



REVIEW OF EPA'S ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM

**REVIEW BY THE TECHNOLOGY
EVALUATION SUBCOMMITTEE OF
THE ENVIRONMENTAL
ENGINEERING COMMITTEE (EEC)**

August 16, 2000

EPA-SAB-EEC-00-012

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Review of EPA's Environmental Technology Verification Program

Dear Ms. Browner:

The Technology Evaluation Subcommittee of the Science Advisory Board's (SAB) Environmental Engineering Committee met March 6-8, 2000 in Washington, DC to review the degree to which quality management is incorporated into the Environmental Technology Verification (ETV) program. The SAB reviewed a proposed framework for this program in 1995 (SAB, 1995) and the Agency's Quality Program (SAB, 1998) and its implementation (SAB, 1999) in 1998. Both the Agency and the SAB agree on the major elements of the Agency's Quality System; the challenge has been its implementation. This letter summarizes the evaluation of the Technology Evaluation Subcommittee while the attached report describes the Subcommittee's views in greater detail.

The ETV is a pilot program designed to test different approaches to environmental technology verification. ETV has tested, or has tests underway for, 150 technologies. Because the technologies addressed are diverse, as are their applications, ETV has made extensive use of stakeholders and technical panels to design testing protocols to assure the data quality needs of the customers for the data are met.

Overall, the ETV program effectively incorporates the Board's 1995 recommendations; the Subcommittee considers the ETV program fundamentally sound and valuable. Moreover, the ETV program has successfully adopted major elements of the Agency's Quality System early, well, and with enthusiasm. While additional Quality System requirements remain to be adopted by the ETV program, what has already been implemented is commendable. The Subcommittee is optimistic that the ETV program's proven success implementing an effective Quality System in a geographically and organizationally diverse and decentralized program will encourage other Agency programs to embrace the Quality System.

In this letter, the Subcommittee would like to highlight three important issues. First, environmental protection still requires the use of effective technologies based on sound scientific principles. As environmental protection moves beyond command-and-control, end-of-pipe solutions to more decentralized and sustainable approaches, the number and variety of decision-makers increase. By encouraging the development and evaluation of innovative technologies, EPA broadens the options available to decision-makers. Programs such as ETV that address the market for credible information on technologies aimed at reducing or eliminating environmental risks are important and will remain so for the foreseeable future.

Second, while the overall framework for the implementation of the ETV program's quality and management plan is in place and functioning, three aspects of the Quality System require more consistent implementation.

- a) The ETV program must consistently employ a systematic data quality planning approach, such as the Data Quality Objective Process (EPA QA/G-4), during the development of generic test protocols and technology specific Test/QA plans.
- b) The verification testing should be a function of the inherent performance variability of a specific technology.
- c) The ETV verification partners and their subcontractors must all fully comply with the Agency's quality system.

Finally, a policy issue directly impacts the ETV program's credibility. This is the option that, at any time, a technology vendor may voluntarily withdraw a product prior to the completion of verification testing provided the government is reimbursed for any incurred costs. The availability of this option means that, if the verification data demonstrate that the technology does not perform as anticipated or advertised, the vendor may effectively "buy back" that data thereby canceling the Agency's disclosure of the technology's performance. In fairness to the ETV program, this policy does not adversely affect the quality of any data actually issued through Agency approved technology verification reports. Furthermore, when the ETV program itself was new and untried, this policy may have encouraged vendor participation. Finally, this option has only been invoked once in over 150 tests completed or underway. Nevertheless, the Subcommittee is convinced that the prerogative of vendors to suppress the disclosure of an unflattering technology evaluation through financial reimbursement detracts from the overall credibility of the ETV program. The Subcommittee, therefore, encourages a modification in program policy.

In summary, the Subcommittee recognizes the ETV program as being largely successful in meeting its goal of generating credible and impartial verification data on environmental technology performance. The Subcommittee attributes this to the program's implementation of

the Agency's Quality System, the effective use of stakeholder advisory groups and the dedication of the ETV program personnel. The Subcommittee looks forward to your response to the advice contained in this report.

Sincerely,

/s/

Dr. Morton Lippmann, Interim Chair
Science Advisory Board

/s/

Dr. Hilary I. Inyang, Chair
Environmental Engineering Committee
Science Advisory Board

/s/

Dr. Michael J. McFarland, Chair
Technology Evaluation Subcommittee
Environmental Engineering Committee

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ABSTRACT

The Technology Evaluation Subcommittee of the Science Advisory Board's (SAB) Environmental Engineering Committee reviewed the extent to which quality management is incorporated in the Environmental Technology Verification (ETV) program.

The Agency's Quality System and ANSI/ASQC E-4 provide an effective framework within which the Environmental Technology Verification (ETV) program has established a multi-tiered quality assurance oversight system. The ETV program has ensured that the appropriate technology verification factors and level of quality management are consistent with marketplace demands by the extensive use of stakeholder advisory groups.

The Subcommittee recommended that the generic test protocols and Test/QA plans be improved by consistent employment of a systematic data quality planning process such as the DQO process (EPA QA/G-4). Consistent use of a systematic data quality planning process will ensure that future verification tests will be designed that reflect the inherent variability in technology performance.

To protect the credibility of the ETV program, verification partners and their subcontractors must comply with the same quality assurance requirements adopted by the Agency.

