Quality Management Plan

Version 1.4
March 2003

Prepared by:

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EPA REVIEW NOTICE

This document has been administratively reviewed by the
U.S. Environmental Protection Agency, and approved for publication.

Quality Management Plan

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This Quality Management Plan has been reviewed and approved by the Greenhouse Gas Technology Center Director, the Southern Research Institute Quality Assurance Manager, the U.S. EPA APPCD Project Officer, and the U.S. EPA APPCD Quality Assurance Manager.

(original signatures on file)

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TABLE OF CONTENTS

Page

PART A: MANAGEMENT SYSTEMS

ABBREVIATIONS AND ACRONYMS

ADQ	Audit of Data Quality
APPCD	Air Pollution Prevention and Control Division
DQO	Data Quality Objective
EPA	U.S. Environmental Protection Agency
ETV	Environmental Technology Verification
GAD	Grants Administration Division
GHG Center	Greenhouse Gas Technology Center
ORD	Office of Research and Development
PEA	Performance Evaluation Audit
QA/QC	Quality Assurance/Quality Control
QMP	Quality Management Plan
QSA	Quality Systems Audit
SOP	Standard Operating Procedure
SOW	Statement of Work
SRI	Southern Research Institute
Test Plan	Test and Quality Assurance Plan. (the GHG center will use integrated Test/QA Plans for verification tests; these terms will be used interchangeably in this document)
TSA	Technical Systems Audit

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Introduction

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

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

To comply with these directives, EPA's Office of Research and Development (ORD) established a five-year pilot program to evaluate alternative operating parameters and determine the overall feasibility of a technology verification program. ETV began in October 1995 and was evaluated through October 2000, at which time ETV prepared a report to Congress containing the results of the pilot program and recommendations for its future operation.

During the years 1995 to 2000, ETV funded and operated 12 pilot projects, each operated by third-party organizations under the auspices of EPA. These "partner organizations" included private sector testing, evaluation, and research companies, state technology evaluation programs, federal laboratories, and industry associations. The ETV program is designed for these programs to continue consolidated into six ETV Centers. The ETV Greenhouse Gas Technology Center (GHG Center) is operated under a partnership with the verification organization Southern Research Institute (SRI).

This Quality Management Plan (QMP) has been developed in accordance with EPA's ETV QMP (December, 2002) and the American National Standards Institute/American Society for Quality (ANSI/ASQC) E4-1994, "*Specifications and Guidance for Quality Systems for Environmental Data Collection and Environmental Technology Programs*". Because credible information is the ultimate product of ETV and the GHG Center, the highest appropriate quality assurance procedures are used throughout the program. The GHG Center QMP is consistent with the policies expressed in the ETV QMP, but provides for a uniform quality system for the GHG Center and takes precedence. This QMP has been reviewed and approved, as indicated by the signatures on the approval page in the front of this document. This QMP sets forth all definitions, procedures, processes, inter-organizational relationships, and outputs necessary to assure the quality of all technical data, analysis and interpretation of these data, planning, and program management. As such, this document serves as the overall program QA standard and as general guidance for implementation. The GHG Center QMP will be reviewed by the SRI QA Manager during the annual review for quality improvement to evaluate the need for modifications or amplification.

Part A of the GHG Center QMP contains the specifications and guidelines that are applicable to common or routine quality management functions and activities necessary to support the GHG Center. Part B of the GHG Center QMP contains the specifications and guidelines that apply to test-specific environmental activities involving the generation, collection, analysis, evaluation, and reporting of test data.

Overview

This overview is included to provide a link between GHG Center activities as outlined in the Research Plan and quality requirements as specified in the QMP. This provides a guideline for day-to-day operations that will help ensure that the QMP is fully implemented as part of normal GHG Center activities.

The overall goal of the GHG Center is to establish, operate, and maintain an independent and credible Center which verifies the performance of global climate change emission reduction and monitoring technologies. In order to achieve these goals, GHG Center activities must be oriented to the market potential of such technologies and responsive to the needs and expectations of buyers, vendors, regulators, and stakeholder members.

The GHG Center recognizes that these customers require good value from the Center's products and services. Credible verification data is the ultimate product of the GHG Center. These data must be obtained at a quality and cost that is consistent with the intended use of the data. Thus, test program design, including quality assurance/quality control (QA/QC), must be carefully focused on and responsive to user needs and market economics in order to provide the value required.

With this in mind, the following general criteria have been established for prioritizing technology focus areas and candidate technologies for testing.

- Market Potential – this includes an assessment of the size and makeup of the customer base, the number of technologies available, capital cost, potential for profitable performance or early payback, and potential to deliver consistently good technical and economic performance
- GHG Emissions Reduction Potential
- Availability – the technology must be commercial or near-commercial
- Suitability for Participation – the verification should yield significant beneficial outcomes for vendors such as increased sales or positive exposure
- Occurrence of Secondary Impacts – technologies which simultaneously reduce greenhouse gas emissions and solve other problems (e.g., environmental, health, economic) will be given special consideration

PART A

MANAGEMENT SYSTEMS

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

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1.0 MANAGEMENT AND ORGANIZATION

This section consists largely of statements describing the GHG Center's commitment to quality, management and quality organization, and responsibility and authority for maintaining quality. This applies generally to all GHG Center management and strategy activities. The main point of this is to establish accountability for managing and implementing the quality system.

1.1 QUALITY POLICY

The GHG Center QMP consists largely of statements and declarations that document quality commitments in specific areas including:

- Quality policy, objectives, organization, and authorities
- Conformance to quality standards, quality system purpose scope, documentation, and review
- Personnel qualifications
- Subcontractor selection and management
- Record keeping
- Suitability and traceability of computer hardware and software
- Planning processes
- Work processes
- Assessment and response
- Quality improvement

The overall GHG Center quality policy is adhered to and consistent with the quality policy stated in the ETV QMP. In brief, this requires that the GHG Center develop and implement an approved quality system consistent with ANSI/ASQC E4. This QMP lays out requirements and implementation plans for this system. It is also required that all verification tests are performed in accordance with approved Test and Quality Assurance Plans (Test Plans). GHG Center management systems and specific plans necessary for compliance with this requirement are detailed in this QMP. In addition, all technical statements in GHG Center Verification Reports must be supported by appropriate data. This QMP lays out data collection, quality control, and record keeping (audit trail) plans to ensure this.

Finally, the GHG Center quality policy is consistent with SRI's quality policy which states:

> Southern Research Institute, including its affiliates and subsidiaries provides products, processes and services of the highest possible quality on a timely basis, that meet or exceed the requirements and expectations of its clients and customers, and that are in compliance with applicable federal, state, and local regulations.

1.2 ORGANIZATIONAL STRUCTURE

The GHG Center has implemented an organizational structure designed to facilitate and assure compliance with, and implementation of, the requirements of this QMP. This organization is consistent with the overall ETV organizational structure. This structure is based on independent and complementary

