

- review and approval of verification organization center/project QMPs
- performance and documentation of independent QSAs of verification organization quality system
- performance and documentation of independent TSAs and PEAs
- review and approval of GVPs, test/QA plans, and verification reports and statements

Note: Evaluations are the responsibility of the appropriate supervisor and are not a record of the ETV program.

3.5.3 Verification organization staff - Verification organizations document and maintain records (such as annual performance reviews) of personnel job proficiency for work performed directly in support of the verification organization ETV activities.

Note: Evaluations are the responsibility of the verification organization and are not a record of the ETV program.

# 4.0 ETV VERIFICATION ORGANIZATION SELECTION

## *4.1 Planning and control of selection process*

*Funding of extramural agreements associated with the ETV program shall be planned and controlled to ensure that the quality of verification tests is known, documented, and meets technical requirements and acceptance criteria of the clients.*

The ETV program is designed to investigate ways to facilitate the verification and use of environmental technology. The ETV program secures verification organizations through appropriate instruments governed by rules found in Title 31, Section 6303, of the US Code, and in EPA Order 5700.1 (*Policy for Distinguishing between Assistance and Acquisition*).

Planning to select verification organizations requires:

- assessing and prioritizing environmental technology categories to be verified by each center/project (i.e., defining the scope of each center/project in terms of technology areas to be tested by that organization)
- establishing ANSI/ASQC E4-1994 as an applicable quality management standard
- issuing solicitations
- selecting the appropriate verification organization based on their experience and proficiency
- managing the selection process to ensure the quality of verification tests includes:
  - -- implementing controls stipulated in EPA policies and procedures for extramural agreements
  - -- establishing specific language in each solicitation requiring development and implementing a quality system consistent with the ETV quality system, and ANSI/ASQC E4-1994. Suggested language is given in Appendix D.
  - -- reviewing the applicant's proposed quality system to verify that it meets the solicitation requirements and provides for quality of verification tests which will be known, documented, and which will meet technical requirements.

## *4.2 Technical and quality requirements*

*Extramural agreement solicitation documents shall contain information clearly describing the technical and quality requirements associated with the verification testing.*

Technical and quality requirements expressed in the solicitation include technical evaluation criteria for technical skills and experience of staff members, and demonstrated experience in the development of quality systems relevant to ETV. The policy in EPA Order 5360.1 A2 pertaining to extramural agreements requires that a verification organization develop and receive EPA approval for a QMP consistent with the ETV QMP (this document) and ANSI/ASQC E4-1994 prior to conducting verification tests. If the verification organization intends to perform verifications by contracting or sub-contracting with other organizations, all of the controls incumbent upon the verification organization specified in Section 4.1 pass through to the contractor or sub-contractor. Verification organization agreements with subcontractors and analytical labs shall include language requiring compliance with this document, the verification organization's QMP, and other relevant QA requirements.

## *4.3 Quality specification/conformance*

*Extramural agreement solicitation documents shall specify the ETV quality requirements for which the verification organization is responsible and how the verification organization conformance to client requirements shall be verified.*

ETV quality requirements for which the verification organization is responsible are specified in this ETV QMP. During verification organization selection, the applicant proposals and written responses to the requirements are reviewed for conformance to the Solicitation specifications. After a verification organization is selected, the EPA quality manager and the ETV center project officer or ESTE project manager review and approve written quality system documents (e.g., QMPs, GVPs, and test/QA plans) for conformance to the EPA and ETV quality policies and procedures. (Note: The EPA director of quality assurance may delegate responsibility for reviewing and approving test/QA plans to the verification organization quality manager provided that the verification organization demonstrates that it has a functioning quality system that has the same rigor and integrity as the EPA quality system and that the verification organization quality manager is independent of the environmental data collection process. EPA retains the right to review and approve any QAPP prepared by verification organizations under this delegated responsibility.)

## *4.4 Peer review of extramural agreements*

*Extramural award documents shall be reviewed for accuracy and completeness by qualified personnel prior to award.*

Peer review is an integral part of EPA's project planning, implementation, and assessment process. Solicitation packages are internally peer reviewed prior to their issuance. Responses to the solicitation undergo a peer review process which supports the award of the extramural agreement. ESTE project task order solicitations that are performed under existing EPA contracts may not require peer reviews.

## *4.5 Conformance of verification testing efforts*

*Appropriate measures shall be established to ensure that the verification testing efforts satisfy all terms and conditions of the extramural agreement. Verification organizations shall have a demonstrated capability to meet all terms and conditions.*

Once a verification organization has been selected, measures to ensure continued conformance to terms and conditions in the extramural agreement are implemented as described in Part A, Sections 8 , 9 , and 10.

# 5.0 DOCUMENTS AND RECORDS

## *5.1 Scope*

*Procedures shall be established, controlled, and maintained for identifying, preparing, reviewing, approving, revising, collecting, indexing, filing, storing, maintaining, retrieving, distributing, and disposing of pertinent quality documents and records. Such procedures shall be applicable to all forms of documents and records, including printed and electronic media. Measures shall be taken to ensure that users understand the documents to be used. Documents and records requiring control shall be identified.*

A document is an instruction, specification, or plan containing information on how the ETV program functions, how specific tasks are to be performed, or how specific products or services are to be provided. Examples include the ETV QMP, the center/project QMPs, GVPs, and test/QA plans. A record is a statement of data and facts pertaining to a specific event, process, or product, that provides objective evidence that an activity has occurred. Examples include verification statements and reports, raw and summary data tables, data notebooks, audit reports, and stakeholder meeting minutes. Documents and records to which this policy applies include:

- ETV QMP (this document)
- extramural agreement records, contracts
- QMPs for ETV centers and ESTE projects or joint QMP/test/QA plans for ESTE projects
- minutes of stakeholder meetings (summary for the record)
- GVPs
- test/QA plans for all verification tests, including standard operating procedures (SOPs)
- raw data (all written and electronic data generated when tests are conducted)
- existing data used in verification reports and statements
- ETV verification reports (comprehensive reports on a technology verification project) and ETV verification statements (summary statement for an individual verification test)
- annual report, including a summary of EPA and verification organization QA activities
- independent assessments of the verification organization quality system and technical systems
- verification organization internal reports of reviews and audits
- reports of internal assessments of the ETV quality system

Information in this section applies to both electronic and printed documents and records, as well as original documents and records developed on behalf of the ETV program that are required to demonstrate the quality of information and data provided in ETV verification reports.

## *5.2 Preparation, review, approval, and distribution*

*Sufficient documents and records shall be specified, prepared, reviewed, authenticated, and maintained to reflect the achievement of the required quality for completed work and/or to fulfill any statutory requirements. Documents used to perform work shall be identified and kept current for use by personnel performing the work. Documents, including revisions, shall be reviewed by qualified personnel for conformance with technical requirements and quality system requirements and approved for release by authorized personnel.*

Table 5.1 lists the pertinent quality documents and records for ETV, the person(s) responsible for preparing and updating these documents and records, the reviewers, those given approval

authority for each record type, and the distribution plan. In Table 5.1, where a procedure is not applicable (e.g., a document is not subject to approval), N/A is entered in the table. All reviewers and approving officials receive copies of the documents and records they review/approve; the Distribution column in Table 5.1 lists only those individuals who receive final copies, in addition to the reviewers and approving official. For revised documents, these same review, approval, and distribution pathways are followed. Unless otherwise noted, material placed on the ETV website is available for public inspection, comment, and use.

## *5.3 Documents and records storage and obsolete documents and records*

*Obsolete or superseded documents shall be identified and measures shall be taken to prevent their use, including removal from the work place and from the possession of users when practical. Maintenance of records shall include provisions for retention, protection, preservation, traceability, and retrievableness. While in storage, records shall be protected from damage, loss, and deterioration. Retention times for records shall be determined based on extramural agreement and statutory requirements, or, if none stated, as specified by the EPA director and EPA line management.*

Obsolete records should be clearly marked as such. These records may be retained in the workplace for historical reference, or they may be removed to archival storage. ETV will follow ORD's Records Management Policy (see Appendix A ), which addresses requirements for indexing, filing, maintaining, retrieving, and disposing of documents and records from all extramural financial agreements. The current minimum requirement is that all records be kept for seven years after the final payment on an extramural agreement.

Any ETV record that is the result of a contract or an agreement falls under EPA Records Control Schedule 003 or Schedule 202 (see Appendix A and http://www.epa.gov/records/) and carry their retention schedules (10 years for grants and other agreements or 6 years and 3 months after close-out for contracts. SITE funded verification records are kept for thirty years as per SITE record schedules. Records are kept under the SITE program.

## TABLE 5.1 Documents and Records Management Scheme

| Record Type | Preparation/Updating | Review and Recommend | Review and Approval | Finals distributed to: |
|---|---|---|---|---|
| ETV quality management plan | ETV directors of quality assurance<br>EPA quality managers | ETV team<br>VO managers | ETV director<br>EPA laboratory directors<br>EPA line management | ETV director or designee for posting to web site |
| CA/IAG/contract records | ETV project officer<br>ESTE project manager<br>VO manager | ETV director | EPA line management | ETV/ESTE project files |
| VO quality management plan | VO manager<br>VO quality manager | EPA quality manager | ETV project officer<br>ESTE project manager<br>EPA quality manager | ETV director or designee for posting to web site |
| Minutes of stakeholder meetings | VO manager | ETV project officer<br>ESTE project manager<br>Stakeholders | N/A | ETV director or designee for posting to web site |
| Generic verification protocol | VO manager | VO quality manager<br>Developer/vendor<br>Stakeholders | EPA quality manager<br>ETV project officer<br>ESTE project manager | ETV director or designee for posting to web site (draft and final versions) |
| Test/QA plan*<br>(including SOPs) | VO manager | VO quality manager<br>Developer/vendor<br>Stakeholders | EPA quality manager<br>ETV project officer<br>ESTE project manager | ETV director or designee for posting to web site<br>Developer/vendor |
| Raw data | VO manager | N/A | VO quality manager | VO project files (EPA can request copies) |
| Existing data | Third-party testing organization | | VO quality manager<br>EPA quality manager<br>VO manager<br>ETV project officer<br>ESTE project manager | VO project files (EPA can request copies) |
| ETV verification report and ETV verification statement | VO manager | ETV director<br>Stakeholders<br>VO quality manager<br>Developer/vendor | EPA laboratory directors<br>EPA quality manager<br>ETV project officer<br>ESTE project manager<br>EPA line management | ETV director or designee for posting to web site |
| Annual report | ETV team<br>ETV coordination staff<br>VO managers | VO managers | ETV director | EPA laboratory directors |
| EPA center and ESTE project QA reviews and assessment reports | EPA quality manager | ETV project officer<br>ESTE project manager<br>VO quality manager<br>VO manager | N/A | ETV/ESTE project files |
| VO internal QA document reviews and assessment reports | VO quality manager | VO manager<br>ETV project officer<br>ESTE project manager<br>EPA quality manager | N/A | VO project files (EPA can request copies) |
| Independent ETV program reviews and assessment reports | EPA directors of quality assurance | ETV director<br>EPA laboratory directors<br>EPA line management<br>EPA quality manager | N/A | ETV program files |
| Email/Memos related to programmatic activities | NA | NA | NA | Person receiving correspondence |

VO = verification organization
N/A = not applicable.