Keywords: environmental, technology, verification, quality

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1. EXECUTIVE SUMMARY

The Technology Evaluation Subcommittee of the Science Advisory Board's (SAB) Environmental Engineering Committee met March 6-8, 2000 in Washington, DC to review the degree to which quality management is incorporated into the Environmental Technology Verification (ETV) program. In this review, the Subcommittee considered the applicability of the ANSI/ASQC E-4 standard; Agency policy, requirements, and guidance; and the experience of the Subcommittee. Appendix A lists the documents reviewed by the Subcommittee including the ETV quality and management plan and quality documents for seven completed pilot studies. The latter included documents such as pilot quality and management plans, generic test protocols and technology specific Test/QA plans. Appendix B is a brief summary of selected documents in EPA's Quality System. Please note that, in this report, the Subcommittee has used the word "Agency" when describing Agency level activities and decisions, such as the Agency's Quality System, policies and requirements. The Subcommittee has reserved the words "ETV program" for decisions and activities within that program.

The Agency's Quality System and ANSI/ASQC E-4 consensus standard provide an effective framework within which the Environmental Technology Verification (ETV) program has established a multi-tiered quality assurance oversight system. In summary, the ETV program has effectively implemented major portions of the Agency's Quality System. ETV has made excellent use of stakeholder advisory groups in establishing technology specific verification factors acceptable to both users of and permit writers for environmental technologies. Because the stakeholder advisory groups have been beneficial, the Subcommittee suggests that the Agency capture its experience in the form of guidance on how future stakeholder advisory groups should be constituted and their specific role in verification test development.

The Subcommittee recommends that the Agency consistently employ a structured data quality planning process such as the Agency's DQO process (EPA QA/G-4) to develop generic test protocols and Test/QA plans. Use of a systematic data quality planning process ensures that the decision-maker's needs are appropriately considered in the development of verification testing procedures and in the reporting of verification test results. In this case, those needs include the environmental marketplace's requirements for a minimum technology performance standard and understanding technology performance variability

Finally, the Subcommittee was alarmed to discover that some ETV verification partners and their subcontractors are convinced that their ETV data collection activities are not subject to the same quality assurance requirements adopted by the Agency. The Agency's Quality System mandates that specific quality requirements be implemented whenever environmental data are collected for or on behalf of the EPA without regard to whether the data collection activity was funded under contract,

grant, or cooperative agreement. Without this element of quality assurance, the future credibility of the ETV program is at risk. The Subcommittee therefore recommends that the ETV program enforce these requirements on all verification partners.

2. INTRODUCTION

2.1 Background

In the early 1990's, government and private sector groups determined that the lack of independent and credible performance data was a major barrier to environmental protection because it impeded the development and use of innovative environmental technology. Based on broad input from technology developers, users and regulators, both the President's environmental technology strategy, Bridge to a Sustainable Future and the Vice President's Reinventing Government: National Performance Review contained initiatives for an EPA program to accelerate the development and use of environmental technology through objective verification and reporting of technology performance. In 1994, the Office of Research and Development's (ORD) National Risk Management Research Laboratory (NRMRL) convened a workshop of ORD managers to formulate a plan for implementing such a program. The plan was modified based on recommendations from the Science Advisory Board (SAB) in May 1995 (SAB, 1995). The Agency formally established the Environmental Technology Verification (ETV) program in October 1995.

The ETV program is currently in the final year of a five-year pilot phase and must soon prepare a report to Congress that will define the future configuration of the program. In October 1999, the Agency requested that the SAB review the extent to which quality management is incorporated into the ETV program.

2.2 ETV Program - Overview

The Environmental Technology Verification (ETV) program has been established by the Environmental Protection Agency (EPA) to document the performance characteristics of innovative environmental technologies across all media and to report this information to the permittees, buyers and users through the issuance of Agency approved technology verification reports. ETV is a voluntary program designed to evaluate the performance of commercial-ready technologies; it is not a technology approval or certification process.

Management oversight of the ETV program is provided by the ETV management team, which consists of approximately twenty (20) EPA Office of Research and Development (ORD) employees assigned to two laboratories: National Risk Management Research Laboratory (NRMRL) and the National Exposure Research Laboratory (NERL). The ETV program funds and manages twelve pilot projects, each representing a broad environmental technology group. The implementation of each pilot project is the responsibility of a third party organization (*i.e.*, verification partner), which operates

under the auspices of the ETV management team. The verification partners, which are selected through open competition, include; private sector testing, evaluation and research companies, state technology evaluation programs, federal laboratories and industry associations. To ensure that verification partners have sufficient program flexibility in responding to the needs of the environmental technology marketplace, cooperative and interagency agreements are used as the principal funding mechanisms for remittal of verification partner services rather than contracts.

The process of formulating a technology verification test involves the collective efforts of the ETV management team, a specific verification partner (and their subcontractors) as well as the representatives of the environmental technology customers (*e.g.*, stakeholder advisory groups). Members of the stakeholder advisory groups are selected to represent the interests of states, technology developers, technology buyers, consulting engineers, and financial institutions. Meeting several times a year, these groups advise the ETV management team on testing priorities, information needs to facilitate decision-making, test protocols to determine technology performance, and information distribution methods that will effectively reach specific customer groups.