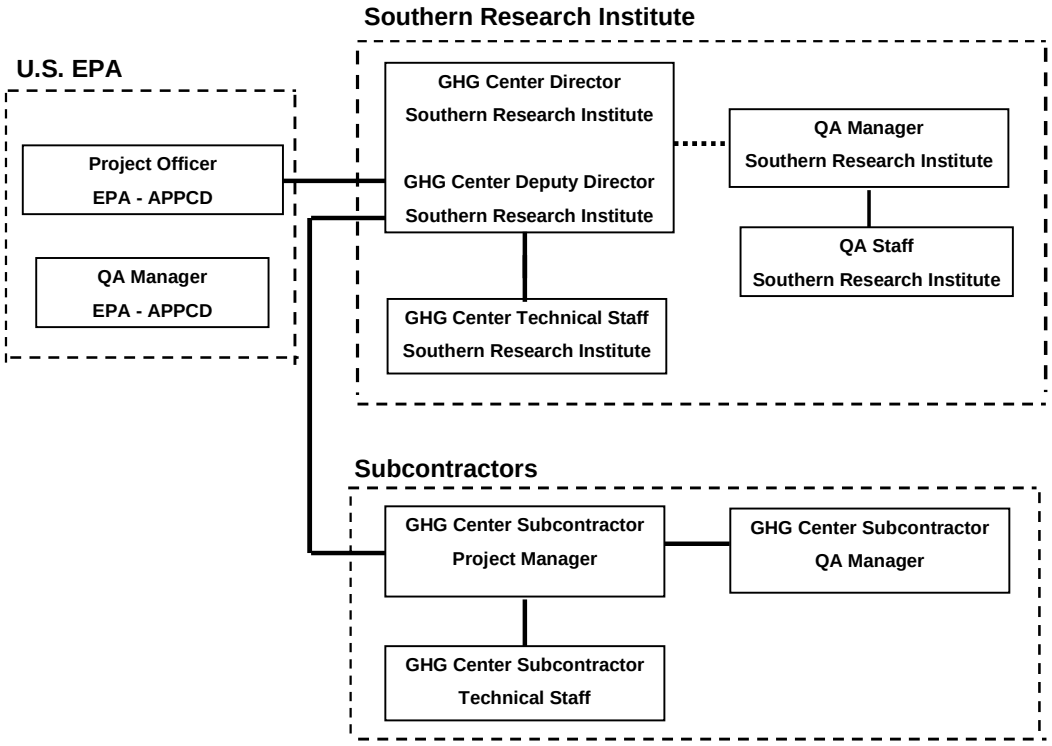
QA and technical/management roles and is outlined in Figure 1 and Appendix A. Key roles are described below.

- **GHG Center Director and Deputy Director -** The GHG Center Director and Deputy Director have overall planning and oversight responsibility for the GHG Center technical activities and subcontractor management. They also have primary responsibility for stakeholder interactions and outreach activities. The Director reports directly to the EPA Air Pollution and Control Division (APPCD) Project Officer. The GHG Center Deputy Director reports directly to the GHG Center Director.

- **SRI QA Manager and QA Staff -** The SRI QA Manager and QA staff are organizationally independent from GHG Center technical staff and management. The SRI QA Manager and staff are responsible for maintaining familiarity with day-to-day planning and technical operations, providing support for QA planning and implementation for verification testing, as well as performing assessments. The SRI QA Manager provides oversight and review of all QA activities.

- **GHG Center Technical Staff -** The GHG Center technical staff have the responsibility to perform assessments of the testing projects to ensure that proper procedures of this QMP are being followed.

Figure 1. Greenhouse Gas Technology Center Organization



1.3 CUSTOMER IDENTIFICATION AND NEEDS/EXPECTATIONS/WORK OBJECTIVES

The overall quality objective of the GHG Center is to meet customer needs. In quality terms, a customer can be any user of ETV products. GHG Center customers may include, but are not limited to:

- Public and private sector buyers and users of GHG mitigation and monitoring technology;
- Developers and vendors of these technologies;
- Consulting engineers involved with design of GHG mitigation strategies; and
- Federal, state, and local government permitting and regulatory agencies.

Customers also include users of ETV data within EPA. These include decision-makers as well as EPA technical staff.

The needs and expectations of these customers include:

- ETV Verification Reports and Verification Statements supported by objective and supportable data of known quality, provided in a timely manner;
- Selection of appropriate technologies and parameters for testing based on a systematic selection process and input from appropriate stakeholder groups;
- Documentation that is accessible and useful for practical application;
- A practical approach in testing which provides efficient, timely, well-documented, and cost-effective technology tests;
- Full disclosure of all testing results including those which do not verify the technology manufacturer's claims; and
- User-friendly documents (e.g., easy to read and to implement).

In addition, internal EPA customers require conformance to EPA management and quality policy, expedited adoption of improved environmental technology, and efficient use of resources.

Specific needs and expectations of GHG Center customers are defined and documented in published and accessible summaries of stakeholder meetings. These needs are defined through discussions between the EPA APPCD Project Officer, GHG Center, and stakeholders and are established in the form of written objectives prior to testing.

1.4 SUBCONTRACTOR RELATIONSHIPS AND QUALITY ASSURANCE

Subcontractors or consultants may be used to support GHG Center efforts on an as-needed basis. Such arrangements are formalized in contracts or purchase orders accompanied by a detailed Statement of Work (SOW). These documents spell out quality requirements, consistent with this QMP, and specific to the tasks to be performed.

1.5 MANAGEMENT RESOLUTION OF QUALITY CONSTRAINTS

In the event that time, cost, or other constraints significantly affect the ability of the GHG Center to fully satisfy ETV quality system requirements, the GHG Center will seek to resolve the problem according to procedures outlined in the ETV QMP. Assessments made by GHG Center technical and QA staff will be reviewed by the SRI QA Manager and the GHG Center Director, to ensure any deficiencies are addressed. This assessment and review/action will be documented and retained in the project files. In addition, this includes timely notification of the EPA APPCD Project Officer of any problems and negotiation of a solution. If a solution cannot be reached, the negotiations will be elevated to the EPA Branch Chief, and/or the ETV Director. If an agreeable solution is not found within current constraints, appropriate action will be taken. This may include increased funding for the benefit of the program, non-funding of extensions, or non-support for Verification Statements. If negotiations are unproductive, the Grants Administration Division (GAD) of EPA will be notified for possible legal action.

1.6 RESOURCES

Sufficient program resources will be allocated to fully satisfy ETV quality requirements as stated in the ETV QMP. These include personnel, budget, communications, and other costs.

1.7 AUTHORITY TO STOP WORK

EPA line management has the authority to stop work for reasons of inadequate safety or quality. EPA may also delegate this authority, and has done so to the GHG Center Director for ensuring compliance with all federal, state, and local health and safety rules during the performance of verification tests. This includes obtaining necessary permits and certifications. In accordance with the ETV QMP (Part A, Section 1.7), the GHG Center has identified one or more individuals who may issue a stop work order in the event that unsafe work or work of inadequate quality is identified. A stop work order may be issued by the GHG Center Director, the GHG Center Deputy Director, or the GHG Center Project Manager. The EPA APPCD Project Officer or EPA QA Manager may directly contact the GHG Center Director upon discovery of inadequate safety or quality in regard to a possible stop work order. In extreme circumstances, the EPA Project Officer may ask GAD to intervene in the stop work process.

2.0 QUALITY SYSTEM AND DESCRIPTION

Approval of this QMP by the parties signing on the approval page is evidence that the GHG Center quality system is planned, established, documented, implemented, and assessed as part of the EPA ETV management system.

2.1 AUTHORITIES AND CONFORMANCE TO ANSI/ASQC E4

The authority for developing appropriate quality systems for ETV is USEPA Order 5360.1. The requirement for assistance agreement holders is found in Federal Register, CFR Parts 30 and 33, February 15, 1996. This QMP complies with ANSI/ASQC E4-1994 (Specifications and Guidance for Quality Systems for Environmental Data Collection and Environmental Technology Programs) and the ETV QMP.

The responsible authorities within the GHG Center for planning, implementing, and assessing issues affecting the quality system will be the technical staff. The responsibility for reviewing the assessments and correcting deficiencies will reside with the GHG Center Director and SRI QA Manager.

2.2 QUALITY SYSTEM DOCUMENTS

The GHG Center quality system is described in this QMP. This QMP is reviewed and approved by the GHG Center Director, SRI's QA Manager, EPA's Project Officer, and EPA's QA Manager. Any revisions will be reviewed and approved in the same manner.

