



Quality Management Plan

for

Texas Engineering Experiment Station

Submitted to

U.S. Environmental Protection Agency

Region 6

1445 Ross Avenue, Suite 1200

Dallas, Texas 75202-2733

April 2, 2009

Quality Management Plan

Texas Engineering Experiment Station

TABLE OF CONTENTS

<u>Section</u>	<u>Heading</u>	<u>Page</u>
	Table of Contents	i
	Approval Page	iii
1	Management and Organization	
	1.1 Texas Engineering Experiment Station	1
	1.2 Mission Statement	1
	1.3 Quality Policy	1
	1.4 Authority of the Quality Assurance Manager	2
	1.5 Technical Activities and Programs Supported	3
	1.6 Management Commitment	3
2	Quality Assurance System Components	
	2.1 TEES Quality Assurance System Description	5
	2.2 Quality Assurance System Components	5
	2.3 Quality Assurance System Tools	6
3	Personnel Qualifications and Training	
	3.1 Statement of Policy	7
	3.2 Ensuring Minimum Training and Skill-level	7
	3.3 Special Personnel Qualification	7
	3.4 Training for Management	8
4	Procurement of Items and Services	
	4.1 Procurement Procedure	9
	4.2 Review of Responses to Solicitation	9
	4.3 Quality Assurance for Procured Items and Services	9
	4.4 Suppliers Quality Related Documentation	9
5	Documents and Records	
	5.1 Identification of Documents Requiring Control	10
	5.2 Conformance Review and Approval	10
	5.3 Document Maintenance	10
	5.4 Ensuring Legal Compliance	10
	5.5 Chain of Custody and Confidentiality Procedures	10

6	Use of Automated Data Processing Systems	
	6.1 Computer Hardware, Software, and Data Recorder Acquisition	11
	6.2 Technical and Quality Requirements	11
	6.3 Information Security Standards Including Provisions for Data Retrieval	11
7	Planning	
	7.1 QA Manager and Principal Investigator Involvement	12
	7.2 Determining Project Goals and Objectives	12
	7.3 Project Scheduling	12
	7.4 Data Quality Needs	12
8	Implementation of Work Processes	
	8.1 Ensuring Work Performance	14
	8.2 Standard Operating Procedures	14
9	Quality Assessment and Response	
	9.1 Annual Assessment	15
	9.2 Corrective Action	15
	9.3 Conflict of Interest	15
10	Quality Improvement	
	10.1 Adverse Conditions Identification, Prevention and Correction	16
	10.2 Process Improvement Communication	16
	Appendices	
	Appendix A: Organizational Charts	17

Quality Management Plan

Texas Engineering Experiment Station

In accordance with EPA Order 5360.1, following is a Quality Management Plan for all work involving the collection or assessment of chemicals, physical or biological factors in the environment performed by TEES, whenever such work is funded wholly or in part by the U.S. Environmental Protection Agency.

Texas Engineering Experiment Station Approvals:

Prepared by:
Lisa Akin
Director, Risk and Compliance
Texas Engineering Experiment Station

Date: _____

Concurred by:
Deena J. Wallace
Interim Associate Agency Director for Administration & Legal Affairs
Texas Engineering Experiment Station

Date: _____

Approved by:
G. Kemble Bennett
Agency Director
Texas Engineering Experiment Station

Date: _____

EPA Approval:

Don Johnson
Regional QA Manager

Date: _____

Quality Management Plan

Texas Engineering Experiment Station

Section 1: Management and Organization

The purpose of this section is to document the overall policy scope, applicability, and management responsibilities of the TEES quality assurance system.

1.1 Texas Engineering Experiment Station (TEES)

The Texas Engineering Experiment Station (TEES) is an agency of the State of Texas and a member of The Texas A&M University System. TEES strives to accomplish its mission while maintaining the highest ethical standards, fiscal accountability and scholarly integrity. We strive to provide an atmosphere of collegial and non-discriminating inquiry in which faculty, researchers, staff and students may pursue excellence. TEES is strongly committed to conducting the highest quality research which will benefit the state and nation in a cost-effective manner and improve the technological base upon which Texas industry is built in order to improve industrial competitiveness and enhance economic growth.

