Verification Testing
of
Air Pollution Control Technology

Quality Management Plan
Revision 2.3

EPA Cooperative Agreement CR-83416901-0
RTI Project 0212320

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Table of Contents

List of Figures

Figure **Page**

List of Tables

Table **Page**

List of Acronyms

ADQ	audit of data quality
ANSI	American National Standards Institute
APCT	air pollution control technology
APPCD	Air Pollution Prevention and Control Division
ASQ	American Society for Quality (formerly ASQC – American Society for Quality Control)
DAS	Discovery and Analytical Sciences
DQI	data quality indicator
DQO	data quality objective
EISD	Environmental and Industrial Sciences Division
EPA	U.S. Environmental Protection Agency
ETS	ETS International, Inc.
ETV	environmental technology verification
GVP	generic verification protocol
ISO	International Organization for Standardization
NIST	National Institute of Standards and Technology
NRMRL	National Risk Management Research Laboratory
OAQPS	Office of Air Quality Planning and Standards
ORD	Office of Research and Development
OTAQ	Office of Transportation and Air Quality
PE	performance evaluation
PO	project officer
QA	quality assurance
QC	quality control
QM	quality manager
QMP	quality management plan
QSA	quality system assessment
RTI	RTI International
SAC	Stakeholders Advisory Committee
SOP	standard operating procedure
SRM	Standard Reference Material
SwRI	Southwest Research Institute
TO	testing organization
TO-QM	testing organization quality manager
T/QAP	Test/quality assurance plan
TSA	technical systems assessment
VR	verification report
VS	verification statement

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1.0 Introduction

This quality management plan (QMP) applies to RTI International's (RTI's) Air Pollution Control Technology Verification Center (APCT Center) operated under U.S. Environmental Protection Agency (EPA) Cooperative Agreement CR-83416901-0. The APCT Center was established in 1995 as part of the EPA's Environmental Technology Verification (ETV) Program to accelerate the development and commercialization of improved environmental technologies through third-party verification testing and reporting on the tested technologies' performance. The APCT Center verifies the environmental performance of commercial-ready technologies in collaboration with qualified testing organizations (TOs). Figure 1 shows the management structure governing this collaboration. Verification provides potential purchasers and permitters with an independent and credible assessment of what they are buying and permitting. Verification testing is performed according to approved protocols. A technology's verified performance is reported in verification statements signed by EPA.

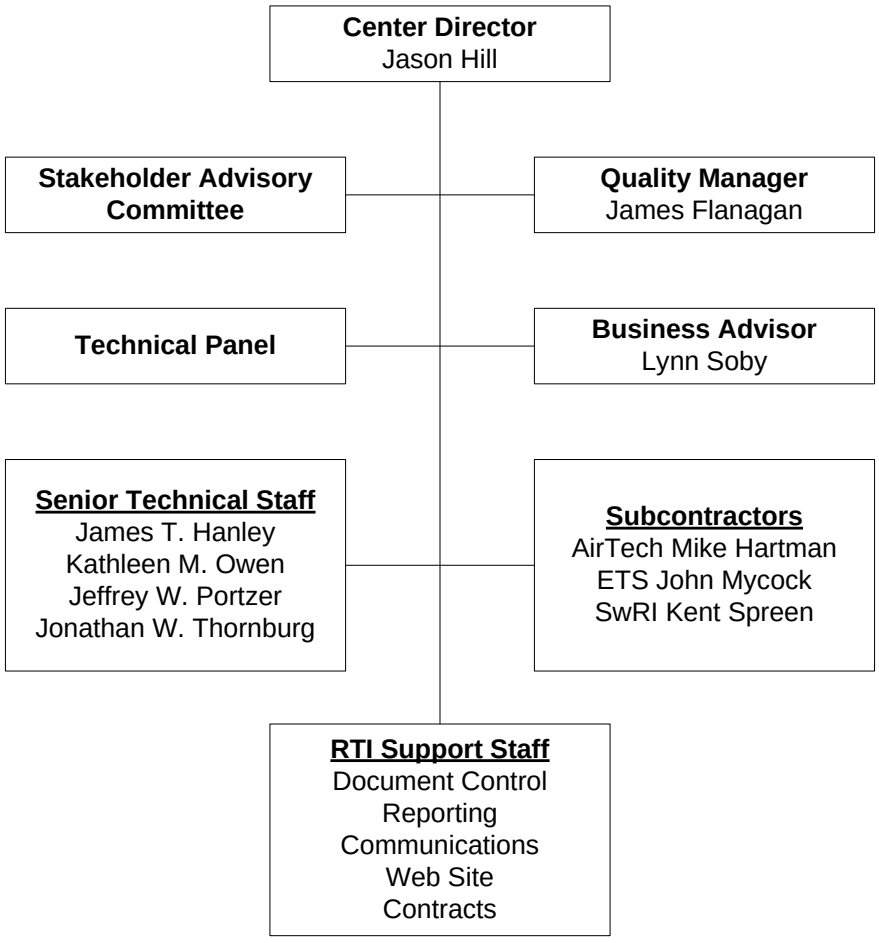

Figure 1. APCT Center Management Structure

The primary objective of the APCT Center is to create a highly credible verification testing program for air pollution control technologies. The quality assurance (QA) activities of this

program are designed to ensure that the results of the verification tests are credible and technically defensible.

This document is the basis for QA for the APCT Center. It describes the policies, organizational structure, responsibilities, procedures, and quality systems that will be followed under this cooperative agreement to meet the requirements of American National Standards Institute/American Society for Quality Standard E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ANSI/ASQC, 1994). This document complies with the EPA document, *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008).

2.0 Part A: APCT Center Management Systems

2.1 Management and Organization

2.1.1 RTI International

RTI is an independent organization dedicated to conducting innovative, multidisciplinary research that improves the human condition. With a worldwide staff of more than 2,600 people, RTI is active in health and pharmaceuticals, advanced technology, survey and statistics, education and training, economic and social development, and environmental protection. Universities in North Carolina founded RTI in 1958 as the first scientific organization in, and the centerpiece of, the Research Triangle Park. Today, RTI serves clients in government, industry, academia, and public service throughout the United States and abroad.

As shown in Figure 2, RTI management has established the following quality policy.

> It is the policy of RTI International to provide our clients superior-quality research, development, and technical services that meet the highest standards of professional performance, satisfy client requirements, and deliver exceptional value. We achieve this through teamwork and by striving to continuously improve our products and services. Furthermore, we work with our clients to define requirements and clarify expectations, including cost and time constraints. We ensure that our products and services comply with requirements and meet or exceed client expectations. Finally, we recruit, develop, and retain highly qualified and motivated staff.

Figure 2. RTI Quality Policy

Figure 3 depicts the RTI management organizational structure relative to the APCT Center. Reporting to the president of RTI, the Discovery & Analytical Sciences Group (DAS) is the RTI technical research group within which the APCT Center is housed. DAS conducts research in several disciplines, including drug discovery, microbiology, analytical chemistry, aerosol filtration, and exposure analysis. DAS employs more than 250 natural and social scientists, engineers, and administrative support personnel. Jennifer Hunter-Cevera, Executive Vice President for DAS, is responsible for all aspects of DAS's financial and technical performance.

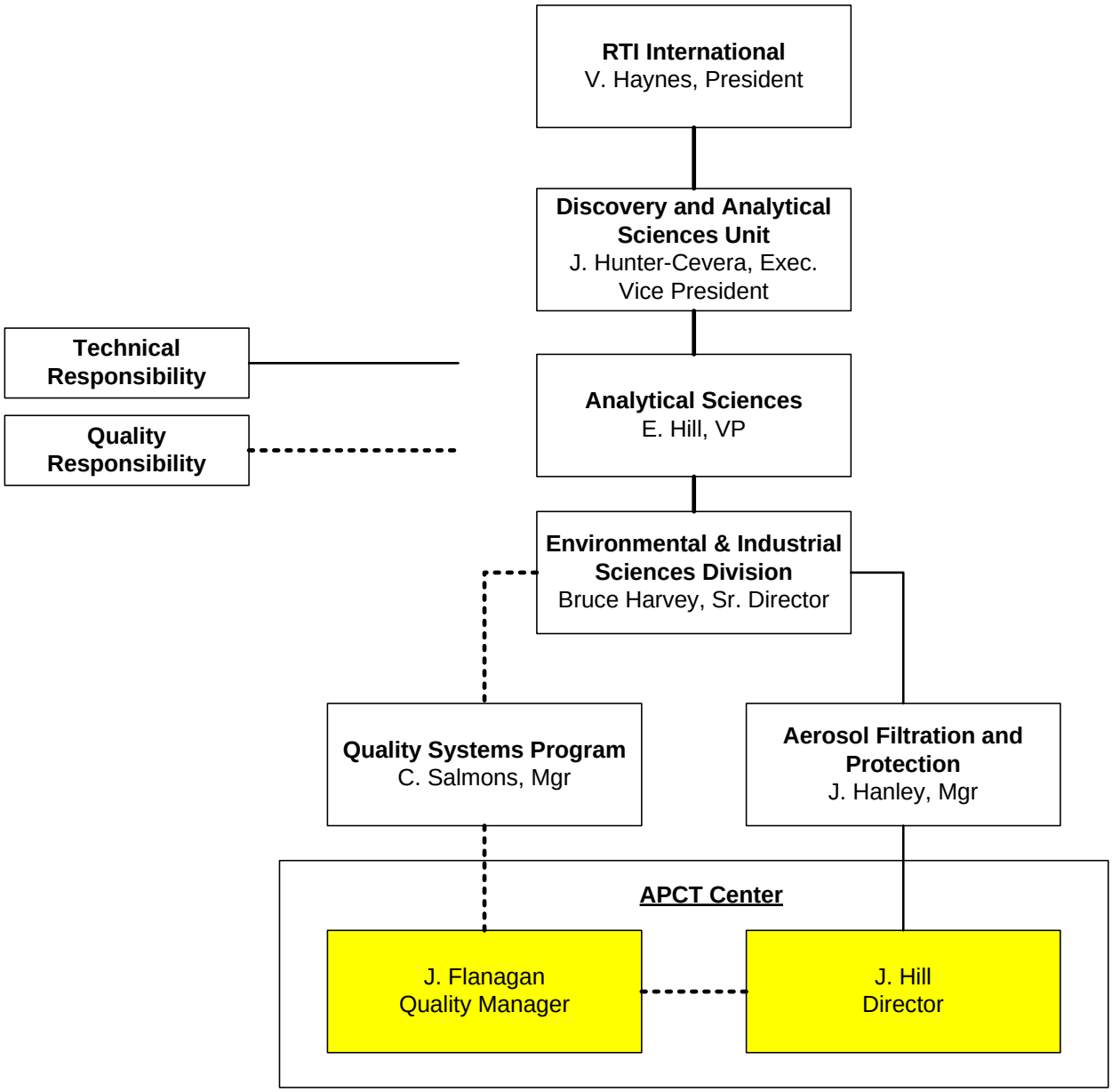

Figure 3. RTI Management Organizational Structure for the *APCT Center*

Within DAS is the Environmental & Industrial Sciences Division (EISD), directed by Bruce Harvey. Providing the management staff for the APCT Center, the Aerosol Filtration and Protection group, managed by James Hanley, conducts research and technology development related to aerosol generation and control related to environmental, building, and personal protection. The APCT Center's technical staff members are drawn from other RTI centers based on their expertise.

Providing QA support for this effort are the staff of the Quality Systems Program, housed within the Analytical Sciences division of EISD, and managed by Cynthia Salmons.