2.3 QUALITY SYSTEM SCOPE

This QMP is the written description of the quality system and contains statements, declarations, and procedures covering the entire scope of the GHG Center quality system. This covers all planning, outreach, management, quality, and technical tasks conducted under the GHG Center. In general, these include:

- Development and approval of this QMP
- Establishment of ranking criteria, and selection of candidate verification technologies
- Solicitation of vendors and support for vendor development of verification applications
- Development of verification protocols (including QA/QC and audit requirements for testing)
- Engineering and cost analysis of vendor applications
- Determination of acceptability, credibility, and usefulness of candidate verification tests
- Development of Test Plans for each selected test or group of tests. (the GHG center will use integrated Test/QA Plans for verification tests; these terms will be used interchangeably in this document)
- Conducting tests and audits
- Data analysis and interpretation
- Data recording, archival, and maintenance of audit trail
- Preparation of Verification Reports and Verification Statements
- Quality Systems Audit, and annual review for quality improvement
- Interacting with stakeholders
- Attending climate change meetings and conferences
- Identification of program partnerships and resources

2.4 QUALITY EXPECTATION FOR PRODUCTS AND SERVICES

The primary products of the GHG Center are the Verification Reports and Verification Statements. The Verification Report is a comprehensive summary of the project and its components. The Verification Statement is a concise summary of the Verification Report intended to report the project's critical and essential data. In addition, there are a number of other documents and materials that are produced during planning, selection, and assessment of candidate technologies and verification testing. These include:

- GHG Center Research Plan
- GHG Center QMP

- Presentation materials to stakeholders
- Pre-test application and guideline materials
- Test Plans for each selected test or group of tests
- Reports on the annual review for quality improvement

Quality means meeting customer needs and expectations. As such, the GHG Center must address the needs and expectations of the users and vendors of GHG mitigation and monitoring technologies in selecting technologies for verification, determining parameters for testing, and in evaluating and presenting verification data. Data quality objectives (DQOs) are also determined according to user needs.

These considerations are market-based. Only commercial or near-commercial technologies will be considered and technologies identified with the greatest market demand will be given highest priority for evaluation.

2.5 QUALITY PROCEDURES DOCUMENTATION

In accordance with the ETV QMP, the GHG Center must operate under a written and approved QMP that is based on ANSI/ASQC E4 and the provisions of the ETV QMP. This document meets these requirements. The original version of this QMP, completed October 21, 1998, was reviewed and approved prior to conducting verification tests. The GHG Center QMP will be reviewed by the SRI QA Manager during the annual review for quality improvement to evaluate the need for modifications or amplification.

2.6 QUALITY CONTROLS

GHG Center quality controls include:

- An approved and implemented QMP. Implementation of this QMP will be verified during the annual review for quality improvement
- Adherence to EPA assistance agreement quality management requirements (i.e., compliance with ANSI/ASQC E4 and the ETV QMP)
- Approved Test Plans for each selected test or group of tests
- Cooperation and coordination with, and planning for oversight of EPA QA management
- Response to any finding of nonconformance
- Assessment of test operations by means of Technical Systems Audits (TSAs), Performance Evaluation Audits (PEAs), and Audits of Data Quality (ADQs)
- Quality Control requirements

2.7 QUALITY SYSTEMS AUDIT (QSA)

EPA has conducted a Quality Systems Audit of the GHG Center QMP, and may conduct additional audits at their discretion. Internal annual reviews for quality improvement will be conducted by the GHG Center and SRI QA Manager. During these reviews, the degree of implementation of this QMP will be assessed, gaps identified, and recommended corrective actions documented.

3.0 PERSONNEL QUALIFICATION AND TRAINING

3.1 PERSONNEL QUALIFICATION AND TRAINING PROCEDURES

Key participants working directly for or on behalf of the GHG Center in support of the overall and/or individual test operations are selected by the GHG Center and evaluated by EPA. Evaluation criteria include relevant education, work experience, and experience in quality management. These qualifications are documented in resumes and personnel files.

All personnel involved in GHG Center technical, administrative, and QA duties have, or will be provided with, training and experience necessary for the tasks they perform. These qualifications are documented as described above. Special training and/or certification requirements for specific verification activities will be documented in the appropriate Test Plans.

3.2 FORMAL QUALIFICATIONS AND CERTIFICATIONS

All personnel will have, or will obtain, formal qualifications and certifications as required by law or contract, and/or as needed to satisfy customer expectations prior to conducting activities with such requirements. This may include, for example, OSHA or MSHA safety certification or ISO 9001 and 14001 certifications. Such requirements will be addressed in the Test Plans specific to each test. Documentation of these certifications will be maintained as part of personnel files and directly by the certified persons.

3.3 TECHNICAL MANAGEMENT AND TRAINING

Appropriate training and qualification procedures will be conducted as needed for each test. Training requirements will be documented when planned, as part of the Test Plans. Documentation stating required training was performed will be maintained as part of the project files. Project documentation is reviewed by the SRI QA Manager, and may be examined by the EPA Project Officer.

3.4 RETRAINING

The need for retraining will be examined when planning verification tests. Retraining will be performed and documented as described above.

3.5 PERSONNEL JOB PROFICIENCY

Evaluations of job proficiency are conducted by the GHG Center Director continually, and are communicated to personnel as needed throughout the year, and formally, during annual performance appraisals. Performance appraisals are confidential personnel records that are not shared with auditors, regulatory agencies, or others outside of SRI.

4.0 SUBCONTRACTOR SELECTION AND MANAGEMENT / PROCUREMENT

GHG Center subcontractors or consultants will be identified and hired on an as-needed basis. Subcontractors will be selected based on qualifications, recommendations, or referrals. Subcontractor work requirements will be documented in a written SOW which will address quality requirements consistent with this QMP and specific to the work to be performed. Subcontractor performance will be evaluated on a continuous basis and non-performance of work or quality problems will be addressed through negotiations. A stop work order may be issued, if necessary, by the GHG Center Director or GHG Center Project Manager. The EPA Project Officer will be kept informed of subcontractor performance.

The procedure for the procurement of items is described in SRI's Internal Specification entitled: Purchasing: QSP 206-1-1.

5.0 DOCUMENTS AND RECORDS

The procedures to handle documentation and record keeping are in accordance with ANSI/ASQC E4 and ETV QMP requirements.

5.1 SCOPE

A document is an instruction, specification, or plan containing information on how the ETV program functions, how specific tasks are to be performed, or how specific products or services are to be provided. Examples include the GHG Center QMP, test/QA plans, and the GHG Center Research Plan. A record is a statement of data and facts pertaining to a specific event, process, or product, that provides objective evidence that an activity has occurred. Examples include verification statements and reports, raw and summary data tables, data notebooks, audit reports, and stakeholder meeting minutes. The scope of documentation and record keeping encompasses all phases of GHG Center operations and includes:

- Identification of records and documents to be maintained as part of the quality system
- Preparation of documents and records
- Information collection
- Filing, storage, archival, and retrieval
- Review, revision, and approval
- Final disposition

This applies to both printed and electronic media. In general, such records and documents will include:

- GHG Center proposals and assistance agreements
- GHG Center Research Plan
- GHG Center QMP
- Memoranda and presentation materials to stakeholders
- Summaries from stakeholder meetings
- Protocol template documents
- Pre-test application guideline materials
- Vendor applications for testing
- Data and records supporting engineering analyses of vendor applications

- Test Plans
- Data collection forms, computer files, field logs, and all other records pertaining to verification test activities
- Verification Reports and Verification Statements
- Audit reports
- Reports on the annual review for quality improvement
- Records of stakeholder interactions and outreach activities
- Chain-of-custody logs
- Confidential evidentiary records
- Standard Operating Procedures (SOPs)
- Any and all other documents, records, or computer files necessary to fully document the quality of all GHG Center activities

5.2 PREPARATION, REVIEW, APPROVAL, AND DISTRIBUTION

Table 5-1 lists all major GHG Center tasks, resulting products, and responsibilities for planning, implementation, support, and review. Table 5-2 lists the records management scheme for the GHG Center. A complete copy of all documents and computer files will be maintained within a master filing system. Documents with a formal revision cycle (i.e., requiring EPA review) are subject to document control (i.e., each document is assigned a unique number, the page number is specified on each page, and that version numbers and dates are assigned to each revision of the document). All management, technical, and QA staff will be trained in document control and maintenance procedures.