* The EPA QAM, after discussion with the EPA Director of QA may delegate this responsibility to the verification organization quality manager. See Section 2.2.2.1, Part B for the TQAP delegation of authority.

# 6.0 COMPUTER HARDWARE AND SOFTWARE

## *6.1 General procedures*

*Computer software and computer hardware configurations used in the ETV program shall be installed/tested/used/maintained/controlled/documented to meet users' requirements and shall conform to this quality policy and applicable consensus standards and/or data management criteria.*

At the program level, ETV does not expect to develop software. At the center/project level, if verification organizations intend to develop software to support their ETV process (or an individual test/QA plan), they should have procedures in place as specified here. If the verification organization uses only commercial software for office operations (e.g., word processing software, spreadsheet software), it is unlikely that they would need specific procedures for assessing software quality. Part A, Sections 6.2 through 6.6, apply only to software and software/hardware configurations developed specifically for the ETV program.

The following are the ETV program procedures which ensure that each center/project controls the quality of all computer hardware/software configurations for the program:

- the ETV center project officer or ESTE project manager and the verification organization discuss and agree upon the computer hardware and software requirements for the center/project and/or for specific test/QA plans;
- once decisions are finalized, the verification organization supplies evidence of meeting all requirements before data collection, reduction, or validation procedures begins;
- for software developed for ETV programs, the verification organization tests all applications and configurations using a test data set or by running a shakedown test of the system to ensure all applications/configurations are operating to specifications. The verification organization must show evidence of a system to maintain, control, and document such software and hardware configurations. This includes, but is not exclusive of: resources to correct any hardware/software failure with minimal downtime to the program, tracking upgrades/revisions to software or configuration changes, documenting software names, versions, and copyright dates, and complete documentation of the code. Complete documentation of code includes the written code with comments structured in a modular form.

## *6.2 Scope of ETV computer hardware/software procedures*

*Computer software and computer hardware/software configurations covered by ETV's quality policy include, but are not limited to:*

- *operation or process control of environmental technology systems (including automated data acquisition and laboratory instrumentation)*
- *and databases containing environmental data*

Computer software and computer hardware/software configurations covered by the ETV QMP (this document) include all agreed upon, center/project-specific applications or configurations. These applications or configurations include, but are not limited to:

- evaluating and reducing environmental data

- reporting environmental data
- databases containing environmental data

## *6.3 Configuration testing*

*Computer hardware/software configurations shall be tested prior to actual use and the results shall be documented and maintained.*

On a center/project level, the verification organization conducts tests of the computer hardware/software configuration using a standard set of testing conditions.

NOTE: The verification organization is required to have a system to document all testing of computer hardware/software configurations, as required by Part A Section 6.1 . A test data set or a standard set of testing conditions should be developed on a center/project basis or on a test/QA plan-specific basis. Maintenance testing should be easily trackable and retrievable.

## *6.4 Measurement and testing equipment configurations*

*Computer hardware/software configurations integral to measurement and testing equipment that are calibrated for a specific purpose do not require further testing unless:*

- *the scope of the software usage changes OR*
- *modifications are made to the hardware/software configuration*.

On a center/project level, verification organizations perform the following procedures (as provided in the verification organization QMP).

Whenever computer hardware/software configurations integral to measurement and testing equipment are calibrated for a specific purpose, further testing is not normally performed unless the scope of the software usage changes or modifications are made to the hardware/software configuration.

In the event either of the above mentioned changes occurs, the verification organization retests the changes as described in Part A Sections 6.1 and 6.3. Retesting is documented to the same extent as the original application/configuration.

## *6.5 Change assessments - configurations, components, and requirements*

*Changes to hardware/software configurations, components, or program requirements shall be assessed to determine the impact of the change on the technical and quality objectives of the ETV program supported.*

The verification organization is responsible for assessing the changes, determining the need for testing, and reporting the assessments to the ETV center project officer or ESTE project manager.

## *6.6 ETV website and ETV database roles and responsibilities*

*The ETV website shall be operated in such a way that it serves all ETV participants and customers through prompt and accurate posting of ETV information and documents.*

The ETV center project officers and ESTE project managers, or alternate(s) designated in writing by these managers, are responsible for promptly sending the following information to the ETV director or coordination staff designee:

- general fact sheets and brochures
- meeting announcements and summaries
- verification organization QMPs
- GVPs (indicating draft or final)
- test/QA plans (indicating draft or final)
- ETV verification statements
- ETV verification reports

The ETV center project officers, ESTE project managers, or verification organization designees are responsible for regularly inputing and/or updating the following types of information contained in the online ETV database:

- vendor contact information and technology information
- technology categories list
- center contact information
- stakeholder member list(s)
- upcoming calendar of events and/or outreach activities
- monthly report (ETV center project officers and ESTE project managers only)
- vendor solicitations
- quarterly tracking document updates (tracking report, protocols list, test/QA plans list, outreach documents list, and conference participation list)
- annual cost questionnaire
- testing events
- quality assurance: QMPs, audits, and other QA information

# 7.0 PLANNING

## *7.1 Systematic planning process*

*A systematic planning process shall be established, implemented, controlled, and documented to:*
- *identify the customer(s), and their needs and expectations*
- *identify the technical and quality goals that meet the needs and expectations of the customer*
- *translate the technical and quality goals into specifications that shall produce the desired result*
- *consider any cost and schedule constraints within which technology test activities are required to be performed*
- *identify acceptance criteria for the results or measures of performance by which the results shall be evaluated and customer satisfaction shall be determined*.

7.1.1 Systematic planning process established for ETV is conducted as follows:
- EPA establishes the number and type of ETV centers and ESTE projects necessary to comply with the Presidential mandate to cover all environmental technologies;
- EPA laid out basic program parameters for ETV in 1997 in the *Environmental Technology Verification Program Verification Strategy*. Since then the program planning has been guided by the *Pollution Prevention Research Strategy* and the *Pollution Prevention and New Technology Multiyear Plan* (2003 draft). In 2006, ORD drafted the *Sustainability Research Strategy* and the *Science and Technology for Sustainability Multiyear Plan (2008-20012)*, which also guide the program;
- based upon the ETV QMP (this document), the ETV director, in consultation with the ETV team and EPA line management, designs an annual budget.
- appropriate ORD personnel are appointed to fill ETV positions. Selection and information on qualifications are presented in Part A, Sections 3.1 and 3.2;
- EPA line management provides resources and planning to support the duties of EPA staff, such as training and travel. Training is discussed in Part A, Sections 3.3 and 3.4;
- verification organizations are selected to manage the ETV centers or verification tests for ESTE projects in conformance with Part A, Section 4.0. EPA's requirements for the appropriate extramural agreement (e.g., CA, IAG, contract) are met;
- after selection, the verification organization, in consultation with the ETV center project officer, establishes stakeholders groups that contain representatives of customer groups of concern to that center's areas;
- the verification organization develop GVPs and/or test/QA plans for verification tests and present them to the stakeholders for review and comment and to the ETV center project officer or ESTE project manager and the EPA quality manager for review and approval;
- the ETV center project officer or ESTE project manager, the EPA quality manager, the verification organization, and the stakeholders group hold at least one joint meeting annually to:
  - -- identify, revise, and/or clarify the technical and quality goals of the work to be accomplished
  - -- translate the technical and quality goals into written specifications that will be used to produce the desired result
  - -- consider any cost and schedule constraints within which test activities are required to

be performed
  -- develop qualitative measures of performance by which the results will be accepted
  -- determine testing priorities and evaluate customer satisfaction.
- take minutes of each meeting by the verification organization and distribute them to participants for comment. Minutes of stakeholders meetings are incorporated within the record management scheme described in Part A, Section 5.0.

7.1.2 Implementation of the systematic planning process

Planning is accomplished through frequent meetings among participants and through posting initial planning documents and stakeholders meeting minutes on the ETV website. Procedures for planning at the center/project level and at the verification test level are addressed in Part B . Procedures for implementing the planning process are detailed below:

- customer identification - ETV customers are identified in Part A Section 1;
- technical and quality goals identification - in addition to the goals identification which occurs at stakeholder meetings mentioned in Section 7.1.1, these are identified during planning meetings with senior management, conference calls with ETV participants, and meetings with EPA quality professionals and technical staff;
- technical and quality goal specifications - the ETV director works with the ETV center project officers, ESTE project managers, EPA directors of quality assurance, and other quality professionals to translate technical and quality goals of the overall program into the ETV QMP;
- cost and schedule constraints - these are discussed during planning meetings with senior management and considered yearly for allocation to ETV centers and ESTE projects;
- measures of performance - the ETV director develops measures of performance for ETV, which are evaluated by the ETV team and verification organizations throughout the course of the program. Appendix B contains the most current measures of performance.

7.1.3 Systematic planning process controls include:

- development and implementation of written procedures (GVPs and test/QA plans)
- requirement of minutes of stakeholders group meetings
- review of verification organization work efforts by the ETV center project officer or ESTE project manager and EPA quality manager

7.1.4 Systematic planning process documentation includes the ETV QMP, the verification organization QMPs, GVPs, test/QA plans, the *Pollution Prevention Research Strategy*, the *Pollution Prevention and New Technology Multiyear Plan* (2003 draft), *Sustainability Research Strategy*, and the *Science and Technology for Sustainability Multiyear Plan (2008-2012)*.

## *7.2 Planning document review*

*All planning documentation shall be reviewed and approved for implementation by authorized personnel before the specific work commences. Such documentation includes but is not limited to test/QA plans and GVPs.*

Planning document review is discussed in Part A Section 5

# 8.0 IMPLEMENTATION OF WORK PROCESSES

## *8.1 Implementation*

*Work shall be performed according to approved planning and technical documents.*

The planning for the implementation of the EPA management and quality work processes is contained in Part A, Section 7.0. The individual center's/project's work is performed according to planning documents written by the center/project. All technology verification work shall occur according to GVPs and test/QA plans developed and agreed upon by EPA, the verification organization, and the developer/vendor. The authors, reviewers, and approvers of these documents are specified in Part A Section 5.0, Table 5.1.

The approved GVPs and test/QA plans shall be present on the site of testing, and the work shall be implemented in accordance with them. During the work phase, modifications to plans and procedures shall be documented, and the modifications shall be incorporated into the final GVPs and test/QA plans. The authors, reviewers, and approvers of changes to these documents are the same as for the original documents and are specified in Part A, Section 5.0, Table 5.1.