2.1.2 Testing Organizations

A TO may be part of RTI, of the subcontractors named below, or of external TOs not affiliated with the APCT Center. TOs that are independent (i.e., not a technology manufacturer's in-house laboratory) may conduct verification tests provided that they work under a generic verification protocol (GVP) that accepts the participation of external TOs. They must also meet EPA quality requirements and all performance requirements in the GVP. TOs that are not independent may conduct verification tests provided that they work under a GVP that accepts the participation of non-independent TOs, and they must also meet EPA quality requirements and the requirements of the GVP.

In addition to RTI personnel, the APCT Center currently consists of the following three subcontractors, who participate as TOs: Air Tech Environmental, ETS International, Inc., and Southwest Research Institute (SwRI). These subcontractors participate as follows:

- Air Tech Environmental provides point source field testing support.

- ETS conducts laboratory verification tests of baghouse filtration products. Its services also include the following project management and technical support: (1) participation in stakeholder and technical panel meetings; (2) preparation of GVPs; (3) marketing; and (4) business planning

- SwRI conducts laboratory verification tests of mobile source emissions control technologies. It provides technical support to RTI as appropriate with its expertise in the area of engine emissions testing and its familiarity with various emissions control technologies.

Other subcontractors may be added, following qualification by the APCT Center, to expand the capability of verifying air pollution control technologies. Participation of these subcontractors depends on the identification of work for which they are suited. Work by subcontractors is implemented by specific scopes of work. The APCT Center director manages all subcontractors.

All APCT Center subcontractors are required to have a quality system that meets *one* of the two following criteria:

- **Either** the system must be documented to conform to the requirements of ANSI/ASQC Standard E4-1994, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC, 1994), and must include a QMP in accordance with the EPA Environmental Technology Verification Quality Management Plan (EPA, 2008) and in accordance with EPA Requirements for Quality Management Plans, EPA QA/R-2 (EPA, 2001a);

- **Or** the system must be registered under International Organization for Standardization (ISO) Standard 9001:2000, Quality Management Systems – Requirements (ISO, 2000) and must possess the Level 1 quality manual, the Level 2 procedural documents (e.g., departmental policy and procedure manuals), and the Level 3 quality documents (e.g., standard operating procedures [SOPs]) that are required for such a registration. It must

also perform any quality activities (e.g., audits of data quality [ADQs]) that are required by EPA, but are not part of their ISO registration.

These quality system requirements and EPA's quality requirements for ETV verification tests are passed on to each TO via this document and via RTI's contractual agreements with the TO.

The APCT Center director and the Center quality manager (QM) ensure that a TO meets EPA's quality requirements and the GVP's performance requirements and that it has a compliant quality system, as determined by their review and approval of the TO's test/QA plan (T/QAP) and by the independent assessments that are conducted of the TO's quality and technical systems staff. Documentation defining the type and extent of oversight by the director over the TO's technical work products is established by the director as part of RTI's contractual agreements with the TO.

Each TO must also prepare a T/QAP in accordance with the requirements for an EPA QA project plan, given in the EPA QMP for the ETV Program (EPA, 2008) and in the guidance document, *EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5* (EPA, 2001b). The test leader and QM of the TO prepare the plan. APCT Center staff may assist the TO in preparing the plan, but the TO retains the final responsibility for the systematic planning for and the subsequent implementation of verification tests that meet EPA quality requirements. The plan is reviewed and approved by APCT Center and EPA. This document is described in greater detail in Section 3.1.2.

The TO prepares any SOPs that are needed for the specific verification test. Although these SOPs may contain proprietary information, they are made available for review by APCT Center staff and by independent assessors, both of which treat any designated proprietary information as confidential. These documents are described in greater detail in Section 3.1.3.

The TO conducts self-assessments of its quality and technical systems, and it allows independent assessments of the systems by the APCT Center QM and the EPA QM. The TO is responsible for developing and implementing corrective actions in response to assessment findings. Assessments are described in greater detail in Sections 3.4 and 3.5. For a summary of test-level responsibilities, see Table 1.

2.1.3 Responsibilities of APCT Center Team Members

The management structure for the APCT Center is presented in Figure 1. The APCT Center director (see Figure 3) manages program activities and coordinates them with the Stakeholders Advisory Committee (SAC). Reporting to the director are an organizationally independent APCT Center QM (see Figure 3), test leaders, and TO quality managers (TO-QMs). Specific responsibilities within the APCT Center are summarized in Table 2, APCT Center Program-Level Responsibilities.

Table 1. APCT Center Test-Level Responsibilities

Responsibility	APCT Center Director*	Quality Manager	Test Leader	Testing QM
Maintain internal communications	X	X	X	X
Oversee verification test activities	X			
Develop and manage verification test budget			X	
Report progress and costs to APCT Center director			X	
Select specific technologies for testing	X			
Prepare T/QAP	X		X	
Assist in development of T/QAP		X		X
Review and approve test-level quality documents	X	X		
Submit test-level quality documents to EPA	X			
Oversee TO-QM activities		X		
Oversee QA aspects of verification tests				X
Select and manage test staff			X	
Conduct verification test			X	
Provide test-level quality training				X
Implement test-level quality training			X	
Assess TO's quality system		X		
Conduct technical assessments of tests		X		X
Conduct ADQ of test data				X
Assess test and ADQ results	X	X		
Develop and implement corrective actions			X	X
Determine effectiveness of corrective actions		X		X
Prepare test documentation			X	
Prepare verification report and statement (VR,VS)	X			
Prepare quality aspects for VR and VS				X
Review and approve test results, VS, and VR	X	X		X
Submit VS and VR to EPA	X			
Store test-level quality documents and test data			X	

Note: ADQ=audit of data quality; APCT=air pollution control technology; QA=quality assurance; TO=testing organization; TO-QM=testing organization quality manager; T/QAP=test/quality assurance plan; VR=verification report; VS=verification statement.

* The director may delegate test-level technical activities in a specific technology area to RTI personnel, but he/she retains responsibility for the quality of any delegated technical activities.

Table 2. APCT Center Program-Level Responsibilities

APCT Center Program-Level Responsibilities	APCT Center Director *	Quality Manager	SAC	Technical Panel
Overall APCT Center program and quality responsibility	X			
Coordinate APCT Center activities with EPA	X			
Develop APCT Center implementation plan	X			
Communicate APCT Center activities to SAC and constituents	X			
Assist in communicating APCT Center activities to constituents			X	
Prepare APCT Center QMP; revise annually as needed		X		
Review and approve APCT Center program-level documents	X			
Implement quality system (as per QMP) in APCT Center	X			
Communicate with EPA QM and TO-QMs		X		
Oversee program-level quality activities		X		
Assess APCT Center quality system on an annual basis		X		
Submit APCT Center program-level quality documents to EPA	X			
Chair and coordinate SAC meetings	X			
Review APCT Center activities and advise director			X	
Select and prioritize technologies, including develop outcome projections.	X			
Provide input for selecting and prioritizing technologies			X	
Provide advice about specific technologies				X
Select technical panel	X			
Chair and coordinate technical panel meetings	X			
Prepare GVPs	X			
Provide input for development of GVP				X
Assist development of quality aspects of GVP		X		
Approve external TOs	X			
Manage subcontractors	X			
Review and approve APCT Center test-level quality documents	X	X		
Oversee verification tests by TOs	X			
Review and approve VRs and VSs	X	X		
Develop impact analyses for verified technologies	X			
Submit test-level quality documents, VR, and VS to EPA	X			
Store APCT Center program-level documents and records	X			

Note: APCT=air pollution control technology; DQO=data quality objective; GVP=generic verification protocol; QMP=quality management plan; QM=quality manager; SAC=Stakeholders Advisory Committee; TO=testing organization; TO-QM=testing organization quality manager; VR=verification report; VS=verification statement.
* The director may delegate program-level technical activities for specific technology areas to RTI personnel, but he/she retains the responsibility for the quality of any delegated technical activities. An RTI staff member is designated to substitute for the APCT Center director when the director is absent.

The APCT Center Director has overall responsibility for APCT Center activities, which include oversight for all verification testing and reporting, negotiations with technology developers and vendors, selection of specific technologies for verification testing, management of RTI personnel, direction of subcontractor efforts, approval of participation by external TOs, and coordination with the SAC and the EPA project officer (PO). The director serves as the chair of the SAC. The director has overall responsibility for quality at the program level and in verification tests. The director may delegate specific technical activities to RTI personnel, but he/she retains responsibility for the quality of any delegated technical activities. The director prepares GVPs and reviews and approves T/QAPs, verification reports, and verification statements. The director submits these documents to the EPA PO for review and approval. Deborah Franke, a senior member of the APCT Center technical staff, reports to the director and substitutes for the director if that individual is absent. She will be responsible for any functions delegated by the director.

The **APCT Center QM** is responsible for preparing and revising this QMP. The QM assists the director in the preparation of GVPs. The QM communicates directly with the EPA QM and with TO-QMs on quality-related issues. The QM reviews and approves T/QAPs, verification reports, verification statements, verification test results, and associated quality records. The QM is free from personal and external barriers to independence, is organizationally independent from data collection activities, and is able to maintain an independent attitude and appearance. The QM provides technical assistance to TOs regarding EPA quality requirements. The QM communicates directly with TO-QMs on quality-related issues. The QM is also responsible for conducting independent assessments of the quality systems of TOs and independent technical assessments (i.e., technical systems audits [TSAs] and performance evaluations [PEs]) of verification tests in cooperation with the EPA QM. The QM is responsible for determining the effectiveness of corrective actions implemented in response to independent assessment findings. The QM will review this QMP on an annual basis and will revise it as necessary to reflect any changes that have occurred in the organization and the policy of the APCT Center or in EPA quality requirements since the last revision. These responsibilities are described in greater detail in Section 2.1.4.

The **SAC** is responsible for advising the director with respect to potentially useful technologies and other program-related issues. With the advice and concurrence of the EPA PO, the director chairs and coordinates the SAC to guide and direct APCT Center activities, to assist in selecting and prioritizing technologies for verification testing, and to serve as a communications link with their constituents. The SAC is made up of 20 to 25 leaders from various segments of the air pollution control community, including regulators/permit writers, technology developers/vendors, buyers/users, environmental associations, and EPA representatives, including the PO. The EPA PO is consulted concerning the director's selection of SAC members. EPA's Office of Research and Development (ORD), its Office of Air Quality Planning and Standards (OAQPS), and its Office of Transportation and Air Quality (OTAQ) are expected to contribute SAC members. The SAC members have broad experience in the air pollution control field. They provide the verification center with a diversity of opinions and viewpoints concerning air pollution control technologies and their application.

For each **TO** (see Section 2.1.2), the **test leader** manages the verification test for a specific technology. The test leader may be an employee of RTI, a subcontractor, or an external TO.

The test leader develops personnel requirements for verification tests, communicates with and coordinates testing staff, identifies candidates for the technical panel, and proposes a budget for the test program from the start of the process through preparation of the verification report. The test leader is responsible for providing personnel to support the technical panel. The APCT VC, in cooperation with the technical panel and the TO-QM, prepares a draft GVP; the TO test leader prepares a test-specific T/QAP, and any needed test-specific SOPs. The test leader is responsible for developing and implementing corrective actions that are taken in response to assessment findings. The **TO-QM** is free from personal and external barriers to independence, is organizationally independent from data collection activities, and is able to maintain an independent attitude and appearance. The TO-QM:

- Provides support and oversight for the QA activities associated with specific verification tests;
- Communicates directly with the QM on quality-related issues;
- Assists test leaders in the preparation of test-specific T/QAPs and any needed test-specific SOPs;
- Conducts self-assessments of the TO's quality and technical systems and determines whether the tests were implemented in accordance with the T/QAP and EPA quality requirements;
- Conducts ADQs of the verification test results;
- Reviews and approves test results, verification reports, and verification statements; and
- Determines whether the test results attain data quality objectives (DQOs) and whether they support the verification reports and verification statements.