5.3 RECORD STORAGE

Current versions of all records and documents (including electronic files) will be stored in a master filing system. Files will be indexed and organized for efficient retrieval and review. A designee of the GHG Center Director has been assigned responsibility for establishing, maintaining, and updating this system.

5.4 OBSOLETE RECORDS

The current version number for controlled documents will be indexed so obsolete documents can be easily identified. All other documents will be dated and the most recently dated document will be identified as the current version. Obsolete documents may be retained for historical reference or removed to archival storage. The minimum storage requirement is that all records be kept for seven years after the final payment on a cooperative agreement.

Table 5-1. GHG Center Tasks

Task	Product	GHG Center Technical Staff	GHG Center Management	SRI QA Management	EPA Project Officer	EPA QA Management	Selected Stakeholders
Identify Candidate Technology Areas	Summary of Executive Stakeholder Meetings	Conduct	Oversee		Review		Review
Review and Rank Technology Areas	Memorandum to Stakeholders	Conduct	Oversee		Review		Review
Identify Technology Candidates	Summary of Stakeholder Technology Area Meetings	Conduct	Oversee		Review		Review
Review, Rank, and Select Technology Candidates	Memorandum to Stakeholders	Conduct	Oversee		Review		Review
Note: This process is repeated as needed in response to customer needs and changing conditions							
Request Applications for Testing	Advertisements/ Notifications / GHG Center Web site / ETV Web site	Conduct	Oversee		Review		
Assess Vendor Applications	Vendor Applications	Conduct	Oversee				
Develop Proposed Test Outline	Test Plan Outline	Conduct	Oversee				
Negotiate/Finalize Test Parameters	Commitment Letters	Conduct	Oversee		Review		
Note: This process is repeated for each selected candidate technology							
Test Plans	Test Plans	Conduct	Oversee	Review	Review	Review	Review
Conduct Testing	---	Conduct	Oversee	Support			
Conduct internal Audits, Assessments (TSA, PEA, ADQ)	Audit Report	Support	Review	Conduct	Review	Review	
Verification Reports	Verification Reports	Conduct	Oversee	Support	Review	Review	Review
Verification Statements	Verification Statement	Conduct	Oversee	Support	Review	Review	
Note: This process is repeated for each verification test							
Research Plan	GHG Center Research Plan	Conduct	Oversee	Support	Review	Review	
Annual review for quality improvement	Review Summary	Support	Review	Conduct	Review	Review	
Quality Systems Audit (QSA)	Report	Support	Review	Review	Oversee	Conduct	

TABLE 5-2. Records Management Scheme for the GHG Center

Record Type	Preparation/Updating	Review	Approval	Finals Distributed To:
Research Plan	GHG Center Technical Staff	SRI QA Manager	GHG Center Director, EPA Project Officer, EPA QA Manager	ETV and GHG Center Webmasters
Quality Management Plan	SRI QA Manager, GHG Center Staff	GHG Center Director	EPA Project Officer, EPA QA Manager	ETV and GHG Center Webmasters
Minutes of Stakeholder Meetings	GHG Center Director	EPA Project Officer, Stakeholders	N/A	Stakeholders, ETV and GHG Center Webmasters
Test and Quality Assurance Plans	GHG Center Project Manager	Vendor, Host Site, Stakeholders	GHG Center Director, SRI QA Manager, EPA Project Officer, EPA QA Manager	Vendor, Host Site, Stakeholders, ETV and GHG Center Webmasters
Generic Verification Protocols	GHG Center Technical Staff	SRI QA Manager, Stakeholders	GHG Center Director, SRI QA Manager, EPA Project Officer, EPA QA Manager	ETV and GHG Center Webmasters
(Internal) QA reviews/ audit reports	SRI QA Manager	GHG Center Director	N/A	EPA Project Officer, EPA QA Manager
Raw Data	GHG Center Technical Staff	GHG Center Project Manager	N/A	EPA can request copies
Verification Report	GHG Center Project Manager	GHG Center technical staff, Vendor, Host Site, Stakeholders, SRI QA Manager	GHG Center Director, EPA Project Officer, EPA QA Manager	Vendor, Host Site, Stakeholders, ETV and GHG Center Webmasters
ETV verification statement	GHG Center Project Manager	GHG Center technical staff, Vendor, Host Site, Stakeholders, SRI QA Manager, EPA Project Officer, EPA QA Manager	GHG Center Director, NRMRL Laboratory Director	Vendor, Host Site, Stakeholders, ETV and GHG Center Webmasters

Note: Entries in approval column assume review by approving official; N/A = not applicable

6.0 COMPUTER HARDWARE AND SOFTWARE

6.1 GENERAL PROCEDURES

Commonly available commercial software used for day-to-day office operations (e.g., word processing, spreadsheet, database, Internet browser) does not require verification or assessment of suitability. However, any specialized software/hardware to be used (e.g., data acquisition, data analysis, instrument operation) in verification testing (even if commercial) will be specified in advance of testing and the suitability of the system to the task will be documented in the Test Plan by means of stating requirements and system capabilities.

It is not anticipated that the GHG Center will develop specialized software or hardware. If such activities become necessary, this QMP will be formally revised as appropriate.

6.2 SCOPE

Computer software and hardware systems/configurations that may be employed in the GHG Center include, but are not limited to:

- Environmental technology operation or process control systems
- Data acquisition and instrumentation systems
- Environmental databases and "expert systems"
- Data reduction and analysis systems

6.3 CONFIGURATION TESTING

Software/hardware to be used in verification testing that plays a critical role will be tested prior to conducting verification studies. A critical role is understood to mean that system failure or improper operation could significantly impact data quality or field operations. System tests will simulate actual field test scenarios and test results will be documented in verification test records and logs. Any required testing and test procedures will be set forth in the Test Plan. In addition, maintenance testing will be specified, performed, and documented in a similar manner.

6.4 MEASUREMENT AND TEST EQUIPMENT CONFIGURATIONS

Measurement and test equipment configurations (including calibration equipment and procedures) to be used in verification tests are specified in the Test Plans. Such systems do not require configuration testing prior to verification unless they are unique or nonstandard, or alterations have been made to standard configurations or calibration procedures. Any nonstandard configurations or configuration changes will be documented in the Test Plan and procedures for verifying performance and suitability will be specified.

6.5 CHANGE ASSESSMENTS

Any changes to planned computer system configurations, measurement and test equipment configurations, or operation procedures will be assessed to determine the impact on data quality. These

assessments will be performed by technical staff directly involved with the changes (with support from QA staff and management as needed) and documented in verification test logs. Testing will be conducted and documented as needed to verify the performance of the changed configurations. In circumstances where it is determined that a change may compromise data quality, approval will be obtained from the GHG Center Director and/or SRI QA Manager.

6.6 ETV AND GHG CENTER WEB SITE ROLES AND RESPONSIBILITIES

The ETV and GHG Center Web sites serve all ETV participants through prompt and accurate posting of ETV information and documents. The GHG Center Director, or designee, will provide final documents and updates of the following information to the ETV and GHG Center Webmasters in a timely manner.