The ETV program has adopted a multi-tiered planning approach for developing technology verification tests. The principal documents that describe the two levels of verification test development include the generic verification protocol and the Test/Quality Assurance (*i.e.*, Test/QA) plan. The generic verification protocol provides testing guidance for a particular technology category (*e.g.*, drinking water particulate removal), but not of a specific product, facility, or specific test event. The generic protocol is designed to be sufficiently broad to direct the testing of various products within the same technology category while providing the necessary framework for development of the more detailed Test/QA plan. The Test/QA plan provides specific instructions for the verification testing of a single product (*e.g.*, bag filters), or a group of products in the same technology category, during a specific test event. The Test/QA Plan is designed to provide sufficient detail to allow a third party to reproduce the verification test results.

The quality management functions and activities necessary to support the ETV program are described in the ETV quality and management plan (QMP). The ETV QMP defines the procedures, processes, inter-organization relationships and outputs that will assure that the quality of both the data and programmatic elements of the ETV program are appropriate for generating information that adequately portrays the performance of commercial ready technologies. Since verification partners bear much of the quality management responsibilities, these organizations are required to develop and implement their own quality management plans consistent with the quality assurance requirements found in the ETV QMP. The compatibility of the ETV QMP and the quality management plans developed by the verification partners assures that the appropriate levels of data collection, quality outputs and customer responsiveness will be met.

2.3 Systematic Data Quality Planning Process

The Agency quality requirements specify that environmental data generated on behalf of or funded by an EPA program must be supported by the use of a systematic data quality planning process. In general, a systematic data quality planning process is a flexible planning tool whose complexity can be modified to suit the specific circumstances of a data collection activity. Use of a systematic data quality planning process assures that the type, quantity and quality of environmental data generated will be appropriate for defensible decision-making. For potential purchasers, permittees and developers of environmental technology, a principal decision is to determine whether the type and quality of data furnished through ETV verification reports adequately portray a technology's performance.

Throughout this report, the Technology Evaluation Subcommittee recommends the consistent use of a systematic data quality planning process for the development of both generic verification test protocols and technology-specific Test/QA plans. The structure of the systematic data quality planning process should provide a convenient and consistent methodology for documenting the data collection activities and for communicating the environmental data collection design to others. The Agency's Data Quality Objectives (DQO) Process (EPA QA/G-4) is an example of a systematic data quality planning process whose implementation will assure that data of an appropriate quality for defensible decision-making are generated.

The ETV program addresses diverse technologies being used by different groups for different purposes. Therefore the systematic data quality planning process employed for verification test development must be flexible. Some technologies are designed to comply with one or more specific regulations. For other technologies no regulatory standard exists.

Where technologies have been developed to meet regulatory requirements, the decision-maker can often easily define the consequences of highly variable technology performance. This makes it easier to employ a systematic data quality planning process to develop a statistically based verification test plan. The following example is for illustration only. In the generic verification test protocol, the decision-maker could establish that all drinking water particulate removal technologies must be supported by a verification test design that limits the decision error rate in meeting a regulatory standard (*e.g.*, pathogen concentration) to no more than ten percent (*i.e.*, 90% confidence level). Once this generic data quality performance criteria was established, technology-specific verification tests (*e.g.*, Test/QA plan) would be designed that reflect the variability of an individual class of drinking water particulate removal technologies (*e.g.*, bag filters). In other words, the technology-specific verification tests (*e.g.*, Test/QA plan) would be designed to ensure that a sufficient amount of technology testing was conducted to support the stakeholder's claim that the performance of all ETV verified drinking water particulate removal technologies have an associated decision error rate of no more than ten percent (90% confidence level).

By taking a systematic data quality planning approach to statistical verification test design, the ETV program assures the potential purchasers, users and permittees of environmental technology that the furnished data are of a known and appropriate quality for decision-making. Moreover, by explicitly considering technology-specific performance variability in the verification test design, technology developers and vendors can recognize an economic benefit resulting from the improvement of overall product reliability.

Not all technologies that contribute to the protection of public health and the environment are governed by regulations. Where the environmental technologies are not intended for use in regulatory compliance programs, decision-makers will need to put more effort into defining their information needs. Clearly articulated decisions and a description of the data needed to support them are necessary inputs to any systematic data quality planning approach. These inputs provide the basis for developing statistically based verification tests. The ETV program's use of stakeholder groups is an especially rich source of information in these situations.

2.4 Charge

The focus of the present SAB review is the degree to which quality management is incorporated into the ETV program. In the months leading up to the SAB meeting, the Agency and the Board agreed upon a charge consisting of the following three questions:

- a) Is the use of the ANSI/ASQC E-4 consensus standard and the maintenance of an active quality assurance oversight implementation adequate to assure that quality management has been appropriately incorporated in the program?
- b) Is the level of quality incorporated into the example protocols adequate to appropriately portray commercial ready technology verification factors?
- c) Are these test protocols adequately comparable to assure that individual technologies tested in the future are fairly and comparably evaluated with those already verified?

2.5 SAB Review Process

The SAB Subcommittee was recruited from the Environmental Engineering Committee (EEC) and its consultants following discussions between the EEC Chair and the Agency. The Subcommittee met in public session on March 6, 7 and 8, 2000 in Washington, DC. This report is based upon written comments prepared before and during the meeting by Subcommittee members. It was approved by the Environmental Engineering Committee at a public conference call meeting May 3, 2000 and subsequently by the SAB's Executive Committee, May 30, 2000.