Verification organizations are responsible for implementing their work processes in accordance with their QAM and with GVPs and test/QA plans. They are responsible for ensuring that subcontractors and analytical labs conform to the requirements of the GVPs and test/QA plans.

## *8.2 Procedures*

*Procedures shall be developed, documented, and implemented for appropriate routine, standardized, special, or critical operations. Operations needing procedures shall be identified. The form, content, and applicability shall be addressed, and the reviewers and approvers shall be specified.*

Procedures for the overall operation of the ETV program are contained in the ETV QMP and in other appropriate EPA policies (e.g., extramural agreement, records management). The individual ETV centers and ESTE projects shall identify and document those operations in their centers/projects requiring procedures as discussed in Part B . Procedures shall be written in a format that can be readily comprehended by the user and shall contain sufficient detail and clarity to ensure that results are achieved effectively. Appropriate operations documents, authors, reviewers, and approvers are specified in Part A Section 5.0, Table 5.1.

## *8.3 Oversight*

*Implementation of work shall be accomplished with a level of management oversight and inspection commensurate with the importance of the program and the intended use of the results, and shall include the routine measurement of performance against established technical and quality specifications.*

EPA line management has responsibility for oversight of verification work processes as discussed in Part A Section 1.0. Verification organization oversight and responsibilities for the verification work processes are given in their QMPs.

# 9.0 ASSESSMENT AND RESPONSE

## *9.1 Numbers and types of assessments*

*Assessments shall be planned, scheduled, and conducted to measure the effectiveness of the implemented quality management systems. Several types of assessments are available for this purpose. Management shall determine during the planning stage the appropriate types of assessment activities. Assessments shall include an evaluation to determine and verify whether technical requirements, not just procedural compliance, are being implemented effectively.*

QSAs and TSAs shall be used to measure the effectiveness of the implemented center/project quality management systems and technical systems. PEAs shall be used to evaluate performance of the center/project technical systems. ADQs shall be used to assess reported data quality. The types of assessments are defined in Part B, Section 4.0.

Verification organization quality managers perform internal assessments of verification organizations. EPA quality managers perform independent assessments of verification organizations. EPA directors of quality assurance perform independent assessments of the ETV program.

Note: General Auditing Guidelines: Because of the high visibility of ETV testing, the systematic planning should provide for sufficient auditing to insure the integrity of the data. The assessments shown in Table 9.1 and the minimum frequency are commensurate with the importance of the ETV program and the intended use of the verification results. The target minimums are a TSA on every test by the verification organization, and at least once per year per center by EPA. If a test is capable of being quantitatively audited and if suitable PEA samples can be prepared, PEAs should be performed on every test by the verification organization and once per year for each center/project by EPA. An ADQ must be performed by the verification organization on a random selection of 10% of all data from each test. An ADQ should be performed at least once per year for each center/project by EPA. In the case of continuously monitoring instruments operating over long periods of time, a representative amount of the data (suggest 10%) may be audited.

In cases where the minimum frequency for these assessments appears to be excessive, the professional judgment of the EPA quality managers will prevail. For example, the EPA quality managers may make an exception to the minimum frequency if multiple verification tests of very similar environmental technologies are being conducted under the same GVP within a relatively short span of time and if the results of the first assessment indicate that the verification test was implemented as described in the test/QA plan and that the measurement data attained their DQOs. In this circumstance, the EPA quality manager may decide that assessments at less than the minimum frequency are effective for monitoring the quality of the multiple, but very similar, verification tests. (Also, see Part B, Section 4.2 for information about assessment frequency.)

**Table 9.1 Assessments**

| Assessment Type | Auditors | Responsible for Corrective Action | Basis for Audit | Minimum Frequency | Reason for Assessment | Report Reviewed by |
|---|---|---|---|---|---|---|
| **Program-Level Assessments** | | | | | | |
| Quality systems audit | EPA directors of quality assurance | ETV program management | ETV QMP | Every 3 – 5 years | Assess management practices for ETV program | EPA laboratory directors<br>ETV director |
| **Center- or Project-Level Assessments** | | | | | | |
| Quality systems audits (internal) | VO quality managers | Verification organizations | Center or Project QMP | Within one year after approval of the initial center QMP, then as requested by EPA | Assess quality management practices of VO | VO managers |
| Quality systems audits (independent) | EPA quality managers | Verification organizations | Center or Project QMP | Within one year after approval of the initial center QMP, then every three years or as needed, | Assess quality management practices of VO | VO managers<br>VO quality managers<br>ETV project officers<br>ESTE project managers<br>EPA directors of QA<br>ETV director |
| Technical systems audits (internal) | VO quality managers | Verification organizations | Test/QA plans | internal: once per test (see Part A, Section 9.1 for exception) | Assess technical quality of verification tests | VO managers<br>EPA quality managers<br>ETV project officers<br>ESTE project managers |
| Technical systems audits (independent) | EPA quality managers | Verification organizations | Test/QA plans | independent: yearly for each center/project (see Part A, Section 9.1 for exception) | Assess technical quality of verification tests | VO managers<br>VO quality managers<br>ETV project officers<br>ESTE project managers<br>EPA directors of QA |
| Performance evaluation audits (internal) | VO quality managers | Verification organizations | Test/QA plans | internal: each test, if feasible (see Part B, Section 4.2 for exception) | Assess measurement performance | VO managers<br>EPA quality managers<br>ETV project officers<br>ESTE project managers |
| Performance evaluation audits (independent) | EPA quality managers | Verification organizations | Test/QA plans | independent: yearly for each center/ project, as appropriate and feasible (see Part B, Section 4.2 for exception) | Assess measurement performance | VO managers<br>VO quality managers<br>ETV project officers<br>ESTE project managers<br>EPA directors of QA |
| Audits of data quality (internal) | VO quality managers | Verification organizations | Raw data and summary data | internal: At least: 10 percent of all of the verification data | Assess data calculations and reporting | VO managers<br>EPA quality managers<br>ETV project officers<br>ESTE project managers |
| Audits of data quality (independent) | EPA quality managers | Verification organizations | Raw data and summary data | independent: yearly for each center/project (see Part B, Section 4.2 for exception) | Assess data calculations and reporting | VO managers<br>VO quality managers<br>ETV project officers<br>ESTE project managers |

## *9.2 Procedures*

*Assessments shall be performed according to written and approved procedures, based on careful planning of the scope of the assessment and the information needed. Assessment results shall be documented and reported to management. Management shall review the assessments.*

Assessments shall be planned according to the scope of the assessment and the information needed. Suitable written procedures for planning and conducting audits shall be contained in the center/project QMPs of the verification organizations and in EPA guidance documents (i.e., *Guidance on Assessing Quality Systems, EPA QA/G-3* and *Guidance on Technical Audits and Related Assessments, EPA QA/G-7*). Assessments are based on interviews, on the physical examination of objective evidence, on results of analysis of PEA samples, and on the

examination of the documentation of past performance. The basis for QSAs of verification organizations is the center/project QMPs. The basis for TSAs of ETV verification tests is the test/QA plans. Results are documented in audit reports, which are reviewed by appropriate management as described in Table 9.1.

Assessments shall occur when verification testing is at a stage where auditing is feasible. Assessments are most effective early in a verification test so that corrective action may be taken before the project has been completed and before all environmental data have been collected. It is better for an auditor to report earlier so that a verification test can generate better data rather than to report later when corrective action is no longer possible.

## *9.3 Personnel qualifications, responsibility, and authority*

*Personnel conducting assessments shall have the appropriate technical or management skills to perform the assigned assessment. Management shall determine and document the level of competence, experience, and training necessary to ensure the capability of personnel conducting assessments. The responsibilities and authorities of personnel conducting assessments shall be clearly defined and documented, particularly in regard to authority to suspend or stop work in progress upon detection and identification of an immediate adverse condition affecting the quality of results or the health and safety of personnel.*

EPA or verification organization management determines and documents the level of competence, experience, and training of their respective audit personnel during hiring and periodic performance reviews. Qualified audit personnel, as listed in Table 9.l, have access to the appropriate management personnel and documents required to perform their audit duties. They must be organizationally independent of the center/program that they are auditing. They have the responsibility and authority to:

- identify and document problems that affect quality of verification results
- propose recommendations for resolving problems that affect quality of verification work processes or results
- independently confirm implementation and effectiveness of solutions

If the auditors identify a significant problem affecting verification data quality, ETV center project officers and ESTE project managers have the authority to request of the verification organization manager that work be stopped until the problem is addressed. If the auditors identify a problem where the health and safety of personnel are in danger, they have the responsibility to bring it to the immediate attention of appropriate EPA management, verification organization management, and onsite testing personnel.

## *9.4 Response*

*Responses to adverse conclusions from the findings and recommendations of assessments shall be made in a timely manner. Conditions needing corrective action shall be identified and the appropriate response made promptly. Follow-up action shall be taken and documented to confirm the implementation and effectiveness of the response action.*

When the recommendations and conclusions from the findings of assessments are adverse, response from the verification organization detailing the corrective action shall be expected within 10 working days of receiving the audit report. The auditors shall follow up with appropriate documentation to confirm the implementation and effectiveness of the corrective action.

# 10.0 QUALITY IMPROVEMENT

## *10.1 Annual review for quality improvement*

*A quality improvement process shall be established and implemented to continuously develop and improve the ETV Quality System.*

The ETV director and EPA directors of quality assurance review the ETV QMP annually and recommend improvements to the plan.

The EPA directors of quality assurance recommend and negotiate quality improvements with the ETV team during the annual meeting and through other business communication channels (e.g., e-mail, teleconferences, etc.)

## *10.2 Detecting and correcting quality system problems*

*Procedures shall be established and implemented to prevent as well as detect and correct problems that adversely affect quality during all phases of technical and management activities.*

ETV center project officer, ESTE project managers, and EPA quality managers report problems in any of the following areas to EPA line management and to the EPA directors of quality assurance and to the ETV Program director:

- adequacy of the ETV quality system
- consistency of the quality system
- implementation of the quality system
- correction of quality system procedures
- completeness of documented information
- quality of data
- quality of planning documents
- implementation of the work process

EPA line managers respond promptly to address correction of the quality problem.

## *10.3 Cause-and-effect relationship*

*When problems are found to be significant, the relationship between cause and effect and the root cause shall be determined.*

The following are general procedures for determining cause-and-effect relationships. Specific procedures are found in the individual verification organization QMP. When problems are *significant*, the verification organization quality manager determines and documents the relationship between cause and effect, and when possible, determines and documents the root cause of the problem. The verification organization quality manager provides this information to the verification organization manager so corrective action can be authorized and implemented. The corrective action may include changes to a GVP, a test/QA plan, the management system or the verification organization's quality system as documented in its QMP.