- Fact sheets and brochures
- Stakeholder lists
- Meeting announcements and summaries
- Test Plans
- Fed BizOpps (FBO) announcements
- Verification Reports and Verification Statements
- Upcoming meetings, presentations, and announcements
- GHG Center newsletters
- Verification guideline documents

7.0 PLANNING

7.1 SYSTEMATIC PLANNING PROCESS

The GHG Center has prepared and distributed a formal Research Plan detailing plans for overall operations. The GHG Center has established, implemented, controlled, and documented a systematic planning process to:

- Identify customers, and their needs and expectations
- Identify the technical and quality goals to meet the customer's needs and expectations
- Translate the technical and quality goals into specifications that produce the desired result
- Consider cost and schedule constraints governing test activities
- Identify acceptance criteria by which results are evaluated

This general process applies to identifying and evaluating candidate technologies for testing. Procedures for planning verification tests are identified in Part B of this QMP. The overall planning process is outlined as follows:

- Stakeholder groups are established that contain representatives of customers concerned with GHG mitigation or monitoring technologies
- Plans for GHG Center operations are presented to stakeholders for review and comment

- Stakeholder meetings are held annually, or as needed, to:
- identify, revise, and clarify technical and quality goals
- consider cost and schedule constraints
- develop useful and applicable quantitative measures of performance
- determine testing priorities
- Summaries of stakeholder meetings are documented and distributed to participants for comment
- Stakeholder meeting summaries are incorporated into the records management scheme described in Part A, Section 5.0 and are posted to the ETV and GHG Center Web sites.
- Planning is implemented through meetings among participants and through distribution of planning documents via the ETV and GHG Center Web sites. Planning process control consists of development and implementation of written procedures, documentation of stakeholder meetings and communications, review and oversight by the EPA Project Officer and EPA QA Manager.

7.2 PLANNING DOCUMENT REVIEW

All planning documents are reviewed and approved for implementation according to procedures given in Part A, Section 5.0, Table 5-2.

8.0 IMPLEMENTATION OF WORK PROCESSES

8.1 IMPLEMENTATION

Planning for implementation is discussed in Part A, Section 7.0. The approved Test Plans serve as the guide for conducting all tasks. In order to ensure that this guide is followed, the Test Plans are used for personnel training and briefings, project tasks and job descriptions, and as a reference during work. Implementation of the Test Plan is verified informally on a day-to-day basis and formally through audits and reviews for quality improvement. These reviews reveal the degree of adherence or exception to the Test Plan in actual work processes. Any deviations from the Test Plan (accidental or intentional) are identified, assessed, and documented.

The approved Test Plans shall be present at the site during testing.

8.2 PROCEDURES

Procedural development will follow a step-by-step process of the testing event. Details will be developed in the Test Plan and will include appropriate data recording and data forms. Work processes characterized by a detailed, reproducible set of procedures will be associated with procedural documents or SOPs to ensure accuracy and consistency. The GHG Center will seek EPA's guidance with obtaining appropriate SOPs, as applicable. The SOPs will primarily be used when repetitiveness is a major issue. The SOPs will also serve as a reference to avoid errors or omissions. Such documents are generally identified in Test Plans; though it is possible that other procedures may require written SOPs. These will be identified and prepared as needed and are subject to documentation and record keeping requirements

as described in Part A, Section 5.0. Procedures that will be developed include sampling and data reporting.

8.3 OVERSIGHT

Test Plan implementation in work processes is overseen primarily by GHG Center technical management on a day-to-day basis. The role of this QMP is to ensure that areas requiring oversight are identified and that procedures are implemented to provide oversight. Table 5-1 (Part A, Section 5.0) lays out oversight and review responsibilities for all major GHG Center tasks. In addition, audits and the annual review for quality improvement serve to document that oversight takes place as intended.

9.0 ASSESSMENT AND RESPONSE

9.1 NUMBERS AND TYPES OF ASSESSMENTS

Sufficient assessments are planned to ensure that ETV quality requirements are met. The number and types of assessments planned, and the responsible parties are identified as follows:

- **Quality Systems Audit** - A Quality Systems Audit (QSA) assesses implementation of the GHG Center QMP. An initial QSA was conducted on this QMP by the EPA QA Manager and will be conducted thereafter as requested. The reviewers seek to verify that each of the commitments made in the QMP has been implemented and document any gaps or deficiencies. A substantial part of this review will be devoted to verifying that records fully document quality. Other subjects of review would include personnel qualifications, subcontractor quality performance, Audit Reports and responses, and implementation of corrective actions. An Audit Report will be by the SRI QA Manager and will be reviewed by the GHG Center Director, EPA Project Officer, and EPA QA Manager. GHG Center management must respond to the review and implement any necessary corrective actions (e.g., a revision of the QMP).

- **Technical Systems Audit** - As defined in EPA QA/G7, Technical Systems Audits (TSAs) are "thorough, systematic, and qualitative audits of the measurement system used in environmental data operations", which "are usually performed on the site of the project." The objective of the TSA is to assess and document acceptability of all facilities, maintenance, calibration procedures, reporting requirements, sampling and analytical activities, and quality control procedures. An approved test/QA plan provides the basis for the TSA. Objective evidence is gathered by interviewing personnel, examining records, and observing project activities. An internal TSA will be conducted by SRI's QA Manager or his designee. Audit findings are brought to the attention of GHG Center management in a written Audit Report. Management will respond by assessing the severity of any problems identified and addressing significant problems by identifying the root cause of the problem and implementing corrective action. A significant problem is one that would cause the test to fail to meet objectives, or would cause results to be unverifiable (e.g., a lack of appropriate documentation of QC tests). TSA Audit Reports will be generated by the SRI QA Manager, and will be reviewed by the GHG Center Director, EPA Project Officer,

and EPA QA Manager. In addition, we anticipate that independent TSAs will be conducted by the EPA QA Manager. GHG Center technical and QA staff will assist in these audits and respond to their findings as required.

- **Performance Evaluation Audit -** A performance evaluation audit (PEA) is a quantitative evaluation of a measurement system. Although each measurement in a test program could be subjected to a performance evaluation, the critical measurements (designated in the test/QA plan) are more commonly evaluated. An evaluation of a measurement system usually involves the measurement or analysis of a reference material of known value or composition. The value or composition of reference materials must be certified or verified prior to use, and the certification or verification must be adequately documented. Ideally, the identity of the reference material is disguised so that the operator or analyst will treat the material no differently than a test program sample. PEAs will normally be conducted by the SRI QA Manager or his designee. They may be combined with a TSA or samples introduced separately as appropriate. For example, PE samples for analytical laboratory audits will typically be included by the sampling field team leader with other field samples. In addition to internal PEAs, we anticipate that independent PEAs will be conducted by the EPA QA Manager. GHG Center technical and QA staff will assist in these audits and respond to their findings as required.

- **Audit of Data Quality** - An Audit Of Data Quality (ADQ) is an examination of the data after they have been collected and 100% verified by project personnel. Assessing whether the Data Quality Indicator (DQI) goals specified in the test/QA plan were met requires a detailed review of the recording, transferring, calculating, summarizing, and reporting of the data. An ADQ typically consists of independent verification and tracing of a representative portion of test results and calculations back to raw data and logs. ADQs will be performed by SRI's QA Manager or his designee for each verification test, and will include at least ten percent of all of the verification data. This ten percent requirement may be relaxed if necessary. An example would be the collection of electronic data over a long period of time that results in the collection of massive amounts of data. In such cases, a systematic sampling approach may be used in which a representative number of raw and summary data are traced and verified, combined with manual verification of the algorithms used for all steps of electronic data processing. ADQ Audit Reports will be generated by the SRI QA Manager, and reviewed by the GHG Center Director, EPA Project Officer, and EPA QA Manager. If test timing is appropriate, the ADQ may be combined with the QA review of the draft Verification Report. In addition, we anticipate that independent ADQs will be conducted by the EPA QA Manager. GHG Center technical and QA staff will assist in these audits and respond to their findings as required.

