Environmental Technology Verification
Water Quality Protection Center
Quality Management Plan

Revision 3
November 2004

Developed by:

NSF International
789 Dixboro Road
Ann Arbor, MI 48105

Authors and Contributors:

Thomas Stevens
Maren Roush

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Thomas Stevens
NSF International
WQP Center Project Manager

Raymond Frederick
U.S. Environmental Protection Agency
WQP Center Project Officer

Bruce DeMaine
NSF International
WQP Center Quality Manager

Carolyn Esposito
U.S. Environmental Protection Agency
WQP Center Quality Manager

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Acronyms and Abbreviations

ANSI	American National Standards Institute
ASQC	American Society for Quality Control
CQAM	Corporate Quality Assurance Manual
E4	ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*
EPA	Environmental Protection Agency
ETV	Environmental Technology Verification Program
GSA	General Services Administration
LQAM	NSF Laboratory Quality Assurance Manual
NERL	National Exposure Research Laboratory
NRMRL	National Risk Management Research Laboratory
NSF	NSF International
ORD	EPA's Office of Research and Development
QMP	Quality Management Plan
SOP	Standard Operating Procedure

Introduction

Background

Environmental Technology Verification Program

The following background information on the ETV Program is excerpted from the Environmental Protection Agency's Environmental Technology Verification Program Quality Management Plan (EPA Report No. EPA/600/R-03/021).

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

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

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

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

Program Description

Developers of innovative environmental technology report numerous impediments to commercialization. Among those most frequently mentioned is the lack of acceptance of vendor performance claims. The success of the pilot program shows that objective, independently acquired, high-quality performance data and operational information on new technologies significantly facilitates the use, permitting, financing, export, purchase, and general marketplace acceptance of such technologies. ETV provides this data and information to the customer groups that require them to accelerate the real world implementation of improved technology. Improved technology more thoroughly, rapidly, and efficiently protects human health and the environment. It is important to stress that the product of ETV is high-quality data and information, not technology approval or endorsement. Although there is substantial EPA involvement in guiding and administering this program, ETV does not provide EPA endorsement or certification of commercial products.

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

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

During 2000 and 2001 the first five centers above were established. The sixth center was not put in place due to a lack of adequate funding to support it. In addition, subsequent to the terrorist attacks of September 11th, 2001, the role of ETV in verifying homeland security type environmental technologies was brought to the forefront. As vulnerabilities in the Nation's critical infrastructure were identified, two areas of particular concern - drinking water supply systems, and the health and safety of the Nation's workforce in their places of employment - became a focus for EPA. ETV was called upon to support the Nation's homeland security efforts by adapting its testing and evaluation process for technologies for protecting and cleaning up drinking water systems and buildings. ORD realized the tremendous testing and evaluation capability that resided in the various technology verification organizations that have been and continue to operate each center, therefore, it was determined to be in the best interest of the Nation to utilize the existing technology verification organizations, where possible and practical, to execute this mission. Three of the existing verification organizations - Battelle, Research Triangle Institute, and NSF International - were enlisted to support the homeland security-related technology testing and evaluation needs. A new center operated by Battelle - the Building Decontamination Technology Center (BDT) - was established, as the existing verification organization funding agreements did not have this type technology verification within their scopes of work.

The homeland security efforts fall into two categories: water security and safe buildings. The water security efforts are being accomplished through the existing cooperative agreements with the AMS, DWS, and WQP centers. The safe buildings efforts are being accomplished through General Services Administration (GSA) contract to two existing verification organizations, Battelle and Research Triangle Institute. Contracts through GSA were chosen in lieu of cooperative agreements because it was believed that for this area the Agency and federal government would have to be directive in many of the elements of the effort: the stakeholders, the test methods, deciding on the technologies to be tested, and possibly other aspects. This was in contrast to the water security effort in which the ETV management process consistent with cooperative agreements was to be followed. None of the contract funding will be commingled with cooperative agreement funding by the technology verification organizations. The ETV project officers have been trained in the distinctions between managing cooperative agreements and contracts.

Operation of the Center

The technology verification organizations are all not-for-profit entities that work with or for EPA through an extramural agreement (a cooperative agreement, an interagency agreement, or an existing General Services Administration (GSA) contract). EPA and the technology verification organization roles are identical to those established during the pilot period. Each agreement has oversight by an EPA project officer who may also be the EPA Center Manager. EPA provides substantial oversight through an active quality assurance program. Each technology verification organization is contractually required to fully implement EPA QA requirements for planning, auditing, and documenting the testing and reporting activities. Qualified peer reviewers are also utilized to review the technical aspects of the test plans and of the final reports.

Program and Quality Management Documents

Several documents define the overall operation of the Program. The first to be published (February, 1997) was the Environmental Technology Verification <u>Strategy</u>. This document describes the goals, customer and key word definitions, basic operating principles, project selection criteria, and the programmatic and budgetary vision of the program. The Strategy is evaluated periodically for the need for modification and amplification. The second major program management document being used by ETV to guide its operation is the ETV Quality Management Plan (QMP).