The responsibilities of the TO-QM are described in greater detail in Section 2.1.4.

Technical panels are convened to provide input to the director in the development of GVPs for a specific technology and to ensure that the interests of their constituencies are met. They provide the director with advice about specific technologies to be selected for testing. Technical panel members include technology developers, technology users, and the regulatory community. The members of each technical panel are technical experts with specialized knowledge and fields of interest that are related to the specific technology being verified and to the associated test methods.

2.1.4 Quality Management

Overall responsibility for quality at the APCT Center program level and in all verification tests remains with the director. The director has resources available to ensure conformance with EPA quality requirements. The director has the authority to issue a stop work order in the event that unsafe work or work of inadequate quality is identified. The director reviews and approves GVPs, T/QAPs, verification reports, and verification statements.

The independence and objectivity of the APCT Center quality system is bolstered by the APCT Center QM being located in a different RTI administrative unit (i.e., the Discovery and Analytical Sciences group, or DAS) from RTI's APCT Center testing personnel (i.e., Center for Aerosol Technology). Likewise, TO-QMs work with test leaders, but are not part of the administrative units generating the verification test data. Reports of quality document reviews, reviews of verification test results, and assessment findings go directly from the QM to the director and from the TO-QMs to the test leaders. These individuals are free of any real or perceived conflicts of interest as might occur from too close of an administrative association with the data collection activities. They have no stake in the outcome of the verification tests other than that the environmental data be collected objectively and in accordance with the quality documents and EPA quality requirements.

The APCT Center QM is responsible for reporting to the APCT Center director whether verification tests are performed in compliance with EPA quality requirements and with the quality requirements in this document, in GVPs, and in test-specific T/QAPs, and whether test results demonstrate that test data attain DQOs. The following are the specific responsibilities of the APCT Center QM:

- Prepares this document, reviews it on an annual basis, and revises it as needed;
- Assists test leaders and TO-QMs regarding quality issues relating to specific verification tests;
- Reviews and approves the GVPs, T/QAPs, and any needed SOPs that are developed by test leaders, TO-QMs, and TOs;
- Communicates with the director, test leaders, TO-QMs, and the EPA QM regarding quality-related issues;
- Conducts self-assessments of the APCT Center quality system, independent assessments of TOs' quality systems, and test-specific technical assessments of verification tests in cooperation with the EPA QM;
- Determines the effectiveness of corrective actions implemented in response to independent assessment findings;
- Reviews and approves the test results and the QA and quality control (QC) data from verification tests to determine whether test data attain DQOs; and
- Reviews and approves verification test reports and verification statements.

TO-QMs handle those QA activities directly associated with specific verification tests. They may be employees of RTI, a subcontractor, or an external TO, but they must be independent of the administrative unit performing the verification tests and must be free of any real or perceived conflicts of interest. Following are the specific responsibilities of the TO-QM:

- Assists test leaders in the preparation of T/QAPs, including data quality indicator (DQI) acceptance criteria that must be attained so that test data attain the DQOs specified in the approved GVP;

- Assists TOs, in cooperation with test leaders, in the preparation of any needed SOPs to be attached to the T/QAPs, if another level of technical detail is needed to describe test activities;

- Communicates with test leaders, TO staff, and the QM regarding quality-related issues;

- Ensures, in cooperation with test leaders, that TOs conduct verification tests in conformance with EPA quality requirements, the quality requirements in this document, GVPs, T/QAPs, and any needed SOPs;

- Oversees test-specific quality training and ensures that all TO personnel understand the QA requirements;

- Conducts self-assessments of the TOs' quality and technical systems and determines the effectiveness of corrective actions implemented in response to self-assessment findings;

- Performs an ADQ for at least 10 percent of verification test data;

- Reviews and approves the test results, and the QA and QC data from verification tests, to determine whether test data attain DQOs; and

- Assists the test leader in the preparation of the quality-related content of each verification report and verification statement.

2.2 Quality System Description

The quality system for the APCT Center has five levels.

The foundation level consists of the *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008), which addresses all aspects of EPA's ETV program, and conforms to the ANSI/ASQC E4-1994 standard (ANSI/ASQC, 1994).

The second level consists of this QMP, which describes APCT Center's quality system. It is a program-specific application of the EPA ETV QMP.

The third level consists of technology-specific GVPs, which apply the principles of the ETV and APCT Center QMPs to specific technology testing scenarios. They are prepared by a Center technical staff person, with the assistance of technical panels and TOs for verification tests of specific technologies. These GVPs are developed with assistance from stakeholder technical panels and are submitted to the EPA PO and EPA QM for approval. These documents define the types and characteristics of data that must be present in verification statements and reports in order for technology-specific verification tests to be accepted as credible by EPA and other stakeholders. Technical panels provide for the verification tests to ensure that the interests of their constituencies are met. The GVPs are applicable to any TO that is approved to perform

verification tests for the APCT Center. They are not specific to a particular TO. The GVPs are developed to assure there is no bias towards or against a specific technology or a specific TO during verification tests. They are based upon detailed examination by all stakeholders of the issues associated with the acceptance of the technologies. They specify strong EPA oversight and QA activities to assure fairness and consistency in the conduct of the verification tests and credibility in the verification test results.

The fourth level consists of the test-specific T/QAP, which is prepared jointly by an APCT Center staff person and the TO. It is reviewed by the APCT Center director and QM and is submitted to the EPA PO AND EPA QM for approval. The T/QAP describes how the TO produces the verification test data as specified in the approved GVP. All data must be generated in accordance with the approved T/QAP.

The T/QAP must meet all the requirements for QA project plans, which are specified in *EPA Requirements for Quality Assurance Project Plans*, EPA QA/R-5 (EPA, 2001b) and contain all the required elements of a QA project plan. Additional information regarding QA project plans can be found in *Guidance for Quality Assurance Project Plans*, EPA QA/G-5 (EPA, 2002a).

The T/QAP must contain a detailed description of the planned verification test, including the TO's organizational structure, its management and personnel, the test schedule, test documentation, sampling and analytical methods, and other operational procedures. It also must specify the QA and QC procedures, calibration traceability, and DQIs for obtaining verification data of sufficient quantity and quality to satisfy the DQOs specified in the GVPs. If GVPs specify the needs of verification data users, then T/QAPs specify what the verification data generators will do to meet these needs. The T/QAP must describe how verification test data will be reconciled with the DQOs. T/QAPs are described in more detail in Section 3.1.2.

The final level consists of the assessments of the TO's quality system and technical assessments (e.g., TSAs, PEs, and ADQs) that will be conducted during the verification tests by the QM in cooperation with the EPA QM. The findings of the quality system and technical assessments will be reported by the QM to the APCT Center director. Assessments of the quality system and technical assessments are described in greater detail in Sections 2.9 and 3.4.

2.3 Personnel Training and Qualifications

The director is responsible for assessing the needs, providing the resources, and monitoring the progress of professional development and general training for RTI-based APCT Center personnel. The director identifies general training needs by evaluating personnel qualifications, experience, and performance based on each position's job description and documented performance expectations, as applicable. General training needs are assessed and documented as part of the evaluation of each employee's performance in the APCT Center.

The QM and TO-QMs are selected based on the following qualifications:

- Educational background or a degree relevant to the application of QA principles to technology demonstration projects and programs;
- Work experience specific to QA of technology demonstration projects 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 APCT QMP; and

- Work experience in quality management and QA.

Assessors have a minimum of 4 years' full-time appropriate practical workplace experience (not including training), at least 2 years of which have been in QA activities. They have undergone training to the extent necessary to ensure their competence in the skills required for carrying out assessments and for managing assessments. They are free from personal and external barriers to independence, are organizationally independent from data collection activities, and are able to maintain an independent attitude and appearance.

Test leaders are selected based on the following qualifications:

- Educational background or a degree directly relevant to the technology;

- Work experience specific to the technology; and

- Work experience in project management.

Test leaders are responsible for assessing TO personnel qualifications to perform verification tests and for identifying test-specific training needs. They identify test-specific training needs by evaluating personnel qualifications, experience, and performance based on the requirements in the project's scope of work. Particular areas that are evaluated include health and safety training and procedures for handling confidential information, as applicable. Training reassessment is conducted whenever an individual's job function changes, such as reassignment to a new work group, job redesign, reorganization, or promotion. Supplemental training is provided when deficiencies in performance are observed.

TO personnel are selected by the test leader based on the following qualifications:

- Educational background and/or a degree directly relevant to the technology; and

- Work experience specific to the technology.

TO personnel assigned to a verification test are given only those tasks and responsibilities that are commensurate with their training, education, and work experience. For example, a laboratory analyst is taught unfamiliar sampling or measurement procedures through externally provided training courses or through in-house training. Personnel performing data verification or validation have the appropriate background in science or engineering and appropriate background in the measurements being verified or validated. They also must demonstrate competence in the measurement procedure to an experienced supervisor.

2.4 Procurement of Items and Services

RTI Policy No. 4001, *Institute Procurement*, and RTI's *Office of Purchasing Standard Operating Procedures Manual* should be consulted for a general description of quality systems

for procurement of items and services. The operations of RTI's Office of Purchasing are included under the certification of one of RTI's separately registered ISO 9001:2000 technical units. Those certified Purchasing procedures apply to all technical units of RTI. The most frequent service procured under this cooperative agreement is verification testing performed by a subcontractor acting as a TO. RTI and its subcontractors have contractual agreements regarding such verification tests, and no new procurement documents are needed for these tests. In preparation for a specific verification test, the director and the subcontractor's management discuss the technical requirements for the test that have been established by the technical panel, and they reach an agreement on the technical activities that the subcontractor will perform to satisfy these technical requirements. The subcontractor also prepares a T/QAP that satisfies EPA's quality requirements and the GVP's quality requirements, including the DQOs for the test. EPA's quality requirements for the ETV Program together with RTI's additions flow through to the subcontractors via the contractual agreements.

During verification tests, the subcontractor management regularly reports its technical progress to the director. The QM assesses the subcontractor's quality system, conducts independent technical assessments during verification tests, and reviews and approves the written reports of ADQs that are conducted by TO-QMs after verification tests.

After the verification test data have been verified by the TO staff, the TO-QM conducts an ADQ, reconciles verification test results with the DQOs, and prepares a written assessment report for review by the APCT Center QM. The test leader, with the cooperation of the TO-QM, prepares the verification report and verification statement, which are reviewed and approved by the director, the QM, and the EPA PO AND EPA QM.

2.5 Records

APCT Center quality records are the following documents:

- APCT Center QMP (this document);
- Minutes of stakeholder meetings and technical panel meetings;
- GVPs;
- T/QAPs and SOPs;
- Raw data (all written and electronic data generated when a verification test is conducted);
- Verification reports and verification statements; and
- Project reviews and assessment reports.

2.5.1 Procedures

- All reports, internal documents and records will be clearly identified by title, date, author or responsible person, and report, version or document number. Document numbers (e.g., SOPs) will follow an organizationally defined numbering system.

- The number of documents being generated for the project is not great enough to warrant a document indexing system. A master list of all documents and records for the project is maintained in the project computer directory.
- Control of quality records, including procedures for identifying, collecting, indexing, accessing, filing, storing, maintaining, and disposing of quality records will follow RTI policies. APCT SOP 100, Document Control, provides detailed procedures for this project.
- Standard RTI procedures for maintaining, establishing, and implementing an appropriate chain of custody and confidentiality for evidentiary records will be followed.
- Obsolete records and documents will be identified as such. They will be maintained in clearly marked separate computer directories or in separate hardcopy files. As appropriate, they will be removed to archival storage once the project is completed. APCT SOP 100, Document Control, provides detailed procedures for this project.
- Record retention times will be based on contractual and statutory requirements or will follow RTI practices.