The GHG ETV Center recognizes that the high visibility of ETV testing makes systematic planning necessary to provide sufficient auditing to insure the integrity of the data and will plan numbers of self assessments in accordance with the targets in this section of the current EPA ETV QMP. The center notes that EPA target minimums are: one QSA (already performed), thereafter, as required; TSAs on every test; PEAs "on each test, as applicable"; and ADQs (on each test) on ten percent of the test data ("ten percent of the test data" means a random selection of ten percent of the data from all of the measured parameters) that has already been 100 percent verified by project personnel. Applicability for PEAs means that the verification has a quantitative measurement parameter capable of being audited.

The current EPA ETV QMP allows for some flexibility in cases where the target minimums appear to be excessive to the verification test planners, and allows their professional judgement to prevail. In the interests of maintaining self-assessments on a continuous and stable level consistent with cost effective use of QA resources, the GHG intends the following principle for planning self assessments when several verifications are conducted for technologies in the same class, involve the same Verification Parameters and measurement systems, and are conducted under either generic verification protocols or test/QA plans that are similar except for specific circumstances of technology or site. For these circumstances the TSA on an early (generally the first) verification of such a technology will incorporate detailed assessment of all major measurement system elements foreseeably expected to be common to other verifications in the technology class. This TSA then can serve as a basic assessment of the verification measurement systems for this class of technology. For subsequent verifications within the class, the self-assessment TSA may be accomplished by a review of any distinct elements in the Test/ QA Plan and confirmation that the established procedures are followed as in the test with the "prototype" TSA.

9.2 PROCEDURES

The GHG Center will implement procedures for conducting assessments as described in this QMP, the operating manuals of EPA quality teams, and EPA guidance documents (EPA QA/G-7). Assessments are based on interviews, on the physical examination of objective evidence, on results of analysis of blind samples, and on the examination of the documentation of past performance. The basis for technical assessments of ETV verification tests is the test/QA plan. Results are documented in audit reports, and reviewed by appropriate management as described in Section 9.1 above.

9.3 PERSONNEL QUALIFICATION, RESPONSIBILITY, AND AUTHORITY

Personnel conducting assessments will be familiar with QA requirements as given in this QMP and referenced documents. They will also be familiar with technical aspects of the GHG Center so that audits and assessments are properly focused, meaningful, and provide useful and constructive results and recommendations. The technical familiarity of assessment personnel will also help to ensure that assessment results are complete and without errors or omissions. Qualified audit personnel will have direct access to management and technical staff and all documents necessary to perform audit duties. Confidentiality agreements will be put in place as needed to ensure access to all necessary material. Audit personnel are organizationally independent of the GHG Center management and report directly to the SRI QA Manager. The GHG Center will provide adequate resources to allow QA staff to perform their duties as provided in this QMP.

9.4 RESPONSE

Audit findings will be detailed in Audit Reports along with recommended corrective actions. Technical management is expected to respond to these findings with an appropriate and agreeable implementation plan for corrective actions in a timely manner (generally within 10 working days of receiving the audit report). Audit Reports will be completed and submitted within 10 working days after conducting the audit. All corrective actions will be in written form and become part of the QMP formal record keeping system as described in Part A, Section 5.0. Follow-up will be conducted by QA staff to ensure that corrective actions are properly implemented in a timely manner.

10.0 QUALITY IMPROVEMENT

10.1 ANNUAL REVIEW FOR QUALITY IMPROVEMENT

The SRI QA Manager, in cooperation with technical staff and management, will initiate an annual review for quality improvement to assess implementation of and possible enhancements to the quality management practices of the GHG Center. In the annual review, the technical and QA staff will review the GHG Center QMP and recommend improvements, if necessary. Findings of the review and any resulting improvement actions will be documented in writing and placed in the GHG Center files. If appropriate, revisions will be made to the QMP and submitted for approval as directed in Part A, Section 5.0.

10.2 DETECTING AND CORRECTING QUALITY SYSTEM PROBLEMS

Procedures for preventing, as well as detecting and correcting problems that adversely affect quality during all phases of technical and management activities are described in this QMP and consist of:

- General quality control checks during day-to-day program operations conducted by technical and management staff
- Specific quality control measures for verification tests as specified in Test Plans
- Periodic audits, assessments, and reviews as specified in Part A, Section 9.0 of this QMP

QA staff are responsible for supporting development of appropriate QA/QC measures, for conducting assessments as scheduled, and for reporting results in a timely manner. GHG Center management and technical staff are committed to appropriate response and implementation of QA recommendations and findings.

10.3 CAUSE AND EFFECT RELATIONSHIP

Findings of s*ignificant* quality problems will require that the root cause of the problem is determined and that the data quality impact of the problem is fully assessed and documented. In general, a significant problem is one that may compromise data quality or the ability to verify that data are of known quality. More specifically, a problem is defined as significant if it necessitates a testing protocol change, a management system change, or a quality system change. The term quality refers to meeting customer expectations for credibility, verifiability, usefulness, and cost.

10.4 ROOT CAUSE

The term “root cause” refers to the irreducible source of the quality problem. When determining cause and effect relationships, it is necessary that root causes are determined so that permanent preventive or corrective measures may be devised and implemented. Determination of root cause always precedes planning or implementation of corrective actions.

10.5 QUALITY IMPROVEMENT ACTION

Findings of significant quality problems, whether with technical aspects of the program, or the quality system itself, require that action is taken to correct the problem as described above. Such actions will be taken in a timely manner so as to avoid perpetuating the problem and minimize impacts on data quality.

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PART B

COLLECTION AND EVALUATION OF ENVIRONMENTAL DATA

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

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1.0 PLANNING AND SCOPING

The function of the GHG Center is to verify performance of commercial and near-commercial GHG mitigation and monitoring technologies. The planning process is described in the GHG Center's Research Plan. The goal of overall program planning is to select and assess candidate technologies for testing, to conduct outreach and strategy work to further the reach and scope of the program, and to ensure customer needs and expectations are met. Quality aspects of these overall planning functions are dealt with in Part A of this QMP. The focus of this section (Part B) is on the verification testing activities themselves.

1.1 SYSTEMATIC PLANNING OF THE VERIFICATION TEST

The type and quality of data needed for the intended use in each verification test are identified using a systematic planning process. Test-specific planning must involve key users and customers of data. It is the responsibility of the GHG Center Director to implement such a process, and the responsibility of the SRI QA Manager to support and verify systematic planning.

According to the ETV QMP, systematic planning may be accomplished through any demonstrated technique. SRI's numerous previous studies conducted under EPA's and other organizations' QA requirements will serve as a model for this process. For verification testing, the general flow for systematic planning is as follows:

- Identify overall test objectives for specific technologies based on evaluations conducted as part of identification and selection of candidate technologies for testing and stakeholder guidance
- Identify quantitative test criteria based on engineering analyses of vendor test applications
- Specify data quality objectives that meet testing criteria
- Identify appropriate test methods and procedures that can produce the quantitative results needed
- Identify QA/QC requirements and procedures specific to selected test methods that satisfy data quality objectives
- Design a test matrix, numbers, and types of tests and testing schedule that provide sufficient data to ensure the validity of the results. The test matrix also provides for necessary calibrations and QC checks
- Document testing procedures (including QA/QC procedures) in a Test Plan
- Obtain review and approval of the Test Plan prior to conducting tests

EPA's formal DQO process is a valuable tool that will be used in the process outlined above. The DQO process is a procedure in which DQOs are designed that meet test objectives according to systematic (and often formal statistical) methods. This process occurs prior to selecting test methods and ensures that the methods and procedures selected provide data of quality necessary to satisfy test objectives.

The Test Plans serve multiple purposes. They document specific plans and procedures for testing. The process of designing and developing a proper Test Plan serves to ensure that systematic planning takes place. The Test Plan must be reviewed and approved and this serves to inform customers, technical staff and management, and QA staff and management of plan details, and provides a check on plan validity and sufficiency. The Test Plan then serves as a guide during testing. Finally, the Test Plan functions as a

formal document against which audits and assessments of proper test implementation may be conducted and test success evaluated. As such, these Test Plans must clearly state test and quality objectives with provisions and methods for assessment.