1.2 Mission Statement

The mission of TEES is to perform engineering and technology-oriented research and development for the enhancement of the educational systems and the economic development of the state of Texas and the nation.

TEES activities support programs of leading edge fundamental and applied research, with a major emphasis on critical interdisciplinary areas. TEES transfers the knowledge gained from research and development activities through programs in intellectual property, commercialization, technology licensing and technical assistance.

1.3 Quality Assurance Policy

TEES regards quality assurance and quality control activities as essential to the integrity of data collection, analysis and evaluation, and vital to the reputation of TEES as providing thorough, unbiased information of relevance to the state, region and country. Scientific data developed by TEES researchers and staff, or from funding provided through TEES, is expected to meet the academic standards necessary for peer review. TEES expects its researchers to publish their findings, but only so long as the findings meet the standards appropriate for a scholarly work and only so long as the presentation of data is professional in quality.

The goal of the Quality Management Plan (QMP) is to ensure that all research findings and recommendations are based on a sound science. To achieve this goal, the QMP provides a number of internal control mechanisms to achieve the following general objectives:

- Project objectives must be clearly identified prior to research projects being undertaken;
- Data collection methods, research methodology, and data analysis models must be clearly defined prior to research being undertaken; and,
- Research must be designed to ensure that the types of data, the number of data samples collected, and the procedures for handling, storing, testing and evaluating data samples, will provide scientifically accurate results for interpretation.

To achieve the objectives enumerated above, TEES is committed to providing sufficient staff resources, adequate time and travel funds for internal independent review, embodied in a meaningful but not onerous management system. Additionally, TEES is committed to ensuring a consistent approach to all EPA-funded research involving the collection or assessment of chemical, physical, or biological factors in the environment. The organizational chart (Appendix A) at the end of this document illustrates the role of different departments/individuals in implementing the Quality Management Plan.

1.4 Authority of the Quality Assurance Manager

This QMP designates the TEES Director for Risk and Compliance as a Quality Assurance (QA) Manager. Because of the location of the TEES Risk and Compliance office in the organization and the nature of that position, the QA Manager is organizationally independent of the research operations of the organization. The Director for Risk and Compliance has similar monitoring activities in the organization in addition to the assignments identified within this document.

The QA Manager is responsible for:

- preparing and annually updating the Quality Management Plan;
- providing guidance to the project Principal Investigator (PI) in the preparation of Quality Assurance Project Plans (QAPPs) [as specified in EPA Requirements for Quality Assurance Project Plans (QA/R-5)(EPA 2001)] ; and
- periodically overseeing the quality of data gathering and/or data compilation, and sample analysis.

Interpretation of research findings shall not be subject to the review of the QA Manager, but shall be solely those of the PI of the research project.

The QA Manager shall be encouraged to submit to the TEES Associate Agency Director for Administration & Legal Affairs, through appropriate administrative channels, recommendations for modifications to the review process for consideration and approval in the annual updating of the TEES Quality Management Plan.

The QA Manager operates as staff to the line organization and is independent of any PIs who may have an EPA funded project.

The QA Manager has access to appropriate levels of management through and including the Associate Agency Director for Administration & Legal Affairs of the Texas Engineering Experiment Station.

The QA Manager and PI will obtain concurrence from appropriate levels of management (Appendix A) on the QMP, QAPP, and Standard Operating Procedures. Any assessments of the quality assurance system will be provided to management.

1.5 Technical Activities and Programs Supported

The specific Quality Management Program as provided for in this document is limited to EPA-funded research involving the collection or assessment of chemical, physical, or biological factors in the environment.

This document will be used to manage projects supported by organizations when using EPA pass-through funds, such as the Texas Commission on Environmental Quality (TCEQ). This document controls the quality program for TEES sub-contractors who receive EPA funding for a specific project. The QA Manager may decide that a QAPP is required from a sub-contractor.