Note: The verification organization quality managers, in accordance with their quality systems,

are continually reviewing and assessing their centers/projects for conformance with their quality documents (i.e., QMP, GVP, test/QA plan). At the program level, independent assessment reports from the individual centers/projects are monitored and evaluated by the EPA directors of quality assurance for trends or recurring problems that are indicative of significant problems affecting the ETV program as a whole. Any such situation is immediately communicated to the ETV director. The ETV director shares the information and any corrective actions with the ETV center project officers and ESTE project managers.

## *10.4 Root cause*

*The root cause should be determined before permanent preventative measures are planned and implemented.*

To guard against implementing ineffective changes, EPA personnel ensure when possible that root causes are determined before preventative measures are planned and implemented.

## *10.5 Quality improvement action*

*Appropriate actions shall be planned, documented, and implemented in response to findings in a timely manner.*

In the event that a significant problem is identified that requires a structural change to the ETV program, the ETV director will initiate discussions with EPA line management appropriate to correct the deficiency. Under extreme circumstances EPA Directors of Quality Assurance may initiate discussions with the Lab Director.

# PART B: COLLECTION AND EVALUATION OF ENVIRONMENTAL DATA

Part A of the ETV QMP contains the specifications and guidelines that are applicable to common or routine quality management functions and activities necessary to support the ETV program.

Part B of the ETV QMP contains the specifications and guidelines that apply to test-specific environmental activities involving the generation, collection, analysis, evaluation, and reporting of test data.

## 1.0 VERIFICATION PLANNING AND SCOPING

The work of the ETV program at the project level is to verify the performance of commercial-ready technologies. As discussed in Part A Section 7.0, the planning process begins with the Statement of Work (SOW) contained in the solicitation. The successful applicant becomes the verification organization for the center.

### *1.1 Systematic planning of the verification test*

*All work involving the generation, acquisition, and use of environmental data shall be planned and documented. The type and quality of environmental data needed for their intended use shall be identified and documented using a systematic planning process. The test-specific planning must involve the key users and customers of the data. ETV* center project officers and ESTE project managers should guide planning activities and ensure that participants are *informed of and understand completely the requirements of each test.*

The programmatic planning for verification of commercial-ready technologies is discussed in Part A Section 7.1.1. This section continues the discussion of systematic planning at the center/project level.

Verification organizations, working with the ETV center project officers or ESTE project managers, begin a systematic process to plan the individual verification tests. Systematic planning may be accomplished through the DQO process (see *Guidance for the Data Quality Objectives Process, EPA QA/G-4*). The planners perform the following actions:

- refine the scope of their respective technology areas
- determine interest in verification from the manufacturers of commercial-ready technologies within the defined scope of the technology areas
- convene stakeholder groups, including representatives of verification customer groups, to provide input during the planning process
- develop DQOs for verification tests based on input from stakeholders and ETV center project officers or ESTE project managers
- mediate and facilitate the stakeholders' identification of technology focus areas
- select technologies for verification based on input from stakeholders and technology developers/vendors
- prepare GVPs which are developed to promote uniform testing procedures for similar environmental technologies and/or test/QA plans to verify the performance of the specific

environmental technologies
- coordinate the review and revision of the GVPs and/or test/QA plans (see the review and approval scheme in Part A, Section 5.0.) keeping in mind both customer and EPA objectives for verification tests
- solicit developer/vendor agreements to participate in verification of their products based on the GVP and/or test/QA plan (some iteration of the two previous points frequently occurs here as the developer/vendors review and request revision of portions of the GVPs and/or test/QA plan)

ESTE project managers, working with verification organizations for ESTE projects, begin a systematic process to plan the individual verification tests. Systematic planning may be accomplished through the DQO process (see *Guidance for the Data Quality Objectives Process, EPA QA/G-4*). The planners perform the following actions:

- refine the scope of their respective technology areas
- determine interest in verification from the manufacturers of commercial-ready technologies within the defined scope of the technology areas
- convene stakeholder groups, containing representatives of verification customer groups, which provide input during the planning process
- develop DQOs for verification tests based on input from stakeholders and the verification organization
- mediate and facilitate the stakeholders' selection of technology focus areas
- selects technologies for verification based on input from EPA labs, regions, and program offices and technology developers/vendors
- prepare GVPs which are developed to promote uniform testing for similar environmental technologies and/or test/QA plans to verify the performance of specific environmental technologies (Note: Although not required, some ESTE projects may develop GVPs.)
- coordinate the review and revision of the GVPs and/or test/QA plans (See the review and approval scheme in Part A, Section 5.0.) keeping in mind both customer and EPA objectives for verification tests
- solicit developer/vendor agreements to participate in verification of their products based on the GVP and/or test/QA plan (some iteration of the two previous points frequently occurs here as the developer/vendors review and request revision of portions of the GVP and/or test/QA plan)

The GVPs and/or test/QA plans describe the experimental approach, with clearly stated test objectives and associated DQOs for the related measurements.

## *1.2 Systematic planning for verification testing*

- *organizations that participate in the test shall participate in the planning.*
- *the scope and objectives of the verification testing and the desired action or result from the work shall be defined.*
- *the data to be collected to achieve verification shall be identified, and the QA and QC requirements to establish the quality of the data shall be defined.*
- *verification tests shall undergo a design process.*
- *verification tests shall be documented.*
- *equipment, operators, and skill levels required for the verifications shall be identified.*
- *any constraints (e.g. time and budget) shall be identified.*

- *conditions, which will suspend work, shall be identified.*
- *assessment tools shall be determined.*
- *methods and procedures for storing, retrieving, analyzing, and reporting the data shall be identified.*
- *methods and procedures for minimizing, characterizing, and disposal of hazardous waste generated during the test shall be identified.*

### 1.2.1 Planning personnel

The verification organization shall coordinate test planning among the participating organizations including EPA, the stakeholders, the vendors, and any testing organizations and laboratories participating in the test. The verification organization, with the concurrence and oversight of the ETV center project officer or ESTE project manager, shall identify the planning roles of the various players, and shall conduct planning activities by shared communication via teleconference, video conference, and in-person meetings, as appropriate, and within the constraints of the budget.

### 1.2.2 Purpose, scope and objectives

The purpose of this testing is to verify the performance of commercial-ready technologies. Another objective is to develop an efficient method for testing commercial-ready technologies. Many of the centers accomplish this objective by preparing GVPs whereby the performance of similar technologies can be verified in the future using the same or similar test/QA plan(s). The characteristics of individual technologies and the specifics of individual tests are described in individual test/QA plan(s), which incorporate the GVP by reference. For some tests the technologies are sufficiently similar that more than one product in the same technology area is tested under the same test/QA plan. Depending on the technology and the test, technologies may be tested on multiple occasions. The testing experience may be used to refine the GVP and/or test/QA plan.

### 1.2.3 Data to be collected and design of experiment

During planning of the technology verification test, the process, environmental, laboratory, response, and QA data to be collected are identified. Also identified are testing organizations, test personnel, skill levels, methods, procedures, and equipment unique to each verification test. Planning is integrated into design as discussed in Part B, Section 2.0.

### 1.2.4 Documentation and reporting

Records generated during the verification tests are listed in Part A, Section 5.0. Records consist of both paper and electronic records. Electronic methods for storing, retrieving, analyzing, and reporting the data are generally commercially available programs for word processing, spreadsheet, or database processing, or commercial software developed especially for data collection and processing on a specific instrument or piece of equipment. Centers may also develop software/hardware configurations, as appropriate, in their technology verification tests. The use of computer hardware and software is discussed in Part A, Section 6.0. Paper records such as field notebooks, bench sheets, field data sheets, custody sheets, and instrument printouts are part of the raw data test record and are kept with the study records.

### 1.2.5 Assessments

The assessment tools and minimum frequencies of assessments for the verification tests are

identified in Part A, Section 9.0. The definitions of the assessment tools and suggested frequencies are given in Part B, Section 4.0.

1.2.6 Constraints, suspension of work, waste minimization and disposal

Verification organizations work under the constraints of time and resources communicated to them by the EPA ETV director and the ETV center project officer or ESTE project manager. When constraints are determined by the verification organization to affect quality, the resolution of the problem proceeds as described in Part A, Section 1.5. Circumstances under which work can be suspended are discussed in Part A, Section 1.7. If waste is generated as part of the verification testing, the verification organization seeks to minimize the amount, and disposes of it in accordance with applicable local, state, and federal laws.

# 2.0 DESIGN OF TECHNOLOGY VERIFICATION TESTS

## *2.1 Design process*

*The design shall incorporate those activities pertaining to verification of performance identified during the planning process, establish test specifications, and identify appropriate controls. The design shall include*

- *selection of field sampling or testing equipment, and its operational parameters, as appropriate*
- *selection of field sampling or testing methods, as appropriate*
- *sample types, numbers, quantities, handling, packaging, shipping, and custody, if applicable*
- *sampling locations, storage, and holding times, if applicable*
- *selection of analytical methods, quality measures of performance, analysis providers, if applicable*
- *requirements for calibration standards, and performance evaluation samples, as appropriate*
- *requirements for field and/or laboratory QA/QC activities*
- *requirements for qualifications of testing, sampling and/or analysis personnel*
- *protection of health and safety of test personnel and the public*
- *readiness reviews prior to data collection*
- *assessments required including technical and performance audits, audits of data quality, and assessments of data use limitations*
- *data reporting requirements*
- *methods for validating and verifying the data*
- *requirements for data security, archival, and retention*
- *integration of time and schedule constraints*
- *procedures for minimization or disposal of wastes generated during verification activities*

2.1.1 Designers

The design of an ETV verification test is provided by a team that includes stakeholders, EPA staff, verification organization staff, and vendors. The output of the design process is a test/QA plan that details the planned tests and documents the rationale, assumptions, and personnel involved. EPA provides guidance for writing test/QA plans in *Guidance on Quality Assurance Project Plans, EPA QA/G-5*. For some classes of technologies, the output may be a GVP.

2.1.2 Objectives

The goal of an ETV verification test is the production of high-quality testing data for use by a decision maker in determining the appropriateness of the technology for the intended use. In designing technology performance verification operations, designers use a modification of the DQO process (see *Guidance for the Data Quality Objectives Process EPA QA/G-4*) for those ETV verification tests for which quantitative goals can be specified. A modification is required because the DQO process is geared toward making a decision. The ETV program does not

participate in making ranking decisions regarding the technologies. It provides unbiased reporting of performance through testing. The objective of the design process is to identify and harmonize all components necessary to conduct a successful test.

### 2.1.3 Design process and components

The planning process considers selection of test parameters, availability of test equipment, availability of testing personnel, optimal test procedures, and the necessary and sufficient data quality indicators for test measurements. The verification test design takes into account constraints of time, scheduling, and resources.