3. RESPONSES TO SPECIFIC CHARGE QUESTIONS

3.1 Is the use of the ANSI/ASQC E-4 consensus standard and the maintenance of an active quality assurance oversight implementation adequate to assure that quality management has been appropriately incorporated in the program?

3.1.1 Findings

The American Society for Quality and the American National Standards Institute jointly issued *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ANSI/ASQC E-4) in 1994. This consensus standard provides the minimum criteria for quality systems for environmental programs and their associated management systems. Although the standard provides the foundation upon which quality systems can be developed, ANSI/ASQC E-4 does not specify in detail how quality systems should be implemented. Therefore, adoption of the standard does not necessarily ensure that quality management will be appropriately incorporated into a data collection program.

The SAB has previously concurred with the Agency's interpretation and implementation of the ANSI/ASQC E-4 consensus standard in the Agency's Quality System (SAB, 1998 and 1999). The Subcommittee now specifically endorses the use of ANSI/ASQC E-4 in establishing a multi-tiered quality assurance oversight system for the Environmental Technology Verification (ETV) program. The Subcommittee is confident that the Agency's Quality System provides an effective framework for generating technology specific data of the appropriate quality for decision-making. This framework includes program and lower level quality and management plans (QMP), generic technology protocols, and project specific quality assurance (Test/QA) plans.

The ETV quality and management plan (QMP) was developed to conform to both the ANSI/ASQC E-4 consensus standard and Agency requirements (EPA Order 5360.1 "Policy and Program Requirements to Implement the Mandatory Quality Assurance Program" and EPA QA/R-2 "EPA Requirements for Quality Management Plans"). The QMP defines the roles and responsibilities of Agency quality managers with respect to the verification partners and their subcontractors. The verification partners and subcontractors, in turn, are required to develop and implement their own QMPs, which describe the quality systems employed during technology verification testing. As a result of the partnership arrangement, the quality of the final product, *i.e.*, technology verification information, depends upon the design and implementation of the QMPs developed by the ETV program, its verification partners and their subcontractors.

To document quality and to maintain continuous quality improvement as required by the Agency's Quality System, the ETV program has established a quality assessment process that consists of management system reviews, technical system reviews, performance evaluations and data audits.

The objective of the assessment process is to ensure that an adequate and appropriate level of quality assurance oversight is maintained for identifying and correcting defects in the quality management system and/or project data prior to the publication of a verification report.

The Subcommittee fully supports the ETV program's decision to employ the ANSI/ASQC E-4 consensus standard in development of its quality and management plan. However, the Subcommittee is concerned by some elements of the ETV program's implementation of its quality and management plan as illustrated by the following observations.

- a) The ETV quality and management plan does not clearly describe the process by which quality assurance oversight workloads are assigned to the Agency quality managers. In half of the twelve (12) example verification protocols and Test/QA plans reviewed, the responsibility for quality management oversight was assigned to a branch chief while, in the remaining six projects, quality management oversight was the responsibility of a divisional manager. The Subcommittee has two concerns. One is whether the resulting workloads allow adequate oversight for all plans. The other is the need to maintain a consistent perspective in quality assurance decision-making.
- b) The Subcommittee endorses the ETV program's current approach for selection of verification partners, which emphasizes technical capabilities as well as an established history of implementing appropriate levels of quality assurance. The Subcommittee recognizes that the verification partner selection process must be flexible to guarantee that technology customer needs are accommodated. However, to ensure consistency in the future development and implementation of quality management across technology areas, the program should develop verification partner selection criteria.
- c) The ETV quality and management plan neglects to address the issue of verification data ownership, use and disclosure. To maintain favorable marketplace support of the ETV program, the Subcommittee encourages the ETV program to carefully review the consequences of the contractual arrangements into which both verification partners and environmental technology vendors enter. Technical credibility requires not only verifying that technology testing results are objective and representative of those found by a disinterested third party, but also that contractual arrangements guarantee that technical data are properly managed by the Agency and its verification partners.

One Subcommittee member expressed concern that the productivity of the Environmental Technology Verification Program was so valuable to the environmental marketplace that it should not be impeded by imposing quality requirements in excess of what is currently being implemented. The remainder of the Subcommittee believed that, because the work performed by ETV is so important, full compliance with the requirements of the Agency's Quality System was essential for the future credibility

of the program. The general form of this concern was addressed in the *Science Advisory Board Review of the Implementation of the Agency-Wide Quality System* (SAB, 1999):

The Subcommittee believes that the Agency's senior management and Congress must recognize that initially, as the Quality System is implemented, there is the potential that the quality of products and services will improve at the expense of the total amount of work performed. The benefits of a Quality System have been argued to be free of costs, but the validity of this assumption is based on the amortization of costs over the longer term.

3.1.2 Recommendations

The Subcommittee supports the ETV program's decision to use the ANSI/ASQC E-4 consensus standard as a framework for the ETV program's quality and management plan. The Subcommittee believes that maintaining proper and consistent quality assurance oversight is essential to the success of the program. Because the organizational positions and workloads vary among those who are currently providing such oversight, the Subcommittee believes it possible that the thoroughness and impact of the oversight may vary as well. Consistency in form is not necessary if consistency in function can be established and maintained. However, the Subcommittee suggests that, to ensure the quality and consistency of the oversight function, the ETV program carefully consider the following.

Because quality assurance oversight workload levels have the potential to impact quality assurance decisions, the Agency should consider workload issues as well as the technical expertise and functional duties of the organizational reporting level when assigning quality assurance oversight responsibility.