If there is a formal Quality Control (QC) Manager assigned and identified in a specific project, that QC Manager shall report incidents that are in violation of the QMP or QAPP to the PI and the QA Manager, who will report the incidents to senior management. For training purposes, the QC Managers shall be available to the QA Manager.

The QA Manager shall periodically contact the project PI to review any project schedule changes that may alter timing of quality assurance review. When a project juncture is reached that requires quality assurance review, the PI is responsible for conferring with the QA Manager for the review. Any substantive finding shall be resolved by consultation between the QA Manager and the PI before the project proceeds.

If there is a dispute regarding quality assurance system requirements, including disputes between the QA Manager and the PI or between the QA Manager and the QC Manager for a specific project, these disputes will be resolved by the Agency Director or designee.

1.6 Management Commitment

TEES shall manage the Quality Assurance Program for funded research. Sufficient resources shall be provided to ensure that both the QA Manager and the PI are able to fulfill their responsibilities under this plan. This plan document and the procedures embodied herein shall not be altered except with the approval of TEES.

The PI and the QA Manager will ensure that the quality assurance system is understood and implemented by providing staff with the Quality Assurance Project Plan developed by the PI and overseeing its implementation.

Quality Management Plan

Texas Engineering Experiment Station

Section 2: Quality Assurance System Components

The purpose of this section is to document how TEES manages its quality assurance system. This section defines the primary responsibilities for managing and implementing each component of the system.

2.1 TEES Quality Assurance System Description

The TEES Quality Assurance System consists of:

- advice and guidance by the Research Services staff and, as requested, the QA Manager to faculty and staff during the preparation of applications for EPA funding;
- designation of the PI's eligibility by the Division Head prior to the submission of the grant proposal to the funding agency;
- preparation of the QAPP by the PI, and independent review of the same by the QA Manager;
- review by the QA Manager of the adequacy of laboratory equipment, field resources, and research personnel;
- periodic review by the QA Manager of data gathering, compilation and analysis, and release of information generated by the funded research;
- periodic review by the QA Manager of the overall Quality Management Plan

2.2 Quality Assurance System Components

Components of the Quality Assurance System consists of:

- Quality Assurance System Documentation: Includes the Quality Management Plan and the relevant Quality Assurance Project Plans.
- Training Programs: All faculty and staff involved in a current EPA funded project undergo a general compliance training to familiarize them with TEES's quality assurance system. The training shall be provided by the QA Manager. The Division Heads review all EPA funding proposals to ensure, among other things, that the individuals proposing the research project have the necessary academic and professional background for the nature of the work. Support staff and student research assistants must have appropriate academic training to enable them to participate in funded research projects. Additional training specific to the project may be provided to the student research assistants by the PI, in keeping

with the TEES mission of providing relevant research experience as part of the overall learning environment.

- Quality Assurance Project Plans: QAPPs are prepared by the PI and reviewed by the QA Manager. Along with a detailed description of the research methodologies, QAPPs shall include schedules that specify specific research milestones requiring review by the QA Manager.
- Data Verification and Validation: All data sampling methodologies are subject to review by the QA Manager.

2.3 Quality Assurance System Tools

Quality Assurance System tools consist of:

- Quality Management Plan: Provides an overall system for implementing quality assurance policies. Because of the mission and focus of the organization, TEES has one QMP for the entire organization.
- Training Programs: Provide a means of ensuring familiarity with the EPA approach to Quality Assurance management by the QA Manager and ensuring compliance with TEES policies by both faculty and staff.
- QAPPs: Provide a project-specific elaboration of the means and methods that will be used in undertaking specific research ventures.
- Data Verification and Validation: Are project-specific and provide the means of ensuring that the number of samples, means of sampling and type of data handling and analysis will enable scientifically-valid interpretations of data.

Quality Management Plan

Texas Engineering Experiment Station

Section 3: Personnel Qualifications and Training

The purpose of this section is to document the procedures for ensuring that all personnel performing work for TEES have the necessary skills to effectively accomplish their work.