The product of the design process is a test/QA plan, which has the following characteristics:

- documents the process and assumptions used for planning, as well as those persons responsible for the planning;
- specifies the field and laboratory tests to be conducted, the baseline parameters, the number of replicate tests, and the controls;
- specifies field and laboratory equipment and optimal operating parameters;
- specifies sampling methods, sample types, numbers, quantities, handling, packaging, shipping, and custody if the testing involves samples; specifies sample locations, storage conditions, and holding times;
- incorporates analysis methods, quantitative measures of performance, calibration standards, calibration check standards, and performance evaluation samples, as appropriate and as identified in the planning process;
- establishes QC check acceptance criteria to ensure attainment of DQOs;
- includes methods and procedures to ensure the test produces data of known and acceptable quality;
- incorporates any other field or laboratory QA/QC activities identified by planners;
- specifies the requirements for qualifications of technical staff responsible for obtaining, analyzing, and evaluating the data;
- incorporates protection of the health and safety of testing personnel and the public;
- incorporates procedures for the minimization and disposal of generated wastes.

### 2.1.4 Assessments

Assessments incorporated into the design include self-assessments (internal audits) by the verification organization 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 Part A, Section 9.0. A suggested schedule of assessments is given in Part B, Section 4.0.

### 2.1.5 Validating, reporting, securing, and archiving data

Data are verified by the data collectors and independently validated by technical assessors as indicated under Audits of Data Quality in Part A, Table 9.1 . Data are reported in ETV verification reports and ETV verification statements. Data records are stored as discussed in Part A, Section 5.0 and in Appendix A .

## *2.2 GVPs and test/QA plans: planning documents from the design process*

*Planning documents from the design process include GVPs and test/QA plans.*

Writing planning documents is generally a lengthy process involving iterations of review and revision. Authors should be knowledgeable of the activity and the equipment described in the planning documents. Two types of planning documents have been identified, as the core documentation needed for operation of an ETV center or ESTE project: the GVP and/or the test/QA plan. The GVP is meant to promote uniform testing for a single center and, therefore, is considered a more general document. The test/QA plan contains the specific information needed to conduct a verification test. In addition, SOPs provide detailed instructions for work processes, such as sampling, analysis, and data analysis, that are conducted during a verification test.

### 2.2.1 Generic verification protocols

GVPs can provide the necessary framework for development of the more detailed test/QA plan. The specific content and level of detail given in GVPs may vary between centers. For some centers, the GVP may be so detailed that the test/QA plan may require very little additional information. For other centers, GVPs may not be appropriate because each of their test/QA plans is very different from others being done by that center. Given the variable nature of the GVP, no specific format has been proposed. GVPs are not developed for all of the technology categories or focus areas that are verified by ETV. Some ETV centers and ESTE projects only develop GVPs after some testing has occurred.

The following issues may be addressed in the GVP:

- 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
- DQOs for verification tests
- QA/QC procedures
- use of existing data
- data handling
- requirements for other documents
- health and safety
- references

The QA/QC section of the GVP typically describes the activities that verify the quality and consistency of the work and provides data quality descriptors, such as accuracy, precision, representativeness, completeness, comparability, and detection limit, as appropriate. Preparation and use of appropriate QA procedures such as QC samples, blanks, split and spiked samples, and PEA samples to verify performance of the technology being tested can be described. Frequency of calibrations and QC checks and the rationale for them can be described. Procedures for reporting QC data and results can be given. Who is responsible for each QA activity, and who has the responsibility for identifying and taking corrective action can be specified. However, if

these items vary between tests within a given center, the more appropriate document in which to describe them may be the test/QA plan.

The GVP may cite documents or procedures that explain, extend, and/or enhance the GVP, such as related procedures, the published literature, or methods manuals. The specific location of any reference not readily available from a full citation in the reference section should be given (as in a facility-specific SOP) or attached to the GVP.

### 2.2.2 Test/QA plans

EPA Order 5360.1 A2 requires that quality systems provide for:

> " (7) Approved Quality Assurance Project Plans (QAPPs), or equivalent documents defined by the QMP, for all applicable projects and tasks involving environmental data with review and approval having been made by the EPA QAM (or authorized representative defined in the QMP). QAPPs must be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers."

Test/QA plans contain the following elements as given in *Guidance on Quality Assurance Project Plans, EPA QA/G-5*. In the ETV QMP, a test/QA plan is identical to a quality assurance project plan (QAPP). The GVP, if one exists, may be incorporated in the test/QA plan by reference. Not all elements listed in EPA QA/G-5 are appropriate to every test. The test/QA plan will note and explain those elements that are not applicable. EPA takes a graded approach to the level of detail expected in a test/QA plan. For highly visible programs such as ETV, a higher level of detail is expected.

Group A: Project Management
This group of QAPP 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 QAPP 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

Existing data can be addressed in QAPP Element B9. EPA Order 5360.1 A2 specifies that a QAPP (or equivalent document) be prepared for any project that generates or uses environmental data to support EPA's objectives. Chapter 3 of *Guidance on Quality Assurance Project Plans, EPA QA/G-5* provides guidance on the preparation of test/QA plans for projects that involve the use of existing data. The existing data policy for the ETV program is given in Appendix C of the ETV QMP (this document). The policy includes a format for QAPPs that exclusively deal with existing data.

Group C: Assessment/Oversight
The purpose of assessment is to ensure that the QAPP is implemented as prescribed. This group of QAPP 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 DQOs

#### 2.2.2.1 Delegation of review and approval of Test/QA plans

Upon a written request from the verification organization, EPA directors of quality assurance may delegate the responsibility for the review and approval of similar test/QA plans for a specific technology class to a verification organization. The following procedure will be followed for delegation:

- Any delegation of test/QA plan review and approval responsibilities from EPA to a verification organization is contingent upon the verification organization's demonstration that (1) it has a functioning quality system that has the same rigor and integrity as the EPA quality system and (2) that the verification organization quality manager is independent of the environmental data collection process. Such a demonstration may be

accomplished during the independent quality systems audits of verification organizations by EPA quality managers (see Section 4.1.1).

- The scope of the delegation will be for test/QA plans that are similar to and of the same technology class as a test/QA plan that has been previously reviewed and approved by EPA. The delegation will not extend across technology classes.

- Based on a discussion with the EPA Center QA Manager regarding review of the previously approved test/QA plan and of the verification organization's demonstration as described above, the EPA directors of quality of assurance may approve or reject the delegation of the test/QA plan review and approval responsibilities.

- The verification organization shall retain the original test/QA plans, the copies of their internal reviews, and the revised test/QA plans so that EPA can conduct an independent review of these documents, either simultaneously or after the fact.

- After the responsibility has been delegated to a verification organization and if the EPA directors of quality assurance determine that the quality of the verification organization's internal reviews was not meeting EPA's expectations, EPA reserves the right to rescind the delegation and/or cease signing the verification statements.

2.2.3 Standard operating procedures

If another level of detail is required for describing test activities, for example operation of an instrument, an SOP may be written and attached to the test/QA plan. The following topics, from *Guidance for Development of Standard Operating Procedures (SOPs),* EPA QA/G-6, may be included (or a reference provided) in the SOP:

- title page
- table of contents
- procedures - the following are topics that may be appropriate for inclusion in technical SOPs, but not all will apply to every procedure or work process detailed:
  -- scope & applicability (describing the purpose of the process or procedure and any organizational or regulatory requirements),
  -- summary of method (briefly summarizing the procedure),
  -- definitions (identifying any acronyms, abbreviations, or specialized terms used),
  -- health & safety warnings (indicating operations that could result in personal injury or loss of life and explaining what will happen if the procedure is not followed or is followed incorrectly; listed here and at the critical steps in the procedure),
  -- cautions (indicating activities that could result in equipment damage, degradation of sample, or possible invalidation of results; listed here and at the critical steps in the procedure),
  -- interferences (describing any component of the process that may interfere with the accuracy of the final product),
  -- personnel qualifications (denoting the minimal experience the SOP follower should have to complete the task satisfactorily, and citing any applicable requirements, like certification or “inherently governmental function”),

  - -- equipment and supplies (listing and specifying, where necessary, equipment, materials, reagents, chemical standards, and biological specimens),
  - -- 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 (such as extraction, digestion, analysis, identification, and counting procedures)
    - --- troubleshooting
    - --- data acquisition, calculations and data reduction requirements (such as listing any mathematical steps to be followed)
    - --- computer hardware and software (used to store field sampling records, manipulate analytical results, and/or report data), and
  - -- data and records management (e.g., identifying any forms to be used, reports to be written, and data and record storage information).
- quality control and quality assurance
  - -- QC activities to allow self-verification of the quality and consistency of the work
  - -- appropriate QC procedures (such as calibrations, recounting, reidentification), QC material (such as blanks - rinsate, trip, field, or method; replicates; splits; spikes; and PEA samples) that are required to demonstrate successful performance of the method
  - -- frequency of required calibration and QC checks and discuss the rationale for decisions
  - -- limits/criteria for QC data/results and actions required when QC data exceed QC limits or appear in the warning
  - -- procedures for reporting QC data and results.

# 3.0 IMPLEMENTATION OF PLANNED OPERATIONS

## *3.1 Implementation of planning*

*Environmental data operations shall be implemented according to the approved planning documents. Deviations shall be documented and reported to and evaluated by management. Approved changes shall be made and distributed to test personnel to replace previous versions of the documents.*

Technology performance verifications are implemented according to the GVPs and/or test/QA plans prepared during planning. During implementation, changes are incorporated, reviewed and approved according to the scheme discussed in Part A, Section 5.0. Test personnel have access to the approved planning documents, approved changes to planning documents, and all referenced documents. The final GVPs and/or test/QA plans are posted on the ETV web page for future use for similar technology verifications.

All implementation activities are documented. Suitable documents are bound notebooks, field and laboratory data sheets, spreadsheets, computer records, and output from instruments (both electronic and hardcopy). All documentation is developed as described in the planning documents. All implementation activities are traceable to the planning documents and to test personnel.

## *3.2 Services and items*

*Only qualified and accepted services and items shall be used in the performance verification operations. Acceptance shall be identified on the items themselves and /or in documents traceable to the items. Tools, gauges, instruments, and other sampling, measuring, and testing equipment used for activities affecting quality shall be controlled as required and, at specified intervals, calibrated to maintain accuracy with specified limits. Documentation of calibration shall be maintained and shall be traceable to the equipment. Periodic preventative and corrective maintenance of equipment shall be performed, and it shall be recalibrated prior to use.*

ETV program services are delivered by the verification organizations, which are accepted via the solicitation, proposal, and extramural agreement process as discussed in Part A, Section 4.0.

Qualified and accepted services and items used in testing are provided for in the verification organization quality systems. The ETV center QMP and ESTE project QMP or joint QMP/test/QA plan contain provisions for acceptance of services and items, and documentation of acceptance. Control of equipment, calibration to maintain accuracy within specified limits, maintenance, and documentation is the responsibility of the verification organization. The verification organization verifies that the tools, gauges, instruments, and any other sampling, measuring, and testing equipment used for activities affecting quality are controlled as required by the planning documents, and calibrated at specified intervals to maintain accuracy within specified limits. Equipment found to be out-of-specification is not used without documented repair and reassessment of performance. All maintained and repaired equipment is recalibrated as necessary before it is used for measurement work.