The Agency should consider an appropriate mechanism to provide consistency in quality assurance decision-making. Although the obvious approach would be assignment of primary quality assurance management responsibility to the same organization level irrespective of the technology undergoing verification testing, the ETV Program could find a different and effective solution.

3.2 Is the level of quality incorporated into the example protocols adequate to appropriately portray commercial ready technology verification factors?

3.2.1 Findings

The ETV quality and management plan describes the process employed for developing the generic verification testing protocols. The Subcommittee supports the Agency's requirement that verification data quality criteria be established through the use of a systematic data quality planning process such as the Agency's Data Quality Objective (DQO) process (EPA QA/G-4) or an equivalent methodology. The Subcommittee endorses the ETV program's extensive use of stakeholder advisory

groups for identification of appropriate technology verification factors as well as for providing practical guidance for addressing the range of field conditions that technologies are likely to encounter.

The test protocols are structurally generic. Additional information is needed to identify all key verification and site-specific factors for specific technologies; therefore, the ETV quality and management plan requires the development of technology specific Test/QA plans. The Test/QA plan is meant to be the equivalent of the Agency's Quality Assurance Project Plan (QAPP), which is described in Agency requirements and guidance (EPA QA/R-5 and EPA QA/G-5). The Test/QA plan provides a second level of assurance that the technology verification test will be performed in a manner that should generate objective and useful information of known quality. To ensure that verification tests accommodate the permutations and range of conditions that technologies are likely to encounter in the field, the Subcommittee recommends that a structured data quality planning process such as the DQO process (EPA QA/G-4) be employed for the development of Test/QA plans.

The ETV program did not consistently consider technology performance variability in the development of the generic technology verification protocols. By establishing data quality performance criteria through the stakeholder advisory process, the extent of verification testing necessary to satisfy the data quality needs of the environmental technology marketplace can be impartially determined and formulated into the specific Test/QA plan. Using the drinking water treatment protocols as an example, ETV might verify the ability of several technologies to reduce the concentration of waterborne pathogens. In this case, the stakeholder advisory group could establish data quality performance criteria for all drinking water technologies subject to this protocol. Once data quality performance criteria are established (e.g., tolerable limits on decision errors) for a general category of environmental technologies (e.g., drinking water particulate removal), a verification Test/QA plan can be developed that objectively reflects the inherent performance variability of a specific technology (e.g., filtration, coagulation/flocculation, etc.). By explicitly defining a minimum data quality performance standard in the generic technology verification protocols and by accounting for technology performance variability in the Test/QA plans, the ETV program not only ensures that verification data of a known and appropriate quality are being consistently generated, but that future environmental technologies will be objectively and impartially evaluated.

The number of samples to be evaluated during verification testing is a function of both the data quality performance criteria established by the stakeholder advisory group and the inherent variability of the specific technology undergoing verification testing. Accounting for variability in the design of environmental data collection activities is not only consistent with the Agency's Quality System (EPA Order 5360.1, EPA QA/R-5), it is necessary to portray the performance of commercial-ready technologies. This SAB report employs the term data quality performance standard to mean the tolerable limits on decision errors as described by Step 6 of the Data Quality Objectives Process (DQO). Without clearly defining a data quality performance standard that considers technology performance variability, potential users of any verified technology will find it impossible to anticipate its performance. Furthermore, by establishing data quality performance criteria in the development of

verification tests, future verification costs can be minimized through eliminating the collection of unnecessary, duplicative or overly precise data.

Finally, the Subcommittee, the Agency, and ETV program management agree that the ETV verification partners and their subcontractors are contractually bound to comply with the Agency's Quality System requirements. Not all verification partners are fully aware that even though cooperative and interagency agreements rather than contracts are being employed for remittal of their services Agency policy clearly states that all work performed by extramural organizations on behalf of or funded by the EPA that involves the collection or use of environmental data in Agency programs shall be implemented in accordance with an Agency-approved quality assurance project plan (QAPP) developed from a systematic planning process (EPA QA/R-5). The environmental data collection activities for which an Agency-approved QAPP is required include all work performed through contracts, interagency agreements, assistance agreements (*e.g.*, cooperative agreements, grants, *etc.*) and in response to statutory or regulatory requirements and consent agreements negotiated as part of enforcement actions (EPA QA/R-5, EPA QA/G-5).

3.2.2 Recommendations

For various ETV protocol categories, small teams of Subcommittee members reviewed specific example protocols. This was done to obtain a sense for the implementation of the quality system at the level where data are actually generated, but not for the purpose of critiquing the individual protocols. Subcommittee teams reviewed the relevant documents for these categories:

- a) Advanced Monitoring Systems Pilot
- b) Air Pollution Control Technologies Pilot
- c) Drinking Water Systems Pilot
- d) Greenhouse Gas Technologies Pilot
- e) Indoor Air Products Pilot
- f) P2 Innovative Coatings & Coating Equipment
- g) Site Characterization & Monitoring Technologies

The following recommendations are based, in part, on the results of those reviews.

Continue Stakeholder Advisory Groups - First, the Subcommittee commends the Agency for its use of stakeholder advisory groups for identifying appropriate verification factors during generic protocol development. It is particularly challenging to involve large numbers of people of diverse backgrounds and varying levels of technical expertise in the development of technical documents. It is an ambitious and largely successful process that provides a useful example to others wishing to undertake similar efforts. The Subcommittee recommends that the Agency continue its use of stakeholder groups.