3.1 Statement of Policy

TEES endeavors to ensure that its staff and affiliated researchers have the knowledge and skills required for research work, and that its staff and affiliated researchers are fully apprised of TEES policies and of the special requirements associated with EPA-funded research projects. Furthermore, TEES encourages projects that provide opportunities for students to participate in research relevant to their fields of study. TEES policy regarding the use of student researchers is to ensure that students awarded research assistantships have appropriate academic backgrounds for the type of research work, and have adequate supervision during the course of a project, said supervision being by faculty or staff with prior relevant work experience.

3.2 Ensuring Minimum Training and Skill-level

The project PI shall prepare and submit to TEES a QAPP that, among other things, identifies all critical staff needs. Critical staff members are those individuals directly involved in data sampling, handling and analysis. When new staff members are to be hired, or student research assistants are to be employed for the project, the QAPP shall identify the desired academic preparation and what, if any, specific job skills are required.

The project PI has lead responsibility to assemble the necessary staff to undertake the project. Often the project itself represents a learning experience for student research assistants. When additional staff or student research assistants are hired, different levels of administrative oversight are applied depending on the number of hours per week and the duration of employment. All new research staff positions, including student research assistants, are processed through the TEES Personnel Services Department.

It is the responsibility of the PI to assess and ensure project personnel maintain quality-related qualifications consistent with the project, particularly as the project develops and possibly changes.

3.3 Special Personnel Qualifications

If any special knowledge, skill, statutory, regulatory, professional or other type of certification, accreditation, or license, or any other specific qualification is required for a project, it is the responsibility of the PI to identify these special attributes and to communicate them to the QA Manager through the relevant QAPP.

3.4 Training for Management

The QA Manager shall be responsible for notifying senior management of any changes in quality related procedures dealing with EPA funded research.

Quality Management Plan

Texas Engineering Experiment Station

Section 4: Procurement of Equipment, Supplies, and Services

The purpose of this section is to document the procedures for purchasing equipment, supplies, and services that directly affect the quality of the EPA-funded research.

4.1 Procurement Procedure

The TEES Procurement Office, in the TEES Fiscal Office, processes purchases over \$5,000. Authority to purchase for amounts less than this are delegated to the TEES divisions. TEES Research Services is responsible for monitoring all financial activity to ensure compliance with applicable federal, state and awarding agency guidelines. Because project regulations are varied and complex, TEES Research Services is available to provide project PIs with assistance in understanding policies, procedures and related guidelines.

The TEES Research Services is responsible for the development and processing of any sub-contracts or grants that are associated with EPA funded projects. The existing TEES process for approval of sub-contracts, etc. will be the same process for EPA projects. TEES relies on existing talents and expertise to ensure complete, accurate and clearly defined documents. The contract personnel will ensure that agreements describe the associated technical and quality requirements and quality assurance system elements for which the subcontractor is responsible, and ensure that the subcontractors conform to TEES's requirements.

4.2 Review of Responses to Solicitation

Specifications for all purchases shall be prepared by the project PI as part of the QAPP. As such, the purchase of equipment and procurement of services are subject to the review of the QA Manager to ensure that said items and services satisfy all technical and quality requirements for the project. Should purchases other than those explicitly identified in the QAPP be proposed, review of the purchase specifications should be made by the QA Manager prior to initiating the purchase.

4.3 Quality Assurance for Procured Items and Services

Once an item or service is procured, it shall be the PI's responsibility to examine the deliverables to verify that the item or service is of acceptable quality, meets the technical specifications, and is compatible with the technical and quality requirements of the project.

4.4 Suppliers' Quality Related Documentation

It shall be the joint responsibility of the PI and the QA Manager to review and approve the suppliers' quality related documentation (e.g., suppliers' QAPPs).

Quality Management Plan

Texas Engineering Experiment Station

Section 5: Quality Documentation and Records

The purpose of this section is to document appropriate controls for quality-related documents and records that are determined to be important to the mission of TEES.