Oversight is the responsibility of EPA, and is conducted through review and acceptance of the verification organization quality system documents, the center/project QMP, and through

independent audits. All of the requirements for quality of goods and services on verification organizations pass through to their subcontractors, including compliance with the center or verification organization QMP. Verification agreements with subcontractors and analytical labs should include this and other relevant quality requirements. Verification organizations must provide oversight of subcontractors and analytical labs to insure QA requirements are met.

## *3.3 Field and laboratory samples*

*Handling, storage, cleaning, packaging, shipping, and preservation of field and laboratory samples shall be performed according to required specifications, protocols, or procedures to prevent damage, loss, deterioration, artifacts, or interference. Sample chain of custody shall be tracked and documented.*

If samples are taken in the field, they are to be handled according to procedures in the test/QA plan. The oversight responsibility of EPA is to determine that the approved QMPs and test/QA plans contain adequate procedures for handling, storage, cleaning, packaging, shipping, and preservation of field and laboratory samples to prevent damage, loss, deterioration, artifacts, or interference. The verification organization must provide adequate chain of custody procedures..

## *3.4 Data and information management*

*Data or information management, including transmittal, storage, validation, assessment, processing, and retrieval, shall be performed in accordance with the approved instructions, methods, and procedures.*

ETV program records and the procedures for handling them are listed in Part A, Section 5.0.

# 4.0 ASSESSMENT AND RESPONSE

## *4.1 Assessment types*

4.1.1 Quality Systems Audits

A quality systems audit (QSA) is an on-site review of the implementation of a verification organization quality system as documented in its center/project approved QMP. This review is used to verify the existence of, and to evaluate the adequacy of, the quality system. A QSA may be an internal assessment or an independent assessment. Because QSAs most effectively lead to the timely correction of identified problems when they are conducted early, they should be performed in the year following the start of a new center/project.. See Part A, Section 4.2 and Section 9.0 for required assessment frequency. Guidance is available for conducting QSAs may be found in EPA's *Guidance on Assessing Quality Systems (EPA QA/G-3).*

4.1.2 Technical Systems Audits

A technical systems audit (TSA) is a qualitative on-site evaluation of sampling and/or measurement systems. The objective of the TSA is to assess and document acceptability of all facilities, maintenance, calibration procedures, reporting requirements, sampling and analytical activities, and quality control procedures. An approved test/QA plan provides the basis for the TSA. Internal TSAs are conducted by the verification organization quality managers and independent TSAs are conducted by EPA quality managers as required by Part A, Section 9.0. Assistance for the TSA may be available to EPA quality managers from QA support contractors. TSAs are most useful when conducted early in the life cycle of a project when corrective actions (if necessary) can be performed that will minimize any loss of data. Guidance for conducting TSAs may be found in EPA's *Guidance on Technical Audits and Related Assessments for Environmental Data Operations (EPA QA/G-7).*

4.1.3 Audits of Data Quality

An audit of data quality (ADQ) is an examination of a set of data after it is collected and 100% verified by project personnel, consisting of tracing at least 10% of the data from original recording through transferring, calculating, summarizing and reporting. (Note: “10% of the data” means a random selection of 10% of the data from all of the measured parameters.) Assessing whether the data quality indicator (DQI) goals specified in the test/QA plan were met requires a detailed review of the recording, transferring, calculating, summarizing, and reporting of the data. ADQs are conducted as required by Part A, Section 9.0. Internal ADQs are conducted by the verification organization quality managers. Independent ADQs are conducted by EPA quality managers. Assistance for the ADQ may be available to EPA quality managers from QA support contractors. Guidance for conducting ADQs may be found in EPA QA/G-7.

4.1.4 Performance Evaluation Audits

A performance evaluation audit (PEA) is a quantitative evaluation of a measurement system. Although each measurement in a test program could be subjected to a performance evaluation, the critical measurements (designated in the test/QA plan) are more commonly evaluated. An evaluation of a measurement system usually involves the measurement or analysis of a reference

material of known value or composition. The value or composition of reference materials must be certified or verified prior to use, and the certification or verification must be adequately documented. Ideally, the identity of the reference material is disguised so that the operator or analyst will treat the material no differently than a test program sample. PEAs are conducted as required in Part A, Section 9.0. Guidance for conducting PEAs may be found in *Guidance on Technical Audits and Related Assessments, EPA QA/G-7*.

## *4.2 Assessment frequency*

*Activities performed during technology verification performance operations that affect the quality of the data shall be assessed regularly, and the findings reported to management to ensure that the requirements stated in the GVPs and the test/QA plans are being implemented as prescribed.*

Because of the high visibility of ETV testing, the systematic planning should provide sufficient auditing to insure the integrity of the data. The types and minimum frequency of assessments for the ETV programs are listed in Part A, Section 9.0. The target minimum types and numbers of assessments for verification tests are the following:

- QSAs - internal assessments by verification organization within one year after approval of the initial QMP, then as requested by EPA , and independent assessments by EPA, within one year after approval of the initial QMP, then every three years; or as needed
- TSAs - internal assessments by verification organization for each test and independent assessments by EPA at a minimum of once per year per center/project;
- PEAs - If a test is capable of being quantitatively audited and if suitable PEA samples can be prepared, internal assessments by verification organization for each test and independent assessments by EPA yearly for each center/project
- ADQs - internal assessments by verification organization of at least 10% of all the verification data from each test; and independent assessment by EPA at a minimum of once per year per center/project

In cases where the target minimums appear to be excessive to the EPA quality managers, their professional judgment will prevail. Additional assessments may be included in individual test/QA plans. Assessments by the verification organization will occur on a continuous and stable level as provided in Table 9.1.

Assessments shall occur when verification testing is at a stage where auditing is feasible. Assessments are most effective early in a verification test so that corrective action may be taken before the project has been completed and before all environmental data have been collected. It is better for an auditor to report earlier so that a verification test can generate better data rather than to report later when corrective action is no longer possible.

ETV center project officers, ESTE project managers, and EPA quality managers may receive and review, on a routine basis, verification organization internal assessment reports and subcontractor internal assessment reports provided by verification organizations.

## *4.3 Response to assessment*

*Appropriate corrective actions shall be taken and their adequacy verified and documented in response to the findings of the assessments. Data found to have been taken from non-conforming equipment shall be evaluated to determine its impact on the quality of the data. The impact and the action taken shall be documented.*

Assessments are conducted according to procedures contained in the verification organization quality systems or the quality procedures available to EPA personnel, as discussed in Part A, Section 9.0. Findings are provided in audit reports. Responses to adverse findings are required within 10 working days of receiving the audit report. Follow-up by the auditors and documentation of response are required.

# 5.0 ASSESSMENT AND VERIFICATION OF DATA USABILITY

## *5.1 Data verification and validation*

*Data obtained during verification tests shall be assessed, verified, and qualified according to their intended use (as verification performance data). Any limitations on this intended use shall be expressed (quantitatively to the extent practicable) and shall be documented in the ETV verification report.*

Data are verified by the data collector. The goal of data verification is to ensure and document that the data are what they purport to be (i.e., the reported results reflect what actually was done). When deficiencies in the data are identified, then those deficiencies should be documented for the data user's review and, where possible, resolved by corrective action. Data verification applies to activities in the field as well as in the laboratory. Data verification procedures are specified in the center/project QMP. Validated data are reported in ETV verification reports and ETV verification statements along with any limitations on the data and recommendations for limitations on data usability. All validated data arising from testing under the ETV program are disclosed in verification reports, even if the technology did not perform to the expectations of the technology provider. EPA provides guidance for writing test/QA plans in *Guidance on Environmental Data Verification and Data Validation, EPA QA/G-8.*

## *5.2 Existing data*

*Any data obtained from sources that did not use a quality system equivalent to the ANSI/ASQC E4-1994 Standard shall be assessed according to approved and documented procedures.*

Existing data may be used for planning and other purposes (e.g., to augment verification testing), subject to rules set up by each center. Although the centers need to establish the quality of these data, as required under EPA Order 5360.1, no ETV-wide guidelines are necessary for the use of existing data for purposes other than for use in ETV verification reports and statements. Existing data used in ETV verification reports and statements that are collected outside the ETV program are subject to rigorous scrutiny according to the procedure in Appendix C.

## *5.3 Reports reviewed*

*ETV verification reports containing data and reporting the results of technology verification performance shall be reviewed independently (i.e., by others than those who produced the data or the reports) to confirm that the data or results are presented correctly. These reports shall be approved by management prior to release, publication, or distribution.*

The procedure for ETV verification report and ETV verification statement review and approval is given in Part A Section 5.0. ETV verification reports and statements are peer-reviewed by the EPA ORD peer review process. ETV verification statements are signed by the respective EPA laboratory directors and the verification organization representative.

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# APPENDIX A: U.S. EPA RECORDS CONTROL SCHEDULE

Applicable records schedules include the following:

| EPA Series No. | Title |
|---|---|
| 003 | Grants and Other Program Support Agreements |
| 006 | Program Management Files (Agency-wide All Programs) |
| 185 | Quality Assurance Project Plans (Agency-wide All Programs) |
| 202 | Contract Management Records (Agency-wide All Programs except Superfund Site Specific) |
| 258 | Final Deliverables and Reports (Agency-wide All Programs) |

Consult the National Records Management Program (NRMP) website (http://www.epa.gov/records/index.htm) for the most recent information on EPA records management**.**

# APPENDIX B: WHAT CONSTITUTES SUCCESS FOR ETV?

## *B.1 Timing*

- For ETV centers, no more than one year for verification organization selection.
- For ETV centers, no more than one year after verification organization selection for completing the organizational phase (i.e., stakeholder selection, technology prioritization, initial GVP and/or test/QA plan development, approval of GVPs and/or test/QA plans).
- For each ETV center and ESTE project verification test, no more than twelve months between vendor agreement and draft final report (excluding the duration of the test)
- No more than two months for EPA approval and one month for publication.

## *B.2 Outcomes*

- EPA client offices use ETV information in mandatory and voluntary compliance and technology assistance programs
- Significant number of States accepts ETV data for permitting.
- Significant number of consulting engineers use ETV data for making technology recommendations.
- Significant number of vendors report a positive experience in ETV.
- Vendors return to test additional technologies under ETV.
- Applications for testing exceed ETV capacity.
- Website survey show positive response. Web site use increases over time
- Vendor sales data; technology use data.