This QMP is prepared by the QM, and is reviewed and approved by the director and the EPA PO and EPA QM. It will be reviewed by the QM on an annual basis and will be updated as necessary. The updated document will be reviewed and approved by the director and the EPA PO AND EPA QM. It will be retained by the APCT Center for a period of not less than 7 years after final payment of the assistance agreement in accordance with the requirements of Part A, Section 5.3 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008). The QM is responsible for establishing procedures to securely store this document.

Minutes from SAC meetings and technical panel meetings are prepared by APCT Center staff and are reviewed by meeting attendees and the director. They are posted on APCT Center web pages (see http://etv.rti.org/apct/advisory/index.html and http://etv.rti.org/apct/tech/index.cfm, respectively). They will be retained by the APCT Center for a period of not less than 7 years after final payment of the assistance agreement. The director is responsible for establishing procedures to securely store these documents.

GVPs are prepared by the APCT director, with the assistance of the APCT Center staff, and are reviewed by technical panels. They will be reviewed by the director and approved by the EPA PO and EPA QM before their use. They will be retained by the APCT Center office for a period of not less than 7 years after final payment of the assistance agreement. The director is responsible for establishing procedures to securely store these documents.

T/QAPs and any technical SOPs that are needed for verification tests will be prepared by the test leaders with the assistance of technology-specific QMs. They will be reviewed and approved by the director, the QM, and the EPA PO and EPA QM before their use. The T/QAPs will be retained by the APCT Center and by the TOs for a period of not less than 7 years after final payment of the assistance agreement. The QM and the test leaders are responsible for establishing procedures to securely store T/QAPs in their respective organizations. The test leader is responsible for establishing procedures to securely store any technical SOPs. Administrative SOPs are numbered consecutively, are stored online in the APCT folder, and are

maintained with other APCT quality documents. The director will request his staff to develop administrative SOPs as necessary, however, he/she maintains responsibility for them.

Raw data (electronic and printed) collected during verification tests, and any calculations or documents derived from such data will be retained by the TO or by the APCT Center for a period of not less than 7 years after the final payment of the assistance agreement. These data, calculations, and documents will be clearly identified by verification test, date, observer/author, and originating TO. The test leader is responsible for establishing procedures to securely store these data, calculations, and documents.

Verification reports, including 3- to 5-page verification statements that thoroughly document the verification test results, will be prepared by the APCT director with input from the APCT QM, TO test leader and TO-QM. The format for the reports will include:

- Thorough description of the technology that was tested;
- Test methods used and a justification for their selection;
- Organizations conducting the test and providing QA oversight;
- Operating parameters and conditions under which the testing was performed;
- Statistical analysis of the test results;
- Reconciliation of the test results with the DQOs;
- Statement regarding independent and self-assessment findings; and
- Any limitations on use of the test data.

The TO will explain and document any necessary deviations from the GVPs or T/QAPs, will document raw data, and will present QA results.

These reports will be reviewed and approved by the director and the QM and submitted to the EPA PO and EPA QM for approval. They will be retained by the APCT Center for a period of not less than 7 years after final payment of the assistance agreement. The director is responsible for establishing procedures to securely store these documents.

Reports of self-assessment findings of TO quality and technical systems will be prepared by the TO-QM and will be sent to the test leader. Reports of ADQs of verification test results will be prepared by the TO-QM and will be sent to the test leader and the QM. Reports of independent assessment findings of TO quality and technical systems will be prepared by the QM and will be sent to the TO-QM and the director. Reports of self-assessments of the APCT Center quality system will be prepared by the QM and will be sent to the director. These reports will be available for review during independent assessments. These reports will be retained by TOs and/or by the APCT Center for a period of not less than 7 years after the final payment of the assistance agreement. The test leader and the director are responsible for establishing procedures to securely store these project reviews and assessment reports in their respective organizations.

2.6 Computer Software and Hardware

Any computer hardware/software configurations developed to support APCT Center verification tests will be tested prior to use. The results of the testing will be documented. The configurations will be properly maintained and documented subsequent to testing. All applications and configurations will be tested using a test data set or by running a shakedown test of the system to ensure that they are operating according to specifications.

The APCT Center or the TOs will maintain, control, and document such configurations, including:

- Retaining computer support personnel to correct any hardware or software failure with minimal downtime to the program;
- Tracking upgrades to hardware and revisions to software developed by the APCT Center or the TOs; and
- Documenting software names, versions, and copyright dates.

The APCT Center expects to use only standard commercial software for office operations (e.g., word processing software, spreadsheet software) and does not expect to establish acceptance criteria for such software. This is consistent with Part A, Section 6.1 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008).

The APCT Center expects to use standard commercial software for data management operations, including data reduction (e.g., spreadsheets). Such calculations will be carefully checked using alternative methods (e.g., calculator) and results will be verified by use of standard input (i.e., "calibration") data. Additionally, they will be spot-checked by the QM (APCT Center and/or TO) as part of the normal ADQ process.

The APCT Center may use computer hardware/software configurations that are integral to measurement and testing equipment that are calibrated for a specific purpose (e.g., engine testing). All computer hardware or software that are anticipated to be used in the APCT Center will only be able to alter the response of the equipment due to alteration of constants (e.g., calibration data). All such operations will be documented in applicable SOPs by the TO.

The APCT Center has no current plans to change any computer hardware/software configurations developed to support the APCT Center or verification tests. Any changes that might occur are unlikely to have an effect on the technical and quality objectives of verification tests because these objectives are established in the GVPs and are independent of any configurations developed to implement the GVPs.

Computer databases containing test data will be password-protected. Electronic data transfers will be protected by encryption or other means to prevent tampering and ensure confidentiality.

2.7 Planning

The director developed an implementation plan for the APCT Center under the previous cooperative agreement. This plan describes the technical approach that will be followed to implement the APCT Center verifications. Elements of the technical approach include the following:

- Organizational Phase/Management – This element discusses management functions, outreach, the SAC, the QMP, GVPs, and technology identification and prioritization.
- Technology Verification – This element addresses vendor solicitation, GVP and T/QAP development, testing and evaluation, QA, verification reports, and verification statements.
- Schedule – This element presents the anticipated project schedule.
- Success Measures – This element describes measures that are planned to ensure the success of the APCT Center.
- Reports – This element describes the reports that the director will submit to the EPA PO.
- Verification Statements – This element describes the verification statements that will summarize the verification test results.

The implementation plan also includes sections on APCT Center management, SAC management, technology verification management, subcontractors, quality management, the APCT Center QMP, and verification QA/QC.

2.8 Implementation of Work Processes

Verification testing will proceed after a GVP and the T/QAP for a specific technology category have been approved by the EPA PO and EPA QM. Depending on the technology type, several T/QAPs can sometimes fall under one GVP. Verification tests will be conducted at locations appropriate for the technology being tested, as established by the approved GVP. The verification test will then be carried out according to the approved T/QAP. The data from the test will be compiled, validated, and reported in a form consistent with the objectives of the test. After the test has been completed and the data have been validated by the TO's staff, the TO-QM will perform an ADQ on the data. See Section 3.3 for more information on the implementation of work processes during verification tests.

2.9 Assessment and Response

The goal of an assessment is accomplished by examining the processes used by an organization to plan, implement, and assess the effectiveness of the QA activities that are described in its QMP and that are applied to programs that collect or use environmental data. The purpose of the assessment is to provide valid feedback to management on the adequacy, implementation, and effectiveness of the quality system. The assessment may also examine human resource issues, such as whether personnel have adequate QA training.

The EPA QM, the QM, and/or the TO-QMs will perform self-assessments and independent assessments of the APCT Center quality system and TOs' quality systems. They will also perform self-assessments and independent assessments (i.e., TSAs and/or PEs) of measurement systems during verification tests. The TO-QM will conduct an ADQ for all critical measurements at the end of each verification test. See Section 3.4 for additional details.

Assessors will have a minimum of 4 years' full-time appropriate practical workplace experience (not including training), at least 2 years of which should have been in QA activities. They will have undergone training to the extent necessary to ensure their competence in the skills required for carrying out assessments and for managing assessments. The assessors assigned to conduct a specific assessment will collectively possess adequate professional proficiency for the tasks required. They will be free from personal and external barriers to independence, will be organizationally independent, and will be able to maintain an independent attitude and appearance. They will use due professional care in conducting the assessment and in preparing related reports.

Assessors will have sufficient authority, organizational freedom, and access to programs, managers, documents, and records to:

- Identify both quality problems and noteworthy practices;
- Propose recommendations for resolving quality problems; and
- Independently confirm implementation and effectiveness of corrective actions.

Reports of self-assessment findings of TO quality and technical systems will be prepared by the TO-QM and will be sent to the test leader. Reports of ADQs of verification test results will be prepared by the TO-QM and will be sent to the test leader and the QM. Reports of independent assessment findings of TO quality and technical systems will be prepared by the QM and will be sent to the TO-QM and the director. Reports of self-assessments of the APCT Center quality system will be prepared by the QM and will be sent to the director. These reports will be available for review during independent assessments.

The reports of assessments of quality or technical systems will contain a statement on the effectiveness of the systems that were assessed. The reports will give all of the details of the assessment necessary to understand the current status of the project and to estimate whether DQOs and DQI acceptance criteria will be attained. It will include an introduction describing the purpose and scope of the assessment, the technical basis for the assessment, an executive summary (as needed), a detailed account of findings and further observations, a list of the assessors, and a list of the TO managers and personnel. The report will recommend corrective actions, if such are indicated by the findings.

Reports of the ADQs will describe the results of custody tracing, a study of data transfer and intermediate calculations, a review of QA and QC data, a study of project incidents that resulted in lost data, and a review of study statistics. The ADQ reports end with conclusions about the quality of the data from the project and their fitness for their intended use.

As specified in Sections A9.4 and B4.3 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008), responses by the assessees to adverse findings and recommendations are required within 10 working days of receiving the assessment report. The lead assessor has the responsibility to correct any errors in fact that are demonstrated by evidence to the contrary. Any disputes encountered as a result of assessments will be presented in writing to the director, who will resolve the disputes. The test leader will be responsible for developing and implementing any corrective actions. The assessors will follow up with appropriate documentation to confirm the implementation and effectiveness of the corrective actions.

If assessors identify a severe problem affecting verification quality, the QM and the TO-QMs will notify the director to halt the verification until the problem is addressed. If assessors identify a problem endangering the health and safety of personnel, they have the responsibility to bring the danger to the immediate attention of the director, the test leader, and the onsite testing personnel.

2.10 Quality Improvement

The APCT Center director is responsible for improving the quality of the APCT Center's system and processes used to plan and produce verification test data. He/she is assisted by the APCT Center QM and all others on the Center team.

Activities will be based on the technical expertise of APCT Center staff and stakeholders, review of the results of verification tests, QA assessment findings, and inputs from many other sources. GVPs will be reviewed with the technical panels and revised to ensure that they are consistent with stakeholder objectives, DQOs, and resource constraints pertinent to actual testing. T/QAPs and SOPs will be reviewed and revised to ensure that the testing environment meets specified DQOs.

When problems with the APCT Center system and processes, or with technology-specific items, are determined by the Center director to be significant, the probable root cause shall be identified and the appropriate changes determined, implemented, and documented in a timely manner.

3.0 Part B: Collection and Evaluation of Environmental Data

This section contains the specifications and guidelines that apply to test-specific environmental activities involving the generation, calculation, analysis, evaluation, and reporting of test data.