Fully Implement a Systematic Planning Process - Second, the translation of the verification factors and generic protocols into specific plans varies among the technology categories. In some cases it appears that a systematic planning process, such as the DQO process, was employed to establish data quality criteria. In other cases a systematic planning process was only partially employed or there were flaws in its application with the result that there were gaps in the logic tying the needs expressed by the stakeholders to the actual testing done.

When the DQO process is not completely implemented, it is impossible to determine whether the testing was designed to provide sufficient data of known quality to allow potential users or purchasers of verified technology to reach defensible decisions regarding anticipated technology performance. To achieve an appropriate level of quality to adequately portray commercial ready technology verification factors, the Subcommittee provides the following recommendations for Agency consideration.

Step 6 of the DQO process (Appendix B) requires that the principal decision-maker specifies a data quality performance criteria (e.g., tolerable limits on decision errors) for a particular technology category. By establishing this standard in the generic test protocol, the inherent performance variability of a particular technology (or group of technologies) may be used to develop a Test/QA plan whose implementation would generate data of a known and appropriate level of quality for decision-making. Development of Test/QA plans that would generate verification data of a known and consistent quality would have happened if all test plans (or equivalent documents) had fully applied a systematic data quality planning process, such as the DQO process.

The full implementation of a systematic planning process is important primarily for the reasons stated above. There are additional reasons why it is important. Vendors pay for the testing; some companies can afford this more easily than others. If data are required above and beyond what is necessary to meet the stakeholder's needs, then the verification process presents a burden to companies with fewer resources. If insufficient testing is done to meet the stakeholder's needs, then the entire market is misinformed about the true capabilities of the technology.

To ensure that all factors are considered and that the generic test protocols are interpreted and applied appropriately, ANSI/ASQC E-4 and Agency Quality System require that a systematic data quality planning process be implemented for ensuring that the correct type and amount of data are collected during verification testing. The Subcommittee recommends that the ETV program always employ the Agency's data quality objectives (DQO) or comparable systematic planning process to define data quality criteria prior to verification testing.

To enable potential technology purchasers and users to anticipate the performance of a verified technology with confidence, the Subcommittee recommends that the verification testing design be formulated based on both the data quality standard established by the stakeholders and the inherent variability of the individual technology.

To ensure that the implementation of the generic test protocols generate data of sufficient quality for defensible decision-making, the Subcommittee recommends that the Agency clearly document how information supplied by stakeholder advisory groups is translated into technology specific sampling strategies.

Enforcement of Agency Quality Assurance Policies for Verification Partners - To establish a consistent level of quality assurance in all data collection activities, the Subcommittee strongly recommends that the ETV program enforce Agency quality assurance policies by requiring that verification partners generate and implement an EPA-approved quality assurance project plan (QAPP), as described in EPA QA/R-5, prior to the collection of any technology verification data.

3.3 Are these test protocols adequately comparable to assure that individual technologies tested in the future are fairly and comparably evaluated with those already verified?

3.3.1 Findings

The purpose in maintaining generic test protocols is to assure that the environmental technology purchasing and permitting community can reach appropriate and defensible decisions. The generic test protocols are characterized by a consistent set of metrics that is designed to facilitate comparisons between similar technologies. Because it is impossible to anticipate all site-specific conditions under which an environmental technology may be operated, development of generic test protocols that permit objective and fair comparisons of related technologies is difficult. Moreover, experience with past operating conditions and matrices may not be sufficient for extrapolating to new environmental technologies and/or operating conditions.

Stakeholder advisory groups were identified by the ETV program as principal participants in the formulation of generic test protocols. These groups, which represent the various interests of the environmental technology marketplace, advise the ETV program on verification testing priorities and information needs for assessing environmental technology performance.

Despite the influence that stakeholder advisory groups have on the development of generic test protocols, the process by which these groups are constituted was not fully described by Agency documentation. The Subcommittee recognizes that, because of the broad diversity in environmental technologies to be verified, the number and type of interests reflected in the stakeholder advisory group membership will vary significantly between technology categories. However, to ensure that future generic test protocols are developed impartially, the process employed to establish the composition of the stakeholder advisory groups and their role in generic test protocol development should be transparent and consistently applied from one technology category to the next.

Although the use of generic test protocols, by themselves, is insufficient to ensure comparability of verified technologies with those to be tested in the future, the use of Test/QA plans in support of the

generic test protocols should provide sufficient program flexibility to permit a fair comparison of future technologies to those already verified.

3.3.2 Recommendations

Guidance for Constituting Stakeholder Advisory Groups - The Subcommittee commends the Agency for its use of a multi-tiered verification-testing program. In general, this approach to technology verification testing provides a flexible framework for establishing a set of key metrics that can facilitate the comparison of previously verified technologies with those that will undergo verification testing in the future. By considering the data needs of environmental technology users through stakeholder advisory groups, the ETV program has effectively captured the essential performance criteria requirements of the environmental technology marketplace. However, to ensure that future technologies will be fairly compared to those technologies already verified, the Subcommittee offers the following recommendation for Agency consideration.

To provide consistency in the process used to develop future generic test protocols and Test/QA plans, the Subcommittee recommends that the ETV program provide guidance on how future stakeholder advisory groups should be constituted and their specific role(s) in verification test development. The Subcommittee is not advocating a rigid and formulaic approach to advisory group formation resulting in an unwarranted consistency between advisory groups for different users of different technologies. The Subcommittee recommends that the ETV program capture what is known about how to do this well, then put it in a document that will assist others. As part of this task, the Agency may wish to consider developing an explication of the verification process.