1.2 SYSTEMATIC PLANNING FOR VERIFICATION TESTING

This section discusses elements of the systematic planning process in terms of the overall QMP. This consists largely of reiterating quality management and accountability issues dealt with in Part A in terms of planning for verification testing.

- **Planning Personnel -** Test planning is the responsibility of GHG Center technical management and staff. Planning is coordinated with input and feedback from GHG Center management, stakeholders, technology vendors, participating test organizations (including test site management and personnel) and laboratories. GHG Center technical management and staff, with concurrence and oversight of the EPA Project Officer, will identify the testing roles of the various participants and clearly communicate these roles to the participants. This could include providing written procedures and/or briefings and training.

- **Purpose, Scope, and Objectives -** The purpose of the verification test is to prove the performance of commercial or near-commercial GHG mitigation and monitoring technologies. In the ETV QMP, development of generic verification protocols or protocol templates for key technology areas is seen as a means to increase the cost-effectiveness and efficiency of the planning process. However, in cases where rather unique technologies are considered for evaluation, the strategy of developing generic protocols may be less efficient than development of general strategies, tools and procedures that allow efficient development of custom test protocols. This is likely to be the case for most of the tests to be conducted at the GHG Center. SRI's extensive experience in designing and implementing environmental tests makes this approach practicable. The specific characteristics of technologies to be tested and the specific design of individual tests is documented in the Test Plans.

- **Data to be Collected and Design of Experiment -** During planning of the technology verification test, the process, environmental, laboratory, response, and QA data needed to satisfy test objectives are identified. This involves consideration of test objectives, characteristics of the technology to be tested, test site, schedule and budget constraints, and data quality objectives. Once data needs have been identified, a formal experimental design is constructed and a test matrix is designed that provides the needed data. The test matrix includes numbers and types of measurements, test schedule, and calibration and QA/QC checks. This includes identification of test methods, procedures, equipment, and instrumentation. The test matrix also identifies personnel involved in each element of the test and outlines their roles and responsibilities. The experimental design and test matrix serve as the framework from which the detailed Test Plans are constructed.

- **Documentation and Reporting -** Record keeping requirements are described in Part A, Section 5.0. The Test Plans will list specific records, logs, and data files to be completed and maintained for each test. Example data collection forms (e.g., spreadsheets, calculations) will also be included as part of the Test Plan. The full set of test documents and files is designed to provide a complete and traceable record that allows raw data records to be validated and clearly linked to Verification Statements. Requirements for electronic forms of documentation are also described in Part A, Section 5.0.

- **Assessments -** Part A, Section 9.0 describes specific assessment tools and assessment frequencies as they apply to the Test Plans, implementation products (audits), and the review cycle. Further discussion of assessment tools for environmental data collection activities (testing) is given in Part B, Section 4.0.

- **Constraints, Suspension of Work –** The GHG Center recognizes that time and resources impose constraints that have the potential to compromise data quality. The key to managing such restraints is planning to recognize their potential impacts and taking appropriate actions to prevent loss or waste of resources, or compromise of GHG Center integrity. Procedures for assessing, managing, reporting, and taking corrective action in such instances are described in Part A, Section 1.5. Instances where suspension of work may be warranted and authority for work suspension are detailed in Part A, Section 1.7.

- **Waste Minimization and Disposal -** If waste is generated as part of verification testing, it will be minimized and disposed of in accordance with local, state, and federal laws.

2.0 DESIGN OF TECHNOLOGY VERIFICATION TESTS

The previous section describes the general flow of the planning process. This section deals with specifics of planning for and designing a verification test.

2.1 DESIGN PROCESS

Verification test design will include those elements identified during planning, and will establish test specifications and identify appropriate controls. In general, this includes elements required for a Category II Test Plan as described in the APPCD Quality Assurance Procedures Manual for Contractors and Financial Assistance Recipients. Commonly this includes specifications for:

- Sampling, testing, and analytical methods and procedures, including quality measures of performance
- Sampling personnel and analytical laboratories (and necessary qualifications and certifications)
- Sampling and analytical equipment and instrumentation and specification of operational parameters
- Sample types and numbers, sampling intervals, quantities, and sample handling, custody and storage
- Sampling locations and means for obtaining representative samples
- Calibration standards, intervals, blanks and spikes, performance indicators
- Field and laboratory QA/QC activities, procedures, schedule
- Health and safety of test personnel and the public
- Readiness reviews prior to data collection
- Required assessments and assessment procedures (TSAs, PEAs, ADQs)
- Record keeping and data reporting
- Data reduction and validation
- Calculation of data quality indicators
- Corrective action
- Data security, archival, and retrieval

- Schedule
- Waste minimization and disposal

Verification design techniques must be consensus-accepted; meaning that the design is based on techniques that have appeared openly in the relevant literature or are EPA, ANSI, or other relevant standard organization approved, and have not been rejected or superceded. New or innovative design techniques should be developed and documented consistent with consensus-accepted approaches. This may include formal statistical experimental design as appropriate. The design accounts for schedule and budget constraints.

The design includes detailed specifications and procedures for conducting assessments identified as necessary during planning. These may include TSAs, PEAs, and ADQs. The type and number of required assessments is given in Part A, Section 9.0.

Data reduction and validation specifications and procedures are included in the design, as well as an overall analytical approach to be used in arriving at final test results. Data are ultimately reported in ETV Verification Reports and results summarized in ETV Verification Statements. Data records are stored and maintained as specified in Part A, Section 5.0.

2.2 GENERIC VERIFICATION PROTOCOLS AND TEST/QA PLANS: PLANNING DOCUMENTS FROM THE DESIGN PROCESS

Two types of planning documents have been identified as the core documentation needed for operation of an ETV center: the generic verification protocol and the test/QA plan. The generic verification protocol is meant to promote uniform testing for a single center and, therefore, is considered a more general document. As implemented at the GHG Center, the generic verification protocol is termed Verification Guideline document and is specific to a major technology class. The test/QA plan contains the specific information needed to conduct a verification test. These documents are described below.

Test/QA plans: The core documentation for the test planning process consists of the test/QA plan (interchangeably termed simply Test Plan in GHG Center documents). Like other ETV centers, the GHG center uses integrated Test/QA Plans for verification tests, each combining all elements of a technical test plan and a Quality Assurance Project Plan (QAPP). GHG Center Test Plans will contain the required elements given in Guidance on Quality Assurance Project Plans (EPA QA/G-5). Though these elements are listed below in the order of EPA QA/G-5, the test plans are typically organized in a more functional format for ease of communication and review by Stakeholders.

Group A: Project Management
- A1 Title and Approval Sheet
- A2 Table of Contents and Document Control Format
- A3 Distribution List
- A4 Project/Task Organization and Schedule
- A5 Problem Definition/Background
- A6 Project/Task Description
- A7 Quality Objectives and Criteria for Measurement Data
- A8 Special Training Requirements/Certification
- A9 Documentation and Records

Group B: Measurement/Data Acquisition
- B1 Sampling Process Design (Experimental Design)
- B2 Sampling Methods Requirements

B3 Sample Handling and Custody Requirements
B4 Analytical Methods Requirements
B5 Quality Control Requirements
B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements
B7 Instrument Calibration and Frequency
B8 Inspection/Acceptance Requirements for Supplies and Consumables
B9 Data Acquisition Requirements (Non-Direct Measurements)
B10 Data Management
Group C: Assessment/Oversight
C1 Assessments and Response Actions
C2 Reports to Management
Group D: Data Validation and Usability
D1 Data Review, Validation, and Verification Requirements
D2 Validation and Verification Methods
D3 Reconciliation with Data Quality Objectives

The QA/QC elements of the Test Plans describe activities necessary to verify the quality of the work. This may include preparation and use of QA procedures such as QC checks and samples, blanks, replicates, and spikes and performance evaluation samples (including development and assessment of data quality indicators obtained from such activities). It is important to specify organizational responsibilities for each QA activity and identification and implementation of corrective actions. Test-specific details of these activities will be given in the Test Plan.