3.1 Planning and Scoping

After a GVP has been approved by the EPA PO and EPA QM, it will form the basis for a T/QAP that will be prepared for each verification test or each group of very similar verification tests. If another level of detail is needed for describing test activities, an SOP will be written and attached to the T/QAP.

T/QAPs and any SOPs that are needed will be prepared by the test leader with the assistance of the TO-QM. They will be reviewed and approved by the director, the QM, and the EPA PO and EPA QM. The test leader and TO-QMs will be responsible for monitoring the implementation of the T/QAPs and any needed SOPs by the TO. All data collected during a verification test must be

generated in accordance with the GVP, T/QAP, and SOPs prepared for that test. The T/QAP and SOPs provide concrete steps to implement the GVP and will provide sufficient detail to demonstrate that:

- The verification test's technical objectives are identified and agreed upon;
- The intended measurements and data acquisition methods are consistent with the verification test objectives;
- DQI acceptance criteria specified in the T/QAP and SOPs are consistent with the DQOs specified in the GVP;
- The assessment procedures are sufficient for determining whether measurement data of the type and quality needed and expected are obtained and whether measurement data attain DQOs; and
- Any potential limitations on the use of the data can be identified and documented.

3.1.1 Generic Verification Protocols

GVPs provide the necessary framework for development of the more detailed T/QAP. The specific content and level of detail given in GVPs may vary between different air pollution control technologies in response to the testing and quality requirements for each technology.

To start the development of a GVP, the test leader, the TO-QM, and other APCT Center personnel will review existing test methods that might be applicable and prepare a review of their strengths and weaknesses. They will prepare a draft GVP for discussion purposes, either by synthesizing existing test methods or using their technical judgment. DQOs for critical measurements will be clearly defined in the draft GVP. During the development of the draft GVP, technical panel members will provide input into the GVP to ensure that their constituents' interests are met. To the extent practical, the GVP will be generally accepted by the technical panel members. The draft GVP will be reviewed by the director and the QM before it is sent to the EPA PO and EPA QM for approval. The GVP will remain a draft document until completion of the first verification so that appropriate corrections can be made.

Each GVP will contain elements that are common to all technologies, as well as elements that are specific to the technology being tested. It will ensure that all important information is obtained from the verification test. Examples of information that could be important are emissions control efficiency, emission rates, energy usage, wastewater and solid waste effluents, byproducts, reliability, operating limitations, operation and maintenance requirements, and scale-up factors or procedures. The GVP must be structured so that any specific information required for compliance with new and existing regulatory standards will be obtained during the verification test. The forms of standards (e.g., whether requirements are based on a percent reduction, outlet emissions limit, or production-based limit) will be considered in developing the GVP.

In general, the GVP may address the following issues:

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

The QA/QC requirements section of the GVP typically describes the activities that verify the quality and consistency of the work. The GVP will include DQOs for critical measurements, which are qualitative or quantitative statements that:

- Clarify the objectives of the verification test;
- Define the most appropriate type of data and amount of data to collect;
- Determine the most appropriate experimental conditions under which to collect the data; and
- Specify tolerable limits on the uncertainty of all critical measurements that will be used as the basis for establishing DQI acceptance criteria, such as accuracy, precision, limit of detection, and correct chemical identification. Limits on uncertainty may also be expressed as tolerable limits on decision errors (for testing hypotheses) or as acceptance widths for confidence or probability intervals (for estimating parameters).

The process of developing DQOs may be viewed as a strategic planning effort, based on the scientific method that is used to prepare for data collection. DQOs apply to all verification tests of a technology. The process is described in *Guidance for the Data Quality Objectives Process, EPA QA/G-4* (EPA, 2006). It provides a systematic procedure for identifying performance variables that must be assessed during the verification tests and the data quality that is needed for a credible measurement of that variable. The DQO process may or may not have a statistical basis as is appropriate for the specific technology to be verified.

The technical panel may suggest specific QA procedures in the GVP or may allow TO-QMs and test leaders to develop these procedures. If these procedures vary between tests, the more appropriate documents in which to describe them may be the T/QAPs and any SOPs that may be needed.

The QA/QC requirements 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 PE 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 technology, the more appropriate document in which to describe them may be the T/QAP.

The GVP may cite documents or procedures (e.g., documentation of related procedures, the published literature, or methods manuals) that explain, extend, or enhance the GVP. 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.

3.1.2 Test/Quality Assurance Plans

T/QAPs are specific for one or more very similar verification tests that are conducted by a particular TO under a particular GVP. These plans address all emissions and process data that will be gathered in the verification test and include a project description, TO management organization and responsibilities, DQI acceptance criteria, site selection and sampling and monitoring procedures, analytical procedures and calibration, data reduction and reporting, QC checks, technical assessments, and calculations. Data quality will be pre-eminent. All QA requirements must be met, including the requirements for review and approval of the T/QAP by the director, the QM, and the EPA PO AND EPA QM.

T/QAPs for the APCT Center must be developed in accordance with *EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5* (EPA, 2001b) and EPA's *Guidance for Quality Assurance Project Plans, EPA QA/G-5* (EPA, 2002a).

The required QA category and associated QAPP requirements for each will be determined by the EPA PO at the beginning of a project, with the concurrence of the EPA QAM. Two QA categories are applicable to verification testing preformed by the APCT VC:

Category II – establishes QAPP requirements for important, highly visible Agency projects involving areas such as supporting the development of environmental regulations or standards;

Category III – establishes QAPP requirements for projects involving applied research or technology evaluations

The graded approach applies to other aspects of the quality system. The following table summarizes these requirements for the two different QA Categories.

QA Requirement	Category II	Category III*
QAPP Preparation	EPA R-5	NRMRL QAPP Requirements
Technical Systems Audits	Required for each project	Two Category III/IV projects/year
Audits of Data Quality**	Required (25% of the data sets)	Not Required

*Additional sets of requirements may also be required depending on the nature of the project.

**If problems are found, all data sets will be audited.

The T/QAP will include the following elements, where appropriate, for the specific verification test and as applicable for the QA Category designation. It must note and explain those elements that are not appropriate for the test:

- Title and approval sheet – Include title of plan, name of the TO, and the names, titles, and signatures of appropriate approving officials, and their approval dates.

- Table of contents and distribution list – List sections, figures, tables, references, and appendices. List all the individuals who will receive copies of the approved T/QAP.

- TO personnel and responsibilities – Identify the individuals participating in the test and discuss their specific roles and responsibilities. Ensure that the TO-QM is independent of the administrative unit generating the data. Provide a concise organizational chart showing the relationships and the lines of communication among all participants, including subcontractors.

- Schedule – The anticipated start and completion dates for the project should be given. In addition, this discussion should include an approximate schedule of important project milestones, such as the start of environmental measurement activities.

- Verification test description and test objectives – State the specific problem to be solved or decision to be made and include sufficient background information to provide a historical and scientific perspective for this particular project.

- Identification of the critical measurements, DQI acceptance criteria for critical measurements, verification test schedule, and milestones – Describe the relationship between DQI acceptance criteria and DQOs specified in the GVP. EPA requires the use of a systematic planning process to define DQOs and DQI acceptance criteria.

- Documentation and records management – Describe the process for ensuring that TO personnel have the T/QAP. Itemize the information and records that must be included in the data report package and specify the desired reporting format for hardcopy and electronic forms, when used. Identify any other records and documents applicable to the project, such as assessment reports and verification reports, that will be produced. Specify or reference all applicable requirements for the final disposition of records and documents, including location and length of retention period.

- Experimental design – Describe the experimental design or data collection design for the verification test. Classify all measurements as critical or noncritical.

- Sampling procedures – Describe the procedures for collecting samples and identify the sampling methods and equipment. Describe the process for preparing and decontaminating sampling equipment.

- Sample handling and chain-of-custody procedures – Describe the requirements and provisions for sample handling and custody in the field, laboratory, and transport. Include examples of sampling documentation.

- Analytical procedures – Identify the analytical methods and equipment required. Where appropriate, the methods can be identified by method number, date, and regulatory or literature citation. List any method performance standards. For nonstandard method applications, appropriate method performance study information must be presented or cited. If previous performance studies are not available, they must be developed during the verification testing and included as part of the project results.

- Test-specific procedures for assessing DQI acceptance criteria – Identify required measurement QC checks for both the field and the laboratory. State or reference the required control limits for each QC check and corrective action required when control limits are exceeded and how the effectiveness of the corrective action shall be determined and documented. Describe or reference the procedures to be used to calculate each of the QC acceptance criteria.

- Instrument calibration and frequency – State the frequency of each type of QC check. Identify the certified equipment and/or standards used for calibration. Describe or reference how calibrations will be traceable to nationally recognized performance standards. If no such nationally recognized standards exist, document the basis for the calibration. Indicate how records of calibration shall be maintained and be traceable to the instrument.

- Data acquisition and data management procedures – Identify and describe all data-handling equipment and procedures to process, compile, and analyze the data. Describe the data management scheme, tracing the path of the data from their generation to their final use or storage. Describe record-keeping procedures. Discuss the control mechanism for detecting and correcting errors and for preventing loss of data.

- Self-assessments of quality and technical systems and ADQs – Identify the number, frequency, and type of assessment activities. Describe how and to whom the results of

the assessments shall be reported. Define the scope of authority of the auditor, including stop-work orders.

- Corrective action procedures in response to technical assessment findings – Discuss how corrective actions will be developed and implemented by the TO in response to assessment findings. Include details on how the corrective actions will be verified and documented.

- Test status reports and assessment reports – Identify the frequency and distribution of reports issued to inform management of the status of the test, assessment findings, and other significant QA problems and recommended solutions. Identify the preparer and recipients of the reports and the actions that recipients are expected to take as a result of the reports.

- Data reduction, data review, data validation, and data reporting – State the criteria used to review and validate (i.e., accept, reject, or qualify) data in an objective and consistent manner. Describe the process to be used for validating and verifying data, including the chain of custody for data. Discuss how issues shall be resolved. Describe how the results are conveyed to the data users.

- Reporting of DQIs for critical measurements and reconciliation of verification test data with DQOs – Describe how the data will be reconciled with the DQOs. Outline the proposed methods to analyze the data and determine possible anomalies or departures from assumptions established in the planning phase of the verification test. Describe how the reconciliation process will be documented.

- Limitations of the data – Describe how issues will be resolved and discuss how limitations on the use of the data will be reported.

Although the approved T/QAP must be implemented as prescribed, it is not inflexible. Because of the complex and diverse nature of ETV Program verification testing, changes to already approved plans are often needed. When such changes occur, the QM will determine if the change significantly impacts the technical and quality objectives of the project. When a change is significant, the test leader, with the assistance of the TO-QM, will modify the plan to document the change and submit the revision for approval by the EPA PO AND EPA QM. The change can be implemented only after the revised plan has been approved.

DQIs are qualitative and quantitative measures of principle quality attributes. They are used in T/QAPs for specifying requirements for the acceptability or utility of measurement data. Historically, DQIs sometimes have been incorrectly equated with DQOs, which are specifications for decision-making. In the ETV Program, DQOs are specified by a technical panel and are documented in the GVP. DQIs and DQI acceptance criteria are developed by a TO to allow it to determine from QC checks during a verification test whether the verification test data will attain the DQOs at the completion of the test.

While DQOs state what the verification test data user's needs are, they do not provide sufficient information about how these needs can be satisfied. The TO staff who will participate in generating the data need to know the DQI acceptance criteria that must be satisfied to attain the

DQOs. One of the most important features of the T/QAP is that it links the DQOs with DQI acceptance criteria. Although the level of rigor with which this is done and documented will vary widely depending on the technology being tested and the measurement systems involved, establishing this linkage in the T/QAP represents an important advancement in the implementation of the APCT Center quality system.