4. ADDITIONAL COMMENTS

This chapter addresses issues that were not included in the charge.

4.1 Does the environmental technology marketplace need an ETV program?

The scarcity of independent and credible technology verification information is one critical barrier to the use of innovative environmental technologies. Therefore, the verification testing information that is provided by the ETV program fulfills an essential need of the environmental technology marketplace. The ETV program also contributes to the efficient operation of the environmental technology marketplace by reducing the transaction costs associated with researching and testing environmental technologies for all potential purchasers and users.

4.2 What is the value added to environmental technologies that are verified through the ETV program?

At the core of the ETV program is responsiveness to the environmental technology customers and suppliers. Responsiveness to the environmental technology customer is successfully demonstrated in the ETV program through the use of stakeholder advisory groups. The stakeholder advisory groups not only provide suggestions as to the minimum level of verification testing but also provide guidance as to the most effective format for presenting verification test results. Similarly, ETV program responsiveness to environmental technology suppliers is established by providing a process for objective and credible technology verification, which improves the market for environmental technology products.

4.3 What factors should be considered in planning the future of the ETV program?

The extensive use of stakeholder advisory groups is a principal factor for the current success of the ETV program. The stakeholder advisory groups provide assurance that the program goals are aligned with the needs of the technology users. To ensure future program success, the Subcommittee recommends that vendors, technology users, citizens' groups as well as local, state and federal government agencies be encouraged to continue their active participation in the development of generic test protocols as well as Test/QA plans.

The ETV program is expected to evolve from a primarily government supported to a privately funded verification program. Nevertheless, the Agency's verification partners identified a continued and substantial EPA oversight role as an important factor for maintaining the program's overall technical credibility. Given the perceived importance of the Agency's continued oversight role by the marketplace, the Agency should carefully evaluate to what extent it can withdraw from the overall management of the ETV program without adversely impacting its marketplace acceptance.

Finally, there is a continuing need to minimize the perception that ETV verification reports constitute an indirect acknowledgment of technology success. The ETV program has emphasized that it is a voluntary program designed to increase market efficiency by providing an independent and credible source of verification information. However, the increased use of verification testing data by permitting agencies in making technology performance decisions may be viewed by the marketplace as a *de facto* technology certification process. Therefore, continued vigilance will be required to avoid the perception that the ETV program is providing an unfair advantage to specific segments of the environmental technology marketplace.

4.4 Policy Factors Affecting Quality Assurance Credibility

Continued private sector support is critical for the future success of the ETV program. This support is based, in part, on the flexibility of the ETV program. Not all vendors are as ready for testing as they may initially believe and the Subcommittee supports the Agency's decision to allow environmental technology vendors permission to review preliminary verification results during the pre-testing phase.

Once testing has begun, however, the situation is different and the Subcommittee disagrees with the policy of allowing environmental technology vendors the opportunity to withdraw their products from full verification testing following full financial reimbursement of any costs incurred by the Agency or its verification partners. This results in the subsequent cancellation of the verification test report. Providing technology vendors the prerogative to "buy back" unfavorable data obtained during actual tests presents an appearance problem which adversely affects the credibility of ETV program. The Subcommittee therefore recommends that the Agency change this policy.

REFERENCES

American Society for Quality Control, Energy and Environmental Quality Division, Environmental Issues Group Specification and Guidelines for Quality Systems for Environmental Data Collection and Environmental Programs ANSI/ASQC E-4 (1994)

EPA Order 5360.1 CHG 1 (1998) *Policy and Program Requirements to Implement the Mandatory Quality Assurance Program* USEPA, Washington, DC April 1984

EPA Requirements for Quality Management Systems, EPA QA/R-2 available through http://www.epa.gov/quality1/qa_docs.html

EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5 available through http://www.epa.gov/quality1/qa_docs.html

Guidance for Quality Assurance Project Plans, EPA QA/G-5 available through http://www.epa.gov/quality1/qa_docs.html

Guidance for the Data Quality Objectives (DQO) Process, EPA QA/G-4 available through http://www.epa.gov/quality1/qa_docs.html

SAB. 1995. EPA's Environmental Technology Innovation and Commercialization Enhancement Program (EnTICE) (EPA-SAB-EEC-95-016). August 21, 1995

SAB. 1998. Science Advisory Board Review of the Agency-Wide Quality Management Program (EPA-SAB-EEC-LTR-98-003). July 24, 1998

SAB. 1999. Science Advisory Board Review of the Implementation of the Agency-Wide Quality System (EPA-SAB-EEC-LTR-99-002). February 25, 1999

APPENDIX A - DOCUMENTS PROVIDED TO THE TECHNOLOGY EVALUATION SUBCOMMITTEE

The following documents were provided to the Technology Evaluation Subcommittee on compact disk.