# APPENDIX C: EXISTING DATA POLICY

## *C.1 Background*

Consistent with the Agency's commitment to increasing efficiency, ETV seeks to identify optimal methods to verify environmental technologies without compromising quality or ETV's independence. One consistent request made by ETV's stakeholders and others has been that existing data (i.e., data collected from outside of ETV) be used for ETV verification. This suggestion is reinforced by the programs of individual states, as well as those of other countries, that routinely consider previously collected data in the verification of vendor claims for a technology. It is also consistent with EPA Order 5360.1, which states:

> "establishes the policy and program requirements for the preparation and implementation of organizational or programmatic management systems pertaining to quality and contains minimum requirements for the mandatory Agency-wide Quality System."

The Order requires that the Quality System provide for:

> "(8) Assessment of existing data, when used to support Agency decisions or other secondary purposes, to verify that they are of sufficient quantity and adequate quality for their intended use."

*Guidance for Quality Assurance Project Plans, EPA QA/G-5* defines existing data as follows:

> "Existing data are data or information that you plan to use that have not been newly generated by your project. They may also be known as secondary data or non-direct measurement."

Compelling arguments exist for using qualified existing data to replace some or all of the data that could be generated under ETV testing and evaluation. Because resources are limited and verification testing is both time-consuming and costly, ETV is able to test a limited number of technologies per year. Further, verification tests can, at best, show the performance of the technology under only limited conditions and limited time periods. Since many technologies have been tested numerous times both before and after reaching a commercially viable stage of development, it is possible that existing data could be used to increase and enhance the scope of center verification tests, with acceptably reproducible and accurate results. A well-developed policy for using existing data could also allow the ETV program to establish reciprocity agreements and exchange data with other testing organizations interested in verifying technology performance using an existing GVP or test/QA plan.[1] These agreements could leverage ETV's ability to verify innovative technologies, increasing the number of technologies verified.

Recognizing that it is neither prudent nor cost-effective to ignore existing data, ETV establishes by this appendix its guidelines for using existing data.

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[1] This includes GVPs or test/QA plans that are jointly developed with other testing organizations and subsequently "adopted" by ETV.

## *C.2 Requirements for reviewing and usinge existing data*

Because the consequences of a serious verification decision error can include the verification of fraudulent claims, litigation, and loss of credibility for ETV, the verification organizations and EPA, it is essential that the data considered as a replacement for verification testing undergo a rigorous process of evaluation using stringent criteria. Thus, in addition to specific requirements for reviewing existing data and ensuring that the origin and quality of the data on which the verification statement rests are known and documented, this appendix also includes minimum acceptance criteria for using existing data to replace verification testing. Table C-1 contains a list of documentation that must be provided to the verification organization to support an existing data review.

**Table C-1. Documentation Needed for an Existing Data Review**

| |
|---|
| Documentation to confirm the third-party testing organization's independence from the vendor |
| Documentation to assess the adequacy of the quality system employed by the third-party testing organization responsible for collecting the data |
| Copies of the protocols and test plans used to collect the existing data |
| A data report containing the data, including associated metadata, that the vendor proposes to be used in place of verification testing. This report will clearly identify which performance objectives/factors found in the test/QA plan are requested to be verified using the existing data. This report must also: (1) explain any qualifications to these data; (2) identify which data were excluded and provide an explanation regarding how and why the data were excluded; (3) identify any organization-specific, legal, or security specifications for the use of the data (e.g., confidential business information); and (4) address other requirements specific to the center. |
| A complete list of all the data and QA/QC data obtained by the third-party testing organization* |
| Letters from the vendor and the third-party testing organization stating that they have disclosed all relevant data that were obtained during the testing of the technology and that the third-party verification organization has accurately reported the quality system employed during testing. |
| A letter from the vendor stating that it has accurately reported the relationship between the vendor and third-party testing organization. |

*A complete set of the data obtained by third-party testing organization will not need to be provided. The vendor must ensure, however, that the verification organization or EPA technical and QA staff (as appropriate) will be able to visit and review the data at the third-party testing facility upon request. The verification organization will be responsible for storing only the data the verification organizations actually used to verify the technology's performance for a minimum of seven years after the final payment of the extramural agreement to the verification organization.

Because technical and monetary resources are limited, centers/projects and EPA need to carefully assess whether an existing data review is an appropriate use of verification organization and EPA resources. Priority consideration will be given to:

- Data submitted for review that were generated by a testing organization that has an agreement with EPA establishing reciprocity requirements with ETV.
- Vendors that want to have data reviewed for a previously verified technology that has either been: 1) tested under different test/operating conditions; or 2) updated and retested to demonstrate changes in the performance of the technology relative to the initial verification.
- Vendors that applied too late to be included for the most recent verification testing on a specific technology category, assuming no additional rounds of testing are anticipated.

The vendor should also be prepared to cover the total cost of the existing data review, including the generation of the test/QA plan and any QA reviews and assessments that may need to be performed.

The following subsections address the major requirements for an existing data review.

### C.3.1 EPA personnel must be notified when a center/project or an ESTE project is considering using existing data to replace verification testing.

EPA personnel, including the ETV director and appropriate EPA QA managers, must be notified when an ETV center or an ESTE project is considering using existing data to partially or totally replace verification testing.

### C.3.2 A test/QA plan, or an amendment to an appropriate existing GVP and/or test/QA plan, will be used to direct the data review effort.

EPA Order 5360.1 A2 specifies that a QAPP, or equivalent document defined by an organization's QMP, must be prepared for any project that generates or *uses* environmental data to support EPA's objectives. To comply with this requirement either a test/QA plan or an amendment to an existing GVP or test/QA plan must be developed to direct the data evaluation effort. This plan will need to go through a review and approval cycle that meets ETV and center/project QMP requirements.

Project personnel should refer to *Guidance for Quality Assurance Project Plans*, EPA QA/G-5 and *Guidance on Environmental Data Verification and Data Validation, EPA QA/G-8,* when developing and reviewing the test/QA plan. Chapter 3 of EPA QA/G-5 contains guidance for projects using existing data and identifies possible changes that could be made to different project plan elements (e.g., for project management, data generation and acquisition, assessment and oversight, and data validation and usability) when existing data are used. EPA QA/G-8 contains guidance to help organizations conduct data verification and data validation activities.

The test/QA plan must clearly identify the intended use of the existing data (e.g., to verify the performance of a technology through the evaluation of specific performance objectives/factors)

and the data quality specifications (e.g., DQOs) used to determine whether the data are of sufficient quality to support their intended use. The plan should also identify the specific procedures that will be followed to perform and document the review and verification process, including the following:

- the procedures to be used by the verification organization to assess the third-party testing organization's independence from the vendor and the controls that were in place to prevent the vendor from influencing the outcome of testing, since only data collected objectively and independently of the vendor may be used to replace verification testing
- the process to be used by the verification organization to assess whether the quality system employed by the third-party testing organization (laboratory or agency) responsible for collecting the data meets the requirements established for ETV
- The procedures to be used by the verification organization to confirm that the GVP or test/QA plan used to collect the existing data was "equivalent" to an existing GVP or test/QA plan[3]
- The specific acceptance criteria associated with using the existing data to verify the performance of the technology (e.g., specific performance objectives/factors identified in the GVP and test/QA plan used to collect the existing data), including the data quality specifications
- The procedures to be used by the verification organization to assess whether the existing data meet ETV's data quality specifications (e.g., DQOs) referenced in the test/QA plan
- Other important features of data quality, such as the level of peer review and the quantity of data that are flagged
- The roles, responsibilities, and qualifications of the different parties involved in reviewing the existing data

The following format can be used for test/QA plans that deal exclusively with existing data:

Section 1.0, Project Objectives, Organization, and responsibilities

1.1 The purpose of study shall be clearly stated.

1.2 Project objectives shall be clearly stated.

1.3 The existing data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

[3] This will not need to be addressed if an existing GVP or test/QA plan was used to collect the existing data.

Section 2.0, Sources of Existing Data

2.1 The source(s) of the existing data must be specified. 2.2 The rationale for selecting the source(s) identified shall be discussed.2.3 The sources of the existing data will be identified in any project deliverable.

Section 3.0, Quality of Existing Data

3.1 Quality requirements of the existing data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the existing data shall be described.

Section 4.0, Data Reporting, Data Reduction, and Data Validation

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (e.g., journal article, final report, etc.).

If an appropriate existing GVP or test/QA plan is not available for the technology category under consideration, and thus not available to serve as the basis for performing an existing data review, an ETV center or ESTE project manager can either:

- Refuse to review the data based on the fact that an appropriate GVP or test/QA plan does not currently exist, or
- Develop (with stakeholder and EPA input) a preliminary list of performance objectives/factors for evaluation and possible data needs, assuming that EPA, verification organization, stakeholders, and vendor support the eventual generation of an GVP or test/QA plan for that technology category.

If, after reviewing the preliminary list of performance objectives/factors and data needs, the vendor is still interested in pursuing an existing data review, the verification organization will proceed with developing a GVP for that technology category with input from the stakeholders and ETV center management or EPA ESTE project management.[4] The new GVP or test/QA plan will serve as the basis for evaluating whether the data/technology meets the same data quality specifications as the data collected in a comparable ETV/ESTE verification test. The vendor will be liable for some or all of the cost of protocol development.

[4] In general, EPA center management consists of the ETV center project officer and EPA quality manager and EPA ESTE project management consists of the ESTE project manager and the EPA quality manager.

### C.3.3 The data were objectively and independently collected by a third-party testing organization.

The verification organization must be provided with written documentation by the third-party testing organization demonstrating its independence from the vendor. This information will need to be made available to the public, preferably through an electronic link to a public information domain.

The verification organization must confirm that the third-party testing organization that collected the data is independent of the vendor and that controls were in place to prevent the vendor from influencing the outcome of the testing. The verification organization will also need to determine whether the third-party testing facility is free from any outside influences -- monetary, organizational, commercial, or otherwise -- which could potentially be perceived as biasing the integrity of the test and the impartiality of the third-party testing organization. If the existing data were collected by the verification organization but not during an ETV-related effort, the verification organization will need demonstrate that no organizational or other conflict exists that could be perceived as biasing the verification organization's ability to impartially review the existing data. The verification organization will need to provide EPA with a written explanation supporting this claim, which EPA personnel, including the ETV center project officer or ESTE project manager, the ETV director and appropriate EPA QA personnel, will review to determine whether the verification organization has successfully demonstrated that no actual or potential bias exists. If EPA believes that the verification organization has not successfully addressed this issue, the existing data cannot be used for verification unless an impartial third-party with the capabilities to perform the review (e.g., another verification organization) can be identified.

The consequences of inaccurately or falsely reporting the relationship between the vendor and the third-party testing organization may include the revocation of the verification, removal of the verification statement and report from the ETV Web site, and the release of an broad announcement by the verification organization stating that the verification has been revoked.

### C.3.4 The quality system employed by the third-party testing organization during the collection of the data meets ETV requirements.