The establishment of acceptance criteria for the DQIs sets quantitative goals for the quality of data generated in the verification tests. For the quantitative measurement parameters, the T/QAP must describe test-specific measurement and calculation procedures for assessing DQIs. Acceptance criteria for DQIs should be consistent with the DQOs in the GVPs and, where possible, acceptance criteria for quantitative DQIs should be derived from quantitative DQOs.

The six principal DQIs that are related to environmental measurements and sampling are precision, accuracy, representativeness, comparability, completeness, and sensitivity. Secondary DQIs include selectivity, recovery efficiency, memory effects, limits of quantitation, repeatability, and reproducibility.

EPA's *Guidance on Data Quality Indicators, EPA QA/G-5i* (EPA, 2007a), provides more information about how to prepare DQIs and how to establish them in the context of DQOs.

3.1.3 Standard Operating Procedures

If another level of detail beyond the T/QAP is needed for describing test activities, technical SOPs must be written by the TO. The SOPs must be prepared and approved before the start of the verification test. They must be available for review by the director, the QM, and EPA as part of the review and approval process for T/QAPs. They must also be available for review during self-assessments and independent assessments. If requested by a TO, the APCT Center and EPA will hold confidential SOPs that are supplied by the TO for review.

A technical SOP is a set of written instructions that document a routine or repetitive activity followed by a TO. The development and use of SOPs are integral parts of a successful quality system because they provide testing personnel with the information needed to perform a job properly, and they facilitate consistency in the quality and integrity of verification test data. SOPs describe both technical and administrative operational elements of a TO that would be managed under a T/QAP. EPA's *Guidance for Preparing Standard Operating Procedures (SOPs), EPA QA/G-6* (EPA, 2007b) provides more information about how to prepare SOPs.

The technical SOP needs to include the specific steps aimed at initiating, coordinating, and recording or reporting the results of the activity, and it should be tailored only to that activity. Cited published methods may not contain pertinent information for conducting the procedure in-house. The SOP should fit within the framework presented here, but this format can be modified, reduced, or expanded as required. The technical SOP should address three areas:

1. Procedural Area – This section can include the following items as appropriate for the verification test:

- Scope and applicability (describing the purpose of the process or procedure and any organizational or regulatory requirements);

- Summary of method (briefly summarizing the procedure);
- Definitions (acronyms, abbreviations, and specialized forms used in the SOP);
- Health and safety warnings (indicating activities that could result in possible personal injury), including medical assistance and site evacuation plans;
- Cautions (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; warnings should also be listed 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);
- Equipment and supplies (listing and specifying, where necessary, equipment, materials, reagents, chemical standards, and biological specimens); and
- Procedure (identifying all pertinent steps, in order, and materials needed to accomplish the procedure). For example:
  - 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 manipulate analytical results and 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).

2. QC and QA Area – QC procedures are designed to allow the evaluation of the quality and consistency of the verification test results by the TO. Examples of QC procedures include instrument calibrations and QC materials (e.g., blanks, split and spiked samples, and PE samples) to verify the performance of the technology being tested. Criteria for determining success can be included in the SOP, as appropriate. The frequency of required calibrations and QC checks and the rationale for the decision regarding the frequency can be described. Acceptance criteria for DQIs and corrective actions required when these criteria are exceeded can be described.

The SOP can specify and describe any QA procedures that are integral parts of the verification test, including self-assessments and independent assessments (e.g., TSAs, PEs, and ADQs). It can specify who or what organization is responsible for each QA activity and where or how PE samples are to be procured and/or verified.

3. Reference Area – The SOP should fully reference related documents or procedures, such as related SOPs, published literature, and methods manuals. However, such reference citations cannot substitute for the thorough description of the method being followed in the TO. All references that are noted in the SOP should be fully cited, and references that are not readily available should be attached to the SOP.

As with the technical SOPs, administrative SOPs can be written for a wide variety of activities (e.g., reviewing documentation such as contracts, T/QAPs and QMPs; inspecting the work of others; determining organizational training needs; developing information on records maintenance; validating data packages; or describing office correspondence procedures). The administrative SOP needs to include a number of specific steps aimed at initiating the activity, coordinating the activity, and recording or reporting the results of the activity. For example, an assessment SOP should specify the authority for the assessment, technical criteria for assessments, what will be done with the results, and who is responsible for developing and implementing corrective action. Administrative SOPs for APCT would be written by RTI staff under the direction of the APCT director.

Technical SOPs are the responsibility of test leaders, who manage the SOPs according to their laboratory quality systems. Administrative SOPs are the responsibility of the APCT director, they are numbered consecutively, maintained in the APCT folder on the RTI server, and handled as other APCT records. The ESE administrative SOPs are available on the RTI intranet and will be used as applicable for APCT.

3.2 Design of Verification Tests

Data collection operations will be performed during the verification tests in conformance with the GVPs and test-specific T/QAPs. These operations must be designed so that one can determine whether the DQOs for the verification tests have been attained. Specific considerations regarding the design of data collection operations will be addressed in the T/QAP for each verification test. EPA has established an Existing Data policy (EPA ETV QMP Appendix C) which much be complied with for APCT.

3.2.1 Intended Use of Data

The key use of information generated by verification tests is to prepare verification statements, which are independent and credible third-party assessments of the environmental performance characteristics of commercially ready technologies through the evaluation of objective and quality-assured data. These statements will include information such as pollutant emissions removal efficiency rates and energy consumption rates as a function of operating conditions. The data thus generated may be used for a variety of purposes, including regulatory compliance decisions. For this reason, it is important that the data be reliable, defensible, and of known quality. Key acceptance criteria are described in the next section.

The APCT Center will not disseminate interim results from verification tests. As such, it will not be necessary to identify and state restrictions on the use of interim results.

3.2.2 Project Requirements for Data Quality Objectives

APCT Center personnel and TO personnel will establish quantitative DQOs in the GVPs with input from technology-specific technical panels. These DQOs address the end use of the data and the data quality required for stakeholder decisions that are based on those data. Thus, the quantitative DQOs address the required quality in terms of tolerable limits for the uncertainty of measurement data from the verification tests. Examples of DQOs include the types of measurements to be made, the critical variables applicable to each technology, and the degree of uncertainty permissible in the verification statement.

During the TO's development of its T/QAP, the higher level DQOs are broken down into component parts in order to derive quantitative DQI acceptance criteria (e.g., precision, accuracy, representativeness, completeness, and comparability) for each critical measurement. DQIs address the requirements that are placed on the nuts-and-bolts aspects of the sampling and measurement systems, which is why they are specified in the T/QAP. Specific procedures for determining attainment of DQI acceptance criteria will be listed in the T/QAP. The T/QAP will be developed by the test leader with the assistance of the TO-QM and the QM. It will be reviewed by the director, the QM, and the EPA QM. Finally, it must be approved by the EPA PO before the verification test begins.

3.2.3 Performance Characteristics for Measurement Methods

Each T/QAP is developed for a verification test of a particular technology by a particular TO. It will list all critical measurements to be made during that test, the procedures to be used for these measurements, and the performance characteristics of the measurement procedures. The APCT Center has extensive experience in developing and verifying new and/or nonstandard environmental measurement methods. Before any new or nonstandard measurement method is used in a verification test, its performance characteristics will be determined over the expected range of test conditions. If previous performance studies for this method are not available, studies will be developed before the verification test and will be included as part of the T/QAP. The types and frequencies of calibrations and the QC samples that are necessary to track a new method's performance will be determined during method validation and specified in the method's SOP.

3.2.4 Use of Accepted Analytical Procedures

Appropriate, approved procedures will be used for sampling and analysis and for method development and evaluation, when available. EPA-approved methods of sampling and analysis will be used whenever possible. The required quality and consistency of these methods and of new or nonstandard methods will be specified in the T/QAP. These methods will be fully described in the T/QAP and in any SOPs that are needed. The APCT Center will also employ standard, recognized statistical and data assessment methods.

3.2.5 Instrument Calibration

Calibration of an analytical method establishes the quantitative relationship between the quantity of the analyte (e.g., in concentration units of parts per million) and the method's response (e.g., in volts). This relationship is used to convert subsequent method responses into the corresponding analyte quantity. Because the response of many methods has the tendency to drift with time, the calibration must be checked periodically to maintain a high degree of accuracy. Sampling and analytical equipment will be calibrated in accordance with the GVP, the T/QAP, and any needed SOPs, and with the sampling or analytical method for which the equipment is used. The frequency of calibration depends upon the type of equipment, the particular compound or element being measured, and the concentration level(s) of the compound or element. Analysts will evaluate instrument performance characteristics such as span drift, zero drift, noise, and linearity.

Analyses must fall within the calibrated range of the instrument. Samples will be screened so that calibration standards are appropriate for the anticipated measurement range of the samples. Calibration standards will be traceable to national standards, such as National Institute of Standards and Technology (NIST) Standard Reference Materials (SRMs) or NIST-traceable weights, when such standards are available. The stability of calibration standards will be monitored through the use of independently prepared samples that are analyzed with the calibration standards.

Calibration documentation will be maintained with each method in a central location and will be readily available for review by assessors and TO management. It will include such information as the instrument being calibrated, raw calibration data, calibration equations, analyzer identifications, calibration dates, certification periods, analyzer locations, calibration standards used and their traceabilities, identification of calibration equipment used, and personnel conducting the calibration.

3.2.6 Sample Collection, Selection, Preparation, and Site Selection

EPA sampling and site selection protocols, where available and appropriate, will be followed for all verification tests. When testing is conducted by RTI or by a TO under RTI's supervision, any needed sampling SOPs will be established before testing begins and will be attached to the T/QAP. If sampling is performed by an unsupervised TO, adequate documentation of samples and the assessment and evaluation of the sampling procedures used to generate the data will be required.

Sample selection will be performed according to an approved experimental design that specifies the number and types of samples to be taken to achieve the DQOs and the specified DQI acceptance criteria described above. Where appropriate, statistical techniques will be used to develop the experimental design. The TO will ensure that all qualitative criteria for sampling representativeness are met so that valid, unbiased test results are obtained. Proper sample collection and statistical sampling techniques will be used where necessary to avoid sampling bias.

3.2.7 Sample Handling, Tracking, Custody, Transportation, and Storage

To ensure that verification test samples and data are both secure and traceable, test leaders and TO-QMs will develop written SOPs for sample handling, sample tracking, and chain of custody. These SOPs will be applicable to specific verification tests and will be documented in the T/QAPs for those tests. They will provide appropriate protection against inadvertent loss of samples or data, will ensure that verification test data generated by the TO are traceable, and will protect participants' proprietary information. A graded approach will be used in these procedures such that documentation and security levels are commensurate with the intended use of the verification test data and the degree of confidence needed in the quality of these data. A general discussion of sample handling and custody is given in EPA's *Guidance for Quality Assurance Project Plans, EPA QA/G-5* (EPA, 2002a).

The written sample custody procedures in the T/QAPs will include the following elements, as appropriate, for the specific verification test:

- List the names and responsibilities of all sample custodians in the field and in laboratories;
- Give a description and example of the sample numbering system;
- Define acceptable conditions (e.g., sample preservation, temperature, transit time, etc.) and plans for maintaining sample integrity in the field prior to and during shipment to the laboratory;
- Give examples of sample log sheets, chain-of-custody forms, and sample labels that will be used to maintain sample custody and to document sample handling in the field and during shipping;
- Describe the method of sealing shipping containers with chain-of-custody seals to detect tampering;
- Describe procedures that will be used to maintain the chain of custody and to document sample handling during transfer from the field to the laboratory, within the laboratory, and among test laboratories;
- Provide for the archiving of all shipping documents and associated paperwork;
- Discuss procedures that will ensure sample security at all times;
- Describe procedures for within-laboratory chain of custody together with verification of the printed name, signature, and initials of persons who are responsible for custody of samples, extracts, or digests during analysis at the laboratory; and
- Describe procedures to document the disposal or consumption of samples.