Introduction

Note to Reviewers

SAB Charge

**Environmental Technology Verification: Review of Quality Management Implementation
ETV Quality Management Plan**

Advanced Monitoring Systems Pilot

Pilot Summary

Protocol for SAB Review

Generic Test/QA Plan for Verification of Portable NO/NO₂ Emission Analyzers

Generic Test/QA Plan for Verification of On-Line Turbidimeters

Background Material

NO/NO₂ Emission Analyzer Technology Profile

Test/QA Plan for Verification of Portable NO/NO₂ Emission Analyzers

Test/QA Plan for Verification of On-line Turbidimeters

Portable Emission Analyzer Verification Report

Pilot Quality Management Plan

Air Pollution Control Technologies Pilot

Pilot Summary

Protocol for SAB Review

Generic Verification Protocol for Paint Overspray Arrestors

Background Material

Test/QA Plan for Paint Overspray Arrestors

Paint Overspray Arrestor Verification Report

Pilot Quality Management Plan

Drinking Water Systems Pilot

Pilot Summary

Protocol for SAB Review

Protocol for Equipment Testing for Physical Removal of Microbiological and Particulate Contaminants
(this protocol contains accompanying test plans)

Background Material

Pilot Quality Management Plan

Greenhouse Gas Technologies Pilot

Pilot Summary
Protocol for SAB Review
Natural Gas Compressor Leak Mitigation Technologies
Background Material
Compressor Rod Leak Mitigation Technology Profile
Test/QA Plan for Static Pac® System
Verification Report for Static Pac® System
Pilot Quality Management Plan

Indoor Air Products Pilot

Pilot Summary
Protocol for SAB Review
Large Chamber Test Protocol for Measuring Emissions of VOCs and Aldehydes
Background Material
Test Plan for Emissions of VOCs and Aldehydes from Commercial Furniture
Verification Report: Emissions of VOCs and Aldehydes from Commercial Furniture

P2 Innovative Coatings & Coating Equipment Pilot

Pilot Summary
Protocol for SAB Review
HVLP Equipment Generic Testing and Quality Assurance Protocol
Background Material
HVLP Spray Guns Testing and Quality Assurance Project Plan
HVLP Spray Gun Verification Report
Pilot Quality Management Plan

Site Characterization & Monitoring Technologies Pilot

Pilot Summary
Protocol for SAB Review
Verification Test Design Elements: Evaluation of PCB Field Analytical Techniques
Background Material
Technology Profile
Evaluation of PCB Field Analytical Techniques—Technology Demonstration Plan
PCB Field Analytical Techniques Verification Report
Pilot Quality Management Plan

Update of Pilots that are not Presenting Protocols

P2 Metal Finishing Technologies Pilot
P2, Recycling and Waste Treatment Systems Pilot
Source Water Protection Technologies Pilot

Wet Weather Flow Technologies Pilot
EvTEC (Independent Entity) Pilot

APPENDIX B- SUMMARY OF ELEMENTS OF THE EPA QUALITY SYSTEM

The Agency's quality **policy** is consistent with ANSI/ASQC E-4 and is defined in EPA Order 5360.1 CHG 1 (1998), the Quality Manual and the organizational components designed for policy implementation as described by the Agency's **Quality System** (EPA QA/G-0). The quality system provides the framework for planning, implementing, and assessing work performed by the organization for carrying out required quality assurance and quality control.

EPA has a comprehensive system of tools for managing its data collection and use activities to assure data quality. The **management tools** used in the organizational level of the EPA Quality System include Quality Management Plans and Management System Reviews. The **technical tools** used in the project level of the EPA Quality System include the Data Quality Objectives Process, Quality Assurance Project Plans, Standard Operating Procedures, Technical Assessments, and Data Quality Assessment.

At the management level, the **Quality System** requires that organizations prepare **Quality Management Plan** (QMP). The QMP provides an overview of responsibilities and lines of authority with regards to quality issues within an organization. Therefore, not only does ETV have a QMP, but the verification partners and subcontractors are required to develop and implement their own QMPs. The ETV program calls these documents **Quality and Management Plans**.

Organizations with **QMPs** review their own performance and develop **Quality Assurance Annual Report and Work Plans** (QAARWP) that provide information on the previous year's QA/QC activities and those planned for the current year. The QAARWP functions as an important management tool at the organizational level as well as at the Agency-wide level when QAARWP supplied information is compiled across organizations.

At longer multi-year intervals EPA conducts periodic **Management System Reviews** for organizations. An **MSR** consists of a site visit; a draft report that details findings and recommended corrective actions, consideration of the reviewed organization's formal response to the draft report and the authoring of a final report.

At the project level, the data life cycle of planning, implementation and assessment becomes important. The data life cycle begins with systematic planning. EPA recommends that this required planning be conducted using the **Data Quality Objectives (DQO) Process**. The DQO process includes seven steps:

1. State the problem

2. Identify the decision
3. Identify the inputs to the decision
4. Define the study boundaries
5. Develop a decision rule
6. Specify tolerable limits on decision errors
7. Optimize the design

The **Quality Assurance Project Plan (QAPP)** is the principal output of the **DQO** process and is the project-specific blueprint for obtaining data appropriate for decision-making. The QAPP translates the DQOs into performance specifications and QA/QC procedures for the data collectors. In the ETV program the **QAPPs** are known as **Test/QA plans**; these provide a second level of assurance that the technology verification test will be performed in a manner to generate objective and useful information of known quality.

The final step in the data life cycle is the **Data Quality Assessment (DQA)** which determines whether the acquired data meet the assumptions and objectives of the systematic planning process that resulted in their collection. In other words, the DQA determines whether the data are usable because they are of the quantity and quality required to support Agency decisions.

APPENDIX C - ROSTERS

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