5.1 Identification of Documents Requiring Control

The PI, as part of the preparation of the QAPP, shall denote those quality-related documents and records that require control. The QA Manager, as part of the review of the QAPP, may further expand the list of documents requiring control. All documents requiring control shall be listed in the QAPP and be subject to EPA review.

5.2 Conformance Review and Approval

Documents and records prepared as part of the quality assurance system requirements and listed in an approved QAPP as requiring control shall be subject to a systematic procedure to ensure their conformance with all technical requirements. The QAPP shall indicate the names of individuals authorized to issue, authenticate, revise and approve such documents. Any changes in the list of individuals so authorized shall be communicated to EPA.

5.3 Document Maintenance

Quality-related documents that are required as part of a project shall be maintained. The PI shall maintain such documents in a project file for a period of not less than three years following the completion of the project. Completion of the project shall mean the end of the grant contract, including final financial and technical reports. If required by EPA, copies of the quality-related documents shall be submitted to EPA as part of the final project report and other project close-out documentation.

5.4 Ensuring Legal Compliance

The project PI, in consultation with the QA Manager, shall be responsible for ensuring that the non-financial, substantive aspects of EPA-funded work are and remain in compliance with applicable statutory, regulatory and EPA requirements for documents and records.

5.5 Chain of Custody and Confidentiality Procedures

The QAPP shall specify appropriate chain-of-custody and, where applicable, confidentiality procedures whenever a project involves the collection, handling, transport and storage of data samples involving chemical, physical, or biological factors in the environment. The QAPP shall indicate the persons authorized to perform such tasks, types of documentation to be maintained, and the numbers and locations of duplicate copies of all chain-of-custody documents.

Quality Management Plan

Texas Engineering Experiment Station

Section 6: Use of Automated Data Processing Systems

The purpose of this section is to document how TEES ensures that computer hardware and software satisfy their intended use.

6.1 Computer Hardware, Software, and Data Recorder Acquisition

TEES has a computer support staff that provides guidance for the acquisition of computer hardware and software. PIs proposing the acquisition of computer hardware or software with a value of more than \$5,000 must first process their request through the TEES Purchasing Manager. The PI will be responsible for assessing and documenting the impact of hardware and software changes; for evaluating and approving updated, expanded or revised computer hardware and software to support data review and reporting activities; and for ensuring that data and information produced from or collected by computers meet applicable requirements and standards.

6.2 Technical and Quality Requirements

Technical and quality requirements for all computer hardware and software purchases are prepared by the PI and upon request may be reviewed by TEES computer support staff.

6.3 Information Security Standards Including Provisions for Data Retrieval

The Division Heads or their equivalents are responsible for ensuring that the TEES information technology security program is in effect and that compliance with TEES Rule 24.99.99.E1 and TEES Standard Administrative Procedures (SAPs) 24.99.99.E1.01 through 24.99.99.E1.20 is maintained for information systems owned and operationally supported by the division. Up-to-date information on this Rule and SAPs is available at <http://tees.tamu.edu/rules>.

Quality Management Plan

Texas Engineering Experiment Station

Section 7: Quality Planning

The purpose of this section is to document how individual data operations are planned within TEES to ensure that data collected are of the necessary and expected quality for their desired use.

7.1 QA Manager and Principal Investigator Involvement

The QA Manager shall inform individuals preparing applications for EPA funding of the quality assurance requirements and advise PIs during the preparation of QAPPs of the need to incorporate systematic planning processes. Whenever the results of a research project have the potential of directly impacting other decision-making processes, the QA Manager shall advise the PI to seek the input of the affected parties during the preparation of the QAPP to ensure that the results are presented in a meaningful manner and meet the needs of the subsequent decision-makers. The QA Manager shall review the plan of work and periodic progress toward the completion of the funded project. Any revisions to the QAPP will be made by the PI and submitted to the QA Manager for concurrence and to any EPA staff as required.