SOPs may be required or useful in instances where complex, repetitive activities or procedures are to be followed. EPA QA/G-6, *Guidance for Development of Standard Operating Procedures (SOPs)* provides guidance which will be used for developing such procedure documents. SOPs will be incorporated into the Test Plan as applicable, either by reference or attachment. Physical copies will be available for review or reference by technical personnel.

Generic verification protocols: These documents provide the necessary framework for development of the more detailed test/QA plan for a given ETV Center. The specific content and level of detail given in generic verification protocols varies between ETV centers. As implemented at the GHG Center, the generic verification protocol is termed Verification Guideline Document and is specific to a major technology class. GHG Center Verification Guideline Documents are typically "how-to" reference documents used as a basis to communicate the common elements in verification planning for the technology class. They are typically written in the format of a Test Plan so that major headings provide an outline, and contain some general text on methodology that might be incorporated into actual Test Plans for subsequent tests. The expected Verification Parameters are described, along with experimental methodology, QA/QC, data flow, and expected performance of both the technology and the verification measurement systems.

Typical headings might include:

GENERAL DESCRIPTION OF THE TECHNOLOGY
OVERVIEW OF THE VERIFICATION STRATEGY
Verification Parameters
Experimental design
Measurement techniques
DATA QUALITY OBJECTIVES AND DATA QUALITY INDICATORS
QA/QC PROCEDURES
DATA ACQUISITION AND STORAGE
DATA REVIEW, VALIDATION, AND VERIFICATION

3.0 IMPLEMENTATION OF PLANNED OPERATIONS

All data collection, analysis, and archival of environmental data will be implemented according to the Test Plan specific to the verification test.

3.1 IMPLEMENTATION OF PLANNING

Verification tests are implemented according to the Test Plans. During implementation, changes are assessed, reviewed, and approved as discussed in Part A, Section 5.0. Planning documents will be structured to serve as an effective guide to test personnel during test operations and will be available on-site for reference. This includes the approved Test Plan, SOPs (as applicable), and any guidance or procedural documents referred to in the Test Plan.

Test activities will be documented in such a manner to allow independent verification of test results based on an examination of records and logs of test activities and raw data. Suitable documentation includes bound notebooks, field and laboratory data sheets, spreadsheets, and computer records and instrument output (both electronic and printed). Documentation procedures for each data collection and analysis activity are spelled out in the Test Plan. All documentation must be identified with specific test activities and the personnel involved (the activity, time, date, and personnel name noted).

3.2 SERVICES AND ITEMS

The quality and suitability of all equipment, supplies, and services used in testing will be assessed prior to testing. Acceptance testing will be completed as necessary. This will be assessed during planning and specified in the Test Plan, including test procedures. Acceptance testing results will be documented as part of the project file. Acceptance testing is not required if not specified in the Test Plan. Measurement equipment may be subject to calibration and associated certifications and documentation. Preventive maintenance will be performed as required based on equipment manufacturer's specifications, or as determined to be necessary by the GHG Center.

3.3 FIELD AND LABORATORY SAMPLES

All field and laboratory samples will be handled as specified in appropriate plans, procedures, or protocols. It is the responsibility of the GHG Center (with EPA review) to determine that the approved Test Plans contain adequate procedures for sample handling to prevent damage, loss, or interferences. Chain-of-custody records will be provided for in the Test Plans as needed.

3.4 DATA AND INFORMATION MANAGEMENT

Data transmittal, validation, assessment, and retrieval will be performed in accordance with approved procedures (documented in the Test Plan). Data handling procedures should be field proven or undergo trial before tests are conducted. All records will be handled according to procedures documented in Part A, Section 5.0. Data management will follow appropriate procedures regarding data security, archival, and retention. These criteria will be spelled out in the Test Plan. Also, regarding traceablility of the data,

there will be procedures detailed in the Test Plan that ensure that data can be traced back to the procedures used to produce the data and to the personnel collecting the data.

4.0 ASSESSMENT AND RESPONSE

4.1 ASSESSMENT TYPES AND FREQUENCY

Activities performed during technology verification performance operations that affect the quality of the data shall be assessed regularly, and the findings reported to management to ensure that the requirements stated in the Test Plans are being implemented as prescribed. Assessment types, frequencies, responsibilities, and reporting requirements applicable to the verification tests are provided in Part A, Section 9. These include TSAs, PEAs, and ADQs.

4.2 RESPONSE TO ASSESSMENT

Findings from assessments are provided in Audit Reports completed as specified in Part A, Section 9.0. These identify the scope and root cause of the problem, recommend corrective action, and provide a quantitative assessment of actual or potential impact on data quality. Data will be evaluated to determine if any data was obtained from a method or instrument that was found to be nonconforming to the specifications. Any such data will be investigated as to what caused the nonconformance and to what impact the nonconformance has on the total test. Management response to adverse findings detailing corrective actions to be implemented are required within 10 working days after receiving the report. Follow-up to verify the efficacy of corrective actions will be performed and documented by SRI QA staff.

5.0 ASSESSMENT AND VERIFICATON OF DATA USABILITY

5.1 DATA VALIDATION

All data will be validated according to criteria specified in the Test Plans. It will be reviewed prior to being reported to ensure that the validity of the data meets what was called out in the Test Plan. Any limitations associated with the data will be defined and reported with the data. An ADQ will be conducted to trace results to raw data, verify calculations, and verify that data quality is suitable for its intended purpose. These audits will be designed to reasonably confirm that all data are of known and suitable quality and will include a subset of at least 10 percent of the raw data values. Since it is common in environmental testing to measure a large number of parameters, audits will focus on critical parameters with consideration of the sensitivity of final results to certain raw data values.

5.2 EXISTING DATA

Existing data (e.g., provided by vendors) may be used for planning and design, but normally would not be used to support verification results unless an ADQ could confirm that the existing data were collected, validated, and reported according to ANSI/ASQC E4 standards.

5.3 REPORTS REVIEWED

The procedure for ETV Verification Reports and Verification Statements review and approval is given in Part A, Section 5.0. ETV Verification Statements are signed by the EPA NRMRL Laboratory Director and GHG Center Director.

6.0 REFERENCES

Environmental Technology Verification Program Quality Management Plan, EPA/600/R-03/021, Cincinnati, OH: U.S. Environmental Protection Agency, 2002.

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

Quality Assurance Procedures Manual for Contractors and Financial Assistance Recipients, U.S. EPA Air and Energy Engineering Research Laboratory. Research Triangle Park, NC. May 1988.

Guidance for Quality Assurance Project Plans, EPA QA/G-5, EPA/600/R-02/009, U.S. Environmental Protection Agency, Washington, DC. December 2002.

EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5, EPA/240/B-01/003, U.S. Environmental Protection Agency, Washington, DC. March 2001.

Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality Related Documents, EPA QA/G-6, EPA/240/B-01/04, U.S. Environmental Protection Agency, Washington, DC. 2001.

Guidance for the Data Quality Objectives Process, EPA QA/G-4, EPA/600/R-96/055, U.S. Environmental Protection Agency, Washington, DC. August 2000.

Guidance on Technical Audits and Related Assessments, EPA QA/G-7, EPA/600/R-99/080, U.S. Environmental Protection Agency, Washington, DC. January 2000.

Guidance for Data Quality Assessment, EPA QA/G-9, QA00 Update, EPA/600/R-96/084, U.S. Environmental Protection Agency, Washington, DC. July 2000.

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Appendix A

Greenhouse Gas Technology Center Organization