Less rigorous documentation of chain-of-custody procedures will be used when:

- Samples are generated and immediately tested within a facility or site; and
- Samples are continuous, rather than discrete or integrated samples, and are subjected to real-time or near-real-time analysis (e.g., continuous monitoring).

A sample custodian will be designated by the TO for any verification test involving large numbers of samples. The sample custodian performs sample-receiving inspection, physical acceptance of a group of samples intended for subsequent treatment or analysis, analysis tracking, and/or sample repository operation.

Necessary preservation techniques will be used for all perishable environmental samples as provided in the applicable methods. Perishable samples will be shipped in coolers with frozen ice-substitute gel packs when temperature control is necessary.

3.3 Implementation of Planned Operations

The verification testing will proceed after the T/QAP has been approved by the EPA PO and EPA QM. Verification tests will be conducted at locations appropriate for the technology being verified, as established by the GVP. A full-scale installation at an industrial facility or a large-scale pilot device operated on a slipstream may be required, or a pilot facility with a source simulator may suffice. Although cost control is important, the most important requirement for a test site is that the data obtained be convincing. The wide variety of facilities available to the APCT Center will ensure that the most suitable and cost-efficient location will be chosen, consistent with the GVP requirements. If no suitable facility is available to the APCT Center, another site will be chosen in consultation with the technical panel and the EPA PO.

Verification tests will be performed in accordance with the T/QAPs. Test leaders will be responsible for implementing the T/QAPs and any needed SOPs, and they will periodically report on the progress of the verification tests to the director. Their progress toward attaining the DQOs will be most directly monitored by the TO-QMs. The QM, under the direction of the director, will be responsible for independent assessments of TO quality systems and technical assessments of verification tests. Such technical assessments may include TSAs and PEs at the test site during verification tests. TO-QMs will conduct self-assessments of the quality and technical systems and ADQs after verification tests have been completed.

Verification tests will be conducted according to the following requirements:

- All critical items and services used during the verification tests will conform to specifications given in the GVPs, T/QAPs, and any needed SOPs.
- All sampling, measurement, and analytical instrumentation and other measurement systems used for critical measurements during the verification tests will be checked to determine whether they comply with DQI acceptance criteria given in the T/QAPs.

- Whenever the measurement systems do not meet the DQI acceptance criteria specified in the T/QAPs, corrective actions will be taken before any further measurements are made to return the measurement systems' performance to acceptable levels.

- Measurement systems will be maintained and repaired in accordance with specifications given in the GVPs, T/QAPs, and any needed SOPs.

- All tools, gauges, and any other ancillary sampling, measuring, and testing equipment used for critical measurements during verification tests will be maintained and repaired in accordance with specifications given in the GVPs, T/QAPs, and any needed SOPs. Equipment found to be out of specification will not be used until it can be recalibrated or repaired and then demonstrated to be functioning within the specifications.

- All measurements and other verification activities will be documented in laboratory notebooks, field and laboratory data sheets, spreadsheets, computer files, and other appropriate storage media.

- Field and laboratory samples will be collected, handled, transported, and stored in accordance with specifications given in the GVPs, T/QAPs, and any needed SOPs. The chain-of-custody process will be maintained in accordance with specifications given in these documents.

- Verification test data will be transmitted, stored, validated, assessed, processed, and retrieved in accordance with specifications given in the GVPs, T/QAPs, and any needed SOPs.

3.4 Assessment and Response

3.4.1 Frequency, Types, and Reporting of Assessments

Sections A9.1 and B4.2 of EPA's *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008) specify that EPA will conduct one independent assessment of the APCT Center's quality system. Additional assessments of APCT Center's quality system will be at a frequency determined by the EPA QM's professional judgment, using the guidelines described in Table 3.

The QM will perform a self-assessment of the APCT Center quality system on an annual basis in conjunction with the annual review and revision, as needed, of this document. This assessment frequency is specified in *EPA Requirements for Quality Management Plans, EPA QA/R-2* (EPA, 2001a). A final report of the assessment findings will be prepared and will be presented to the EPA PO, the EPA QM, and the director.

The QM will perform at least one independent assessment of each TO's quality system. These assessments will be conducted in accordance with EPA's *Guidance on Assessing Quality Systems, EPA QA/G-3* (EPA, 2003). The frequency of additional independent assessments of the quality system will be determined by the QM in consultation with the EPA QM, and will be based on their professional judgments. Factors that will be considered in making this determination include the state of the TO's quality system during previous independent

Table 3. Schedule of Assessments

Assessment Type	Assessment Subject	Assessment Authority	Assessor	Minimum Frequency	Assessment Purpose	Report Recipient
Quality systems audit	APCT Center quality system	Approved APCT Center QMP (this document)	APCT Center QM	Within one year after approval of the APCT QMP, then as requested by EPA	Evaluate effectiveness of APCTVC quality system with respect to QMP	APCT Center director
Quality systems audit	TO quality system[H]	Approved TO quality manual*	APCT Center QM	Prior to data collection and as specified in the approved T/QAP	Evaluate effectiveness of TO quality system[H]	APCT Center director EPA PO EPA QM TO PM TO QM
Self Quality systems audit	TO quality system[H]	Approved TO quality manual*	TO QM	Prior to APCT QSA of TO	Evaluate effectiveness of TO quality system[H]	TO director, copy to APCT center director
Technical systems audit	TO measurement systems[H]	Approved T/QAP	APCT Center QM	Once per test, unless lower frequency is pre-approved by the EPA QM	Evaluate compliance of TO measurement system with approved T/QAP	APCT Center director EPA PO EPA QM TO PO TO QM
Performance evaluation audit	TO measurement systems[H]	Approved T/QAP	APCT Center QM	Each test, if feasible and as specified in the approved T/QAP	Evaluate compliance of TO measurement system with approved T/QAP	APCT Center director EPA QM
Audits of data quality	Raw test data and summary data	Approved T/QAP	TO QM	Each test	Evaluate compliance of achieved measurement quality with respect to approved T/QAP and assess data calculations at a rate of at least 10%	APCT Center QM EPA QM

Note: This table identifies APCT Center-initiated assessments. We plan to coordinate with EPA staff to facilitate their awareness and participation, if desired. QM = quality manager; TO = testing organization.
* Regardless of title (e.g., quality manual, quality systems manual).
[H] With respect to Environmental Technology Verification Program/APCT Center responsibilities.

assessments and self-assessments, the level of verification testing by the TO, and the quality of the verification tests that the TO has performed. The QM and the EPA QM may also determine that an additional assessment is needed if there has been a significant change to the quality system. In instances in which corrective action is needed to address findings from a previous assessment, followup assessments may be necessary. A final report of the assessment findings will be prepared and will be presented to the EPA PO, the EPA QM, and the director.

TO-QMs will perform self-assessments of the TOs' quality system at the frequency specified in the quality documentation of the TO. Final reports of self-assessments will be available for review during independent assessments.
The QM will perform at least one independent technical assessment of each TO's technical systems. These assessments will be conducted in accordance with EPA's *Guidance on Technical Audits and Related Assessments for Environmental Data Operations, EPA QA/G-7 Final* (EPA, 2000). In instances in which a TO is operating under multiple GVPs or multiple T/QAPs, multiple independent technical assessments may be necessary. The frequency of additional independent technical assessments will be determined by the QM in consultation with the EPA QM based on their professional judgments. Factors that will be considered in making this determination include the state of the TO's technical systems during previous independent assessments and self-assessments, the level of verification testing by the TO, and the quality of the verification tests that the TO has performed. The QM and the EPA QM may also determine that an additional assessment is needed if there has been a significant change to the technical systems, such as one that requires the revision of a previously approved T/QAP. In instances in which corrective action is needed to address findings from a previous assessment, followup assessments may be necessary. A final report of the assessment findings will be prepared and will be presented to the EPA PO, the EPA QM, and the director.

TO-QMs will perform self-assessments of the TOs' technical systems at the frequency specified in the TO's T/QAP. Final reports of self-assessments will be available for review during independent assessments.

TO-QMs will perform ADQs for a random selection of 10 percent of all the verification data for every verification test in accordance with Sections A9.1 and B4.2 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008). Final reports of the ADQs will be prepared and will be submitted with the verification report to the EPA PO, the EPA QM, the APTC Center director, and the APTC Center QM.

3.4.2 Assessments of Quality Systems

A quality system assessment (QSA) is an evaluation of an organization's relevant quality system practices. The focus of the assessment is on the organization's quality system rather than on its technical systems or the quality of data and information the organization produces to support a verification statement. Assessments are designed to evaluate and provide objective feedback on the organization's quality system. An assessment seeks to determine if the system has been fully implemented and is operating in the manner prescribed by the organization's approved QMP and if it is consistent with current EPA quality requirements. An assessment determines if an organization's QMP, quality management structure, policies, practices, and procedures are effective as implemented in assuring that environmental data have adequate quality for their intended purpose.

The criteria for assessments of the APCT Center's quality system will be this document. The criteria for assessments of a TO's quality system will be its own quality system documents. These assessments will be conducted in accordance with EPA's *Guidance on Assessing Quality Systems, EPA QA/G-3* (EPA, 2003).

The process of assessing a quality system includes the following four stages:

1. Planning the Assessment – The scope of the assessment must be determined. The scope may be very broad because the EPA PO may be interested in assessing how well the APCT Center's quality system is being applied in general. However, the EPA PO may also have specific questions that need to be addressed. Next, an assessment team will be identified. Team members should have sound interviewing skills, no conflicts of interest, competency in the technical fields being reviewed, and a thorough knowledge of quality management principles. During the planning stage, the team identifies the technical criteria (e.g., its QMP) and other background information for assessing the organization's quality system. The team will then determine what interviews and document reviews are necessary to properly assess the quality system. After the team has compiled and reviewed this information, it will develop a draft assessment plan, which the EPA PO will review.

2. Conducting the Assessment – Upon arrival at the assessment site, the assessment team first will meet with the organization's management and key personnel. Next, the team will interview management and key personnel as noted and scheduled in the assessment plan. The team also may review relevant files and consider case studies. The team will present its initial impressions of the information that it gathered during an exit meeting.

3. Evaluating the Results – The assessment team will assemble and review the information gathered during the assessment and will evaluate it based on the technical criteria documented in the assessment plan. The team then will formulate preliminary findings and recommendations in a written draft findings report.

4. Reporting the Findings and Recommendations – The draft findings report will be sent to the assessed organization for review. This step is important to ensure that there are no factual errors in the final report. The assessed organization's comments on the draft findings report will be reconciled by the assessment team. A final report of the assessment findings will be prepared by the lead assessor.

3.4.3 Technical Assessments

A technical assessment is a systematic and objective examination of a verification test during its implementation phase to determine whether environmental data collection activities comply with the T/QAP, whether they are implemented effectively, and whether they are suitable to achieve DQOs that have been specified in the GVP and DQI acceptance criteria that have been specified in the T/QAP.

A technical assessment is primarily a management tool and secondarily a technical tool. Technical assessments play an important role in documenting the implementation of the T/QAP. They provide management a tool to determine whether data collection activities are being implemented as planned. They provide management with both an increased understanding of the performance of critical measurements and a basis for improving such measurements. They also provide management a tool to take action to correct any deviations that are discovered.