7.2 Determining Project Goals and Objectives

The PI proposing EPA funded research projects must identify the project's goals and objectives. Due to the diversity of potential research topics that may be proposed, no specific guidance is given to researchers. However, all research proposals are expected to clearly articulate their purpose and, where applicable, the expected use of the information that is to be developed. Only when a proposal is of an applied research nature, and only when a specific policy or operational decision is to be made based on the research findings, will the systematic Data Quality Objectives process [as specified in *EPA Guidance for the Data Quality Objectives Process (QA/G-4)(EPA 2006)*] be applied.

7.3 Project Scheduling

General project schedules are to be provided as part of the proposal for research funding. More specific project schedules are to be developed as part of the QAPP for EPA funded projects. Specific project schedules are to identify all applicable regulatory thresholds, contractual deliverables, the timing of resource needs (i.e. staff, materials, equipment and supplies), etc.

7.4 Data Quality Needs

The type and quantity of data needed, sources of data, means of obtaining data, methods for analyzing data, determination of how the data will be used to support the project's objectives, and the performance criteria to be used for measuring quality, including existing data, are to be identified by the PI in the QAPP and are subject to review by the QA Manager.

All acquired data will be analyzed, evaluated and assessed against its intended use and any quality performance criteria by the PI and be subject to review by the QA Manager. A detailed description of this process shall be contained in the related QAPP.

Quality Management Plan

Texas Engineering Experiment Station

Section 8: Implementation of Work Processes

The purpose of this section is to document how work processes are implemented within TEES to ensure that data or information collected are of the necessary and expected quality for their intended use.

8.1 Ensuring Work Performance

The PI will ensure that the work is performed according to the approved QAPP and other related planning and technical documents. The role of the QA Manager is that of oversight. As such, the QA Manager provides a substantive review of the QAPP and periodic technical review of research procedures.

8.2 Standard Operating Procedures

The QAPP should clearly identify the standard operating procedures intended to be used to conduct the funded research project.

Quality Management Plan

Texas Engineering Experiment Station

Section 9: Quality Assessment and Response

The purpose of this section is to document how TEES determines the suitability and effectiveness of the implemented quality assurance system and the quality performance of the environmental programs to which the quality system applies.

9.1 Annual Assessment

No less than annually, this QMP shall be reviewed, revised if necessary, and resubmitted to EPA for review and reauthorization. The responsibility for ensuring the timely annual review of the QMP shall be that of the QA Manager. Comments shall be solicited from any PI involved in EPA research and subject to this QMP document. Comments shall be solicited by e-mail or memo. The QA Manager will compile comments and make recommendations for changes to the TEES Associate Agency Director for Administration & Legal Affairs. Upon approval of the TEES Agency Director, the QA Manager is authorized to formally submit the reviewed and, if necessary, revised copy of the QMP to EPA.

9.2 Corrective Action

Should problems arise regarding the implementation of the QMP, or should the personnel change relative to the administration of the QMP, a review of the QMP will be undertaken by the QA Manager, even if such review is at times other than the required annual review. In any such review, comments will be solicited from persons who have direct experience with the QMP process and can provide the TEES Associate Agency Director for Administration & Legal Affairs with knowledgeable input regarding necessary changes. In the event of differences of opinion regarding aspects of the QMP, the TEES Agency Director shall ultimately determine what, if any, changes are necessary and appropriate to the QMP. Until such time as EPA has approved a modified QMP, the prior, approved QMP shall remain in effect.

9.3 Conflict of Interest

There exists within TEES a process to reveal and appropriately manage conflict of interest. The process will be employed as prescribed in the relevant TEES Rules and Standard Administrative Procedures.

Quality Management Plan

Texas Engineering Experiment Station

Section 10: Quality Improvement

The purpose of this section is to document how TEES modifies and improves its quality assurance system.