Only data collected under a well-defined, documented quality system will be considered for verification. The verification organization must be provided with written documentation by the third-party testing organization describing the quality system employed during the generation of the existing data. The verification organization will review this documentation to determine whether the quality system meets ETV requirements. Quality systems that *conform* to, or are *modeled* (see next sentence for further clarification) after, ANSI/ASQC Standard E-4, 1994 or ISO Standard 9001:2000 have been determined to meet ETV requirements. When a testing organization's quality system is *modeled* after one of the above standards, a point-by-point analysis may need to be performed to determine whether the quality system used to collect the existing data meets ETV's quality system requirements (i.e., ANSI/ASQC Standard E-4, 1994 or ISO Standard 9001:2000). It is also possible that a quality system and/or technical systems audit

may also be performed as part of the existing data review, at the EPA's or the verification organization's request.

In the event that either the verification organization and/or EPA center management or EPA ESTE project management determine that the documentation is insufficient to assess whether the third-party testing organization's quality system or technical systems meets ETV QA requirements, the verification organization, EPA center management, or EPA ESTE project management will either:

- Discontinue the existing data review based on the fact that appropriate quality system or technical system documentation was not provided, or
- Perform an independent on-site assessment of the third-party testing organization's quality system and/or technical systems.

Such assessments will parallel EPA's assessments of verification organizations and verification organization's assessments of its subcontractors.

The consequences of inaccurately or falsely reporting the quality system employed by the third-party testing organization may include the revocation of the verification, removal of the verification statement and report from the ETV Web site, and the release of a broad announcement by the verification organization stating that the verification has been revoked.

### C.3.5 The data were collected using either an existing GVP or test/QA plan *or* an "equivalent" protocol or test/QA plan developed outside of ETV that clearly and comprehensively describes the procedures used to test the technology, collect and analyze the data, and ensure data quality.

The verification organization, the ETV center project officer or ESTE project manager, and EPA QA managers must be provided with copies of the GVP, the test/QA plan and/or other written documentation used by the third-party testing organization to generate the existing data. If the testing organization used an existing GVP or test/QA plan to collect the existing data, this documentation will be reviewed to determine whether the testing organization properly implemented the GVP or test/QA plan during the tests.

If the third-party testing organization did not use an existing GVP or test/QA plan, a point-by-point comparison must be made by the verification organization quality manager between the "equivalent" test plan used to collect the existing data and the existing GVP or test/QA plan. This review will assess whether the procedures in the testing organization's test plan meet the data quality and usability requirements referenced in the corresponding ETV documents. This review will assess all the QAPP elements listed in Section 2.2.2 of Part B of the ETV QMP.

When similar but different sampling and analytical methods were used by the third-party testing organization (e.g., to collect, analyze, review, or reduce the data), method validation needs to be provided to confirm that the methods will be adequate for the intended use of the data. Project personnel should refer to Section 2.2.4 of *Guidance for Quality Assurance Project Plans, EPA QA/G-5* for information about method validation data. After this validation is completed, the

verification organization must document the dissimilarities, whether the verification organization considers the methods to be equivalent and why, and possible impacts these dissimilarities could have on the data and evaluation of the performance objectives/factors.

### C.3.6 The data are of sufficient quality and quantity to verify the technology's performance, as determined by the performance objectives/factors, QA/QC requirements, and data quality specifications referenced in the test/QA plan.

The third-party testing organization must provide a data package/report that is of sufficient quantity and quality to support the evaluation of the technology's performance. The verification organization should also receive letters from both the vendor and the third-party testing organization stating that they have disclosed all relevant data that were obtained during the testing of the technology. These letters are designed to ensure that partial data sets reflecting unusually high levels of performance (e.g., data sets that are not representative of the system's true or typical performance) are not sent for review.

During the existing data review, the verification organization will determine whether the dataset is complete, preferably during an on-site visit to the third-party testing organization. The verification organization will assess whether sufficient information is available on the source of the data and their quality specifications. They will also confirm that the data appear to have been collected following the protocols and test/QA plans provided by the vendor or the third-party testing organization.

The verification organization must also perform an independent ADQ for 10 percent of the existing data. This random selection of data points is traced from the raw data set to the final report. Section 4 of Part 2 of the ETV QMP discusses ADQ requirements. This audit can either be performed at the verification organization's facility or the third-party testing organization's facility, as convenient for both parties.

The verification organization should also document how well the data meet the acceptance criteria in the test/QA plan for different performance objectives and whether the QA/QC requirements and data quality specifications in the test/QA plan have been met. This documentation should also describe which performance objectives were adequately addressed by the existing data and which were not, as well as any caveats that must be attached to the data.

The verification organization will be responsible for storing only the raw data actually used to verify the technology's performance for a minimum of seven years after the final payment of the extramural agreement to the verification organization. If the data were reviewed under an unfunded agreement with EPA, the verification organization will be responsible for storing the raw data used to verify the technology's performance for a minimum of seven years after the verification report is issued. The consequences of submitting false, inaccurate, or incomplete data packages may include the revocation of the verification, removal of the verification statement and report from the ETV Web site, and the release of a broad announcement by the verification organization stating that the verification has been revoked.

### C.3.7 The minimum acceptance criteria identified in Table C-2 must be satisfied to use existing data in a verification report and statement.

After completing the review, the verification organization must determine whether the criteria in Table C-2 have been met. If these criteria gave been met, the existing data can be used, either alone or in combination with verification testing results, to verify the performance of the technology. The verification organization must ensure that *all* of the critical measurements and data quality specifications identified in the existing GVP or test/QA plan are fully addressed before developing a verification statement and report. "Partial" verification reports and statements must not be generated.[5]

In addition to reporting on the performance of the technology as determined during the existing data review, the verification report must identify which performance objectives were addressed by the existing data and which were not. The report must also include any caveats that need to be attached to the data. The EPA quality manager and the ETV center project officer or ESTE project manager will review the data and determine whether can be used to replace verification testing during their review of the verification report.[6] EPA center management and ESTE project management will need to confirm that the criteria outlined in Table C-2 have been met before EPA can approve the verification report or statement.

**Table C-2. Minimum Acceptance Criteria for Existing Data**

| Criteria |
|---|
| Data were collected objectively by an independent third-party testing organization. |
| Data were collected using GVPs and test/QA plans provided to the verification organization |
| The quality system employed by the third-party testing organization during the collection of the data meets ETV requirements. |
| The GVP or test/QA plan used to collect the data is “equivalent”* to the existing ETV verification protocol or test/QA plan. |
| The data are quality assured and meet the minimum QA/QC requirements and data quality specifications referenced in the test/QA plan. |
| The data meet the acceptance criteria referenced in the test/QA plan. |
| The data are of sufficient quality and quantity to verify the technology’s performance, as determined by the performance objectives/factors referenced in the test/QA plan. |

* Equivalence will be determined relative to the critical measurements and data quality specifications

[5] Some the ETV test/QA plans or protocols may state that the vendor or center can choose: (1) a subset of critical factors/objectives; or (2) a subset of specific conditions/sites. This may need to be considered during the existing data review.

[6] EPA’s involvement in the existing data review may occur earlier in the data review and reporting process, at the discretion of the EPA quality manager, the ETV center project officer, or the ESTE project manager.

### C.3.8 Data Evaluation Panel Review

If the VO determines that the criteria listed in Table C-2 have been met, a Data Evaluation Panel (DEP) may be formed at the verification organization's or EPA's request. The DEP will consist of at least four qualified members: a verification organization representative[7], the ETV center project officer or ESTE project manager, the EPA quality manager (and/or an appropriate designee, if the EPA quality manager performed portions of the data review), and an outside expert. (Note: The outside expert can be an EPA employee who is not a member of the ETV team.) The members of the DEP must be credible, experienced, knowledgeable, and qualified in the technical area critical to the technology being evaluated. DEP members must also be free of any real or perceived conflict of interest with the commercial vendor of the technology they are evaluating and cannot have been involved in the collection of the data being evaluated. The ETV center project officer or ESTE project manager, EPA QA representative, and the outside expert also cannot have been directly involved in the actual existing data review.

After the DEP is formed, the verification organization will forward the following to the panel:

- The test/QA plan (including deviations)
- A data review report documenting the verification organization 's findings and whether the criteria in Table C-2 have been met, including how well the data meet the acceptance criteria and data quality specifications (e.g., DQOs) referenced in the test/QA plan.
- Appropriate sections of the original data package.

The panel will review these materials and determine:

- Whether they agree with the verification organization 's conclusions/recommendations
- Whether they believe that these conclusions/recommendations are adequately supported by the review performed by the center.

The DEP's evaluation shall follow the procedures and criteria developed by the verification organization and EPA for other technology verifications conducted by the center.

The verification organization will be given the opportunity to respond with opposing recommendations, either alone or after contacting the third-party testing organization for clarification. The verification organization can only proceed with verifying the technology using existing data if the DEP concurs with its recommendation.

[7] Although a verification organization representative will serve as a member of the DEP, this representative will not be responsible for evaluating/commenting on the quality of the existing data review and conclusions/recommendations generated during the data review process. This representative will instead answer any questions that other DEP members have and respond to their comments.

### C.3.9 References

*American National Standard Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*. ANSI/ASQC E4-1994. Milwaukee WI: American Society for Quality, 1994.

*Quality Management Systems—Requirements*. ISO 9001:2000. Geneva Switzerland: International Organization for Standardization (ISO), 2000.

*Guidance for Developing Quality Systems for Environmental Programs (QA/G-1)*, EPA/240/R-02/008 Washington DC: U.S. Environmental Protection Agency, 2002.

*Guidance on Environmental Data Verification and Data Validation (QA/G-8)*, EPA/240/R-02/004, Washington DC: U.S. Environmental Protection Agency, 2002.

*Guidance for Quality Assurance Project Plans (EPA QA/G-5)*, EPA/240/R-02/009, Washington DC: U.S. Environmental Protection Agency, 2002.

*Policy and Program Requirements for the Mandatory Agency-wide Quality System*. EPA Order 5360.1 A2. Washington DC: U.S. Environmental Protection Agency, 2000.

# APPENDIX D: RECOMMENDED LANGUAGE FOR SOLICITATION OF VERIFICATION ORGANIZATIONS

Verification organizations in the ETV program are solicited via CAs, IAGs, or contracts. Appropriate language must be incorporated into the solicitation and/or the award/agreement documentation by the Grants Administration or Contracts Management. The following language and supporting documentation are recommended to be included in the solicitation for the verification organization, whether competitive or non-competitive.

**Quality Assurance Requirements**

The awardee shall comply with the following:

Before award, the proposal shall include a copy of the offerer's QMP describing the quality system that provides the framework for planning, implementing, and assessing work performed to carry out the required QA and QC activities.

After award, the awardee must submit a QMP prepared in accordance with the *EPA Requirements for Quality Management Plans (QA/R-2)* and the requirements as described in the latest version of the ETV QMP. The center QMP must be approved by the ETV center project officer or ESTE project manager and EPA quality manager before testing begins.