The criteria for a technical assessment of a TO will be the TO's T/QAP. The TO documents the implementation of the T/QAP. Proper use of technical assessments ensures that collected environmental data are defensible. They can uncover deficiencies in physical facilities, equipment, planning, training, operating procedures, technical operations, custody procedures, documentation, and QA.

Guidance for conducting technical assessments is given in EPA's *Guidance on Technical Audits and Related Assessments for Environmental Data Operations, EPA QA/G-7 Final* (EPA, 2000).

Technical assessment tools include the following:

- TSAs qualitatively document the degree to which the procedures and processes specified in the approved T/QAP are being implemented.
- PEs quantitatively document the ability of a measurement system to obtain acceptable results that are generated for a sample that originates outside of the verification test.
- ADQs examine verification test data (hardcopy and/or electronic) after they have been collected and verified by TO personnel.
- Surveillance assessments are used to continuously or periodically assess the implementation of an activity or activities to determine conformance to established procedures and protocols. Surveillance assessments include the APCT review of TO ADQ reports and supporting documentation.

At least one TSA will be conducted for each TO. The number of PEs that will be performed during a verification will be indicated in the T/QAP. The TO-QM will conduct an ADQ of a random selection of 10 percent of the data for all measured parameters at the end of each verification test in accordance with the requirements of Sections A9.1 and B4.2 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008). The TO-QM will determine if these measurements allow attainment of the DQOs specified in the GVP and the DQI acceptance criteria specified in the T/QAP.

Technical Systems Audits. TSAs are thorough, systematic, qualitative, onsite assessments of the TO's measurement systems used to collect data. They also determine that TO personnel and equipment are physically in place and functioning as stated in the planning documents. Assessors travel to the verification site, gather objective evidence, and produce a written findings report. Objective evidence is gathered by interviewing TO personnel, examining verification documents and records, and observing verification activities.

A TSA is often conducted shortly after a verification test starts to allow for early corrective action. For longer tests, TSAs are performed on a regular schedule throughout the life of the test. TSAs may be performed in conjunction with PE assessments.

Assessment checklists are prepared based on the T/QAP and other planning documents, which are the technical criteria for the assessment. Any undocumented or unauthorized deviation from the T/QAP will be noted during the TSA and will be included in the written assessment report.

The draft findings report will be sent to the assessed organization for review. This step is important to ensure that there are no factual errors in the final report. The assessed organization's comments on the draft findings report will be reconciled by the assessment team. A final report of the assessment findings will be prepared by the lead assessor.

Performance Evaluations. A PE is a quantitative assessment in which data are generated by a measurement system for a sample whose composition is known to the assessor. Alternatively, an assessor may make collocated measurements using equipment of documented high quality. Normally PEs are performed as part of a TSA and are performed by RTI and/or EPA. Although a PE can identify a problem quantitatively, it typically cannot determine the cause of the problem. To the extent possible, a PE sample will not be distinguishable in any way to the measurement system from actual samples. It will mimic actual samples in all possible aspects, except that its composition will be unknown to the analyst and known to the assessor. It will be treated routinely and not subjected to any special treatment. It will be used to determine if the measurement system's results are within the DQI acceptance criteria specified in the T/QAP. PE results will be used to estimate the degree of bias in the measurement system.

A draft report of the PE findings will be sent to the assessed organization for review. This step is important to ensure that there are no factual errors in the final report. The assessed organization's comments on the draft report will be reconciled by the assessment team. A final report of the PE findings will be prepared by the lead assessor.

3.4.4 Audits of Data Quality

An ADQ is an examination of data (hardcopy and/or electronic) after they have been collected and verified by TO personnel. It is conducted to determine how well the measurement system performed with respect to the DQOs specified in the GVP and DQI acceptance criteria specified in the T/QAP, and to determine whether the data were accumulated, transferred, reduced, calculated, summarized, and reported correctly. It documents and evaluates the methods by which decisions were made during treatment of the data. It ensures that files are being maintained and secured, that chain-of-custody records are complete, and that raw data records are complete and in good order. Computer security will also be reviewed.

Questions to be answered in an ADQ include:

- Is there sufficient documentation of all procedures used in the data collection effort to allow for repetition of the effort by a person or team with technical qualifications similar to those of the original data collector?
- Can the data be replicated by the original data collector?
- Is there sufficient documentation to verify that the data have been collected and reported according to these procedures?
- Is enough information provided to allow a potential user to determine the quality and limitations of the data and whether the intended use of the data is appropriate?

- Are the data of sufficient quality to attain DQOs, DQI acceptance criteria, and other measurement performance criteria?

ADQs entail tracing data through their processing steps and duplicating intermediate calculations. A representative set of the data is traced in detail from raw data and instrument readouts through data transcription or transference through data manipulation (either manually or electronically by commercial or customized software) through data reduction to summary data, data calculations, and final reported data. The focus is on identifying a clear, logical connection between the steps. Particular attention is paid to the use of QC data in evaluating and reporting the data set. For a large project, a statistical approach may be necessary to determine a representative number of data sets to be examined.

A typical ADQ will begin by reviewing available data from a verification test, by determining needed missing data, and by devising a plan for the assessment. The plan will usually include steps involving pursuing all available needed data, collecting it, and conducting an extensive review of the entire collection. Verification data will be statistically analyzed to determine whether they can be used to obtain a valid estimate of the DQIs. Statistical analyses of data will include, at a minimum, the average value of each parameter and its estimated uncertainty. When necessary, APCT Center or TO statisticians can provide more advanced data evaluations.

The TO-QM prepares a report that details the results of chain-of-custody tracing, a study of data transfer, recalculations, a review of QA data, a study of project incidents that resulted in lost data, and a review of study statistics. The report states whether these measurements allow attainment of the DQOs specified in the GVP and the DQI acceptance criteria specified in the T/QAP. The ADQ report ends with conclusions about the quality of the data and their fitness for their intended use. The ADQ report is submitted with the verification report to the director, the QM, the EPA PO, and the EPA QM for review.

3.4.5 Corrective Action

Any member of the APCT staff or TO staff may initiate a corrective action at any time. The corrective action will describe the deficiency found and identify the root cause. Corrective actions will be tracked by APCT staff under the supervision of the APCT director and will be handled in a timely manner relative to the severity of the problem.

After an assessment, the TO is responsible for developing, implementing, and documenting corrective actions. It is critical that any necessary corrective action be timely and effective. In some situations, additional assessments may be needed to verify the effectiveness of the corrective actions. The TO will use a corrective action form to document any deficiencies that require action and the proposed resolution. This form will include the signatures of the individual identifying the need for corrective action and the individual responsible for implementing the corrective action. The problem requiring corrective action, the proposed corrective action, and the approach for evaluating the corrective action will be described.

The proposed corrective action should be reviewed by the lead assessor. This process helps ensure that the planned actions will be effective in resolving the problem areas and deficiencies reported by the assessment team.

The test laboratories will be responsible for the development of effective corrective actions of the problem areas or deficiencies discovered during the assessment. They will provide a written response to all assessment findings. Each finding will be addressed with specific corrective action steps and a schedule to implement them. Responses to adverse findings are required within 10 working days of receiving the assessment findings report in accordance with the requirements of Part B, Section 4.3 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008). The corrective action should address the following:

- Measures to correct each deficiency;
- Identification of all root causes of significant deficiencies;
- Determination of the existence of similar deficiencies;
- Corrective actions to preclude recurrence of similar deficiencies;
- Assignment of corrective action responsibility; and
- Completion dates for each corrective action.

Test laboratories will implement corrective actions and provide requested evidence of correction. Once such evidence is received, the technical assessment will be closed unless a reassessment is planned.

3.5 Assessment and Verification of Data Usability

Data verification will be performed by the TO in accordance with the quality requirements of the T/QAPs and any needed SOPs. As part of preparing a T/QAP, a TO will develop methods to reconcile measurement data with DQOs. Usually, the T/QAP will specify DQI acceptance criteria that allow TO personnel to determine during verification tests whether the DQOs will be attained at the end of the test.

Verification test results will be evaluated to determine the completeness, correctness, and conformance/compliance to these requirements. The goal of the data verification is to ensure and document that the results are what they purport to be, that is, that the reported results reflect what was actually done. When deficiencies in the results are identified, they will be documented for review by the director, the QM, the EPA PO, and the EPA QM. Procedures for data verification are given in EPA's *Guidance on Environmental Data Verification and Data Validation, EPA QA/G-8* (EPA, 2002c). All validated data arising from the verification tests will be disclosed in verification reports, even if the technology did not perform to the expectations of the technology provider.

QA/QC summaries will accompany regular progress reports for ongoing verification tests. QA summaries will include quantitative assessments of DQIs such as bias, precision, and completeness. Bias will be determined using personnel, equipment, and spiking material or reference material as independent as possible from those used in the calibration of the measurement system. Precision will be determined from replicate measurements of the same analyte. When possible and appropriate, the analyte will be divided in the field and will be

preserved separately to assess the variability of sample handling, preservation, and storage, along with the variability of the analytical component of the measurement system. Completeness will be determined as the percentage of valid data out of the number of trials necessary to meet statistical design goals. Qualitative statements about sampling representativeness and comparability will be provided.

For verification reports and verification statements submitted to the director from a TO, adequate QC data must be available in the submission to assess whether the DQOs and the DQI acceptance criteria were attained. After completion of a verification test, the TO-QM will prepare the QA section of the verification report, which will describe both qualitatively and quantitatively the reliability and uncertainty inherent in the results. It will present the results of all QA activities, identify any quality problems encountered, and discuss the resolution of those problems through corrective action procedures. The QM and the EPA QM will review verification reports and verification statements to confirm that the verification test results are presented correctly.

The TO-QM will conduct an ADQ of a random selection of at least 10 percent of all verification data for each verification test in accordance with the requirements of Part B, Section 4.2 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008). The procedures for conducting an ADQ are described in Section 3.4 and in EPA's *Guidance on Technical Audits and Related Assessments for Environmental Data Operations, EPA QA/G-7 Final* (EPA, 2000). As part of the ADQ, the TO-QM determines whether QC data attain DQI acceptance criteria and reconciles measurement data with DQOs. The ADQ report is submitted with the verification report for the director, the QM, the EPA PO, and the EPA QM to review.

3.6 Record Keeping and Data Management

GVPs will be retained by APCT Center for a period of not less than 7 years after the final payment of the assistance agreement in accordance with the requirements of Part A, Section 5.3 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008). T/QAPs also will be retained by APCT Center for a period of not less than 7 years after the final payment of the assistance agreement. The director is responsible for establishing procedures to securely store these documents.

Any SOPs, any raw data (electronic and printed) collected during verification tests, and any calculations or documents (including verification reports and verification statements) derived from such data will be retained by TOs and/or by APCT Center for a period of not less than 7 years after the final payment of the assistance agreement in accordance with the requirements of Part A, Section 5.3 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008). These data, calculations, and documents will be clearly identified by verification test, date, observer/author, and originating TO. The test leader and/or the director are responsible for establishing procedures to securely store these data, calculations, and documents.

Any project reviews and assessment reports that are generated by the TOs or by APCT Center will be retained by the originating organization for a period of not less than 7 years after the final payment of the assistance agreement in accordance with the requirements of Part A, Section 5.3 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008).

The test leader and/or the director are responsible for establishing procedures to securely store these project reviews and assessment reports.

Verification reports and verification statements will be retained by APCT Center for a period of not less than 7 years after the final payment of the assistance agreement in accordance with the requirements of Part A, Section 5.3 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2008). All validated data arising from the verification tests will be disclosed in verification reports, even if the technology did not perform to the expectations of the technology provider. The director is responsible for establishing procedures to securely store these verification reports and verification statements.

4.0 References

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