10.1 Adverse Conditions Identification, Prevention and Correction

Quality assurance system improvement is intended to be an on-going process. Researchers and PIs may periodically note changes that can prevent adverse conditions or improve the standard operating procedures, administrative processes, and quality assurance system. Recommendations for changes in quality assurance systems that impact the QMP or related quality assurance/quality control systems shall be made to the QA Manager. The QA Manager shall take such recommendations under advisement in the annual assessment of the QMP and in other quality assurance system activities.

10.2 Process Improvement Communication

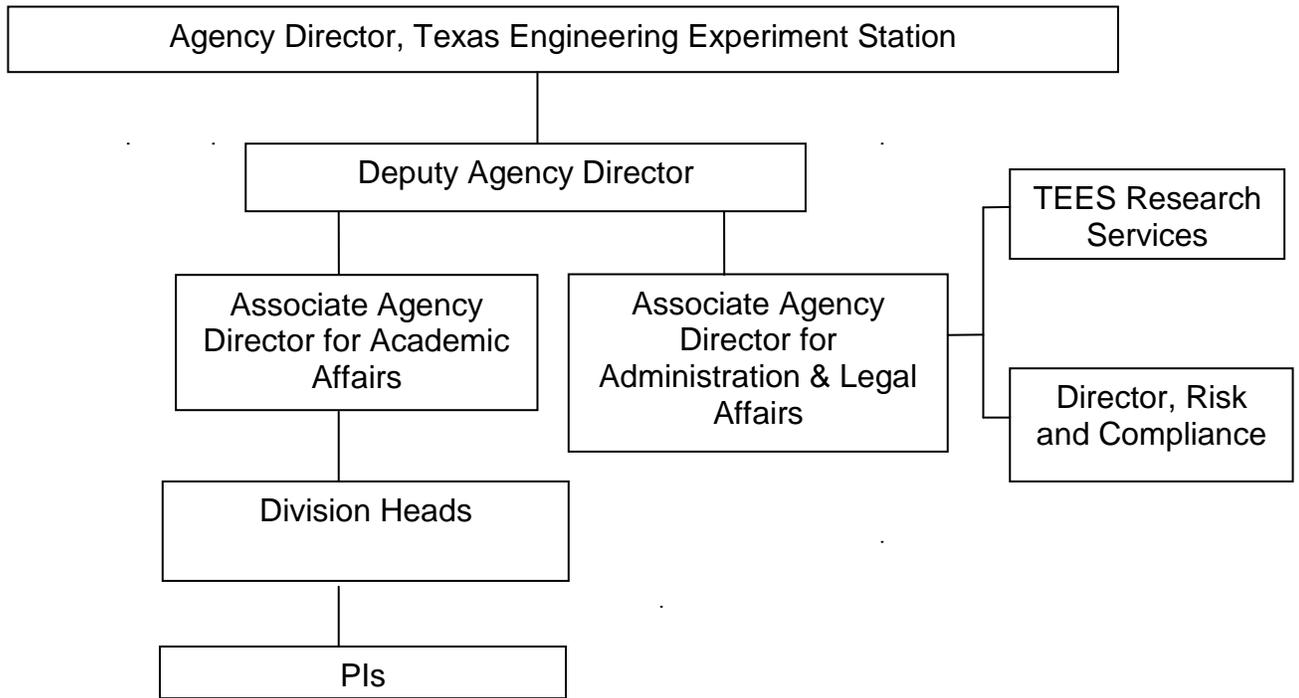
All users, both primary and secondary, of information collected and analyzed as part of EPA-funded projects shall be identified as part of a QAPP. PIs shall have the obligation of treating such users as "customers," and ascertaining the types of information, form of presentation and the likely use of information by such customers. Customer feedback shall be encouraged and, where appropriate, mechanisms for soliciting such input shall be identified in the QAPP.

Quality Management Plan
Texas Engineering Experiment Station

Appendix A:
Organization Charts

Quality Management Plan
Texas Engineering Experiment Station

Agency Organization Involving Senior Management, PIs and QMP



Quality Management Plan
Texas Engineering Experiment Station

Principal Investigator & QA Manager Communications & Reporting