The ETV Quality Management Plan

The ETV QMP uses the structure, policies, and standards established in the American National Standard *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (E4)[1]*. This document "…describes a basic set of mandatory specifications and non-mandatory guidelines by which a quality system for programs involving environmental data collection and environmental technology can be planned, implemented, and assessed." Based on the structure and standards of E4, the ETV QMP contains the definitions, procedures, processes, inter-organizational relationships, and outputs that assure the quality of both the data and the programmatic elements of ETV. Part A of the ETV QMP contains the specifications and guidelines that are applicable to common or routine quality management functions and activities necessary to support the ETV program. Part B contains the specifications and guidelines that apply to test-specific environmental technology testing activities involving the generation, collection, analysis, evaluation, and reporting of test data. The ETV QMP was also developed in accordance with *EPA Requirements for Quality Management Systems[2]*, a document that provides the development and content requirements for Quality Management Plans for organizations that conduct environmental data operations for EPA through contracts, assistance agreements, and interagency agreements; however, it may be used by EPA as well.

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

WQP Center

The U.S. Environmental Protection Agency's partner in the ETV Water Quality Protection (WQP) Center is NSF International (NSF), a not-for-profit, non-governmental organization that provides public health and safety-based risk management solutions and is dedicated to protection of the environment. The goal of the WQP Center is to verify commercial-ready environmental technologies that protect ground- and surface waters from contamination. Under the WQP Center, technologies are evaluated by a third party organization, following technically sound test procedures, appropriate QA/QC, and a managed process, to provide purchasers, specifiers and permitters with credible and relevant data.

Verification protocols are developed for specific technology areas following an open process with broad-based stakeholder input. The protocols then serve as templates for developing test plans for the evaluation of individual technologies at specific locations. Verification reports detailing the results of the technology evaluations are made publicly available to assist in marketing, purchase and permitting of the technologies. Verification statements, executive summaries of each verification test, are also provided.

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[1] American Society for Quality (ASQ); <u>American National Standard and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs</u>; ASQ, Milwaukee, Wisconsin, 1994. (E4)

[2] U.S. Environmental Protection Agency; <u>EPA Requirements for Quality Management Systems</u>, EPA/240/B-01/002; 2001 (available on the Internet at www.epa.gov/quality/qs-docs/r2-final.pdf).

WQP Center - Quality Management Plan

As the Verification Organization for the WQP Center, NSF is required to maintain a center-specific QMP that adheres to the guidelines set forth in the American National Standard*, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (E4) and the ETV QMP. NSF has prepared a *Water Quality Protection Center Quality Management Plan* (WQP QMP) that outlines NSF's quality systems and demonstrates conformance with the relevant provisions of E4, EPA QMP Requirements, and the ETV QMP.

Many of the provisions of E4 and the ETV QMP were already addressed in NSF's existing management and quality systems, as documented in the NSF Corporate Quality Assurance Manual, the NSF Laboratories Quality Assurance Manual, NSF Standard Operating Procedures (SOPs) and other NSF documents. The NSF documents that are relevant to the operation of the WQP Center are referenced herein. Other provisions of E4 and the ETV QMP (particularly Part B, Collection and Evaluation of Environmental Data) are addressed in the SOPs, Protocols, and Test Plans developed specifically for the WQP Center

The purpose of the WQP QMP is to provide the definitions, procedures, processes, inter-organizational relationships, and outputs that assure the quality of both the data and programmatic elements of the WQP Center. Sections 1 through 4 of the WQP QMP contain the specifications and guidelines that are applicable to common or routine quality management functions and administrative activities necessary to support the WQP Center. These sections also detail the organizational structure of both NSF and the WQP Center

Sections 5 through 6 of the WQP QMP contain the specifications and guidelines that apply to test-specific environmental activities involving the generation, collection, analysis, evaluation, and reporting of data.

1. Management Systems

1.1. Management and Organization

1.1. WQP Center Quality Policy

The quality system for the WQP Center seeks to be consistent with that of the ETV Program, EPA QMP Requirements, and industry consensus standards. To that purpose, the quality system for the WQP Center conforms to the relevant provisions of the ETV QMP, EPA QMP Requirements, and E4. Attachment A is a table that lists the requirements of E4 and the NSF Reference Documents (SOPs) that fulfill them. In addition, all SOPs referenced herein are included in Appendix A. Each verification test shall be performed according to planned, documented, and approved test/QA plans, which are developed by NSF International or a subcontractor in accordance with NSF SOP AA-394-0002. All technical statements in ETV verification reports shall be supported by the appropriate data.

The quality management system for NSF International is described in the *NSF Corporate Quality Assurance Manual* (CQAM), NSF Document Control No. AF-700-0002, which is included in Appendix A. The CQAM documents NSF's Corporate Mission, Corporate Values, Quality Policy and Objectives, Quality System Document Structure, and General and Administrative Structure. In addition, the CQAM describes the quality systems in place for all of NSF's operations.

1.2. Organization Structure

1.2.1. NSF Corporate Organization Structure

The NSF corporate organization structure is described in Section 4 of the CQAM.

1.2.2. Center Structure – NSF Personnel

The WQP Center is one of two ETV Centers operated under separate cooperative agreements between NSF and EPA. The NSF ETV Centers are overseen by the Vice President, Research. Training records of NSF staff are available from NSF's Human Resources Department for review by EPA, upon request. Listed below are the general functional responsibilities of the NSF personnel associated with the WQP Center.

1.2.2.1.   Vice President, Research
Gordon Bellen, 734-827-6840

Responsibilities include:

- providing leadership on Center initiatives and long-term goals;
- overseeing outreach activities, including those that impact multiple ETV Centers or other NSF Programs; and
- communicating with NSF Chief Executive Officer, Corporate Officers, and Senior Management regarding ETV activities.

1.2.2.2.   Project Manager, WQP Center
Thomas Stevens, 734-769-5347

Responsibilities include:

- reporting to Vice President, Research;
- establishing, attending, and conducting meetings of stakeholders;
- maintaining communication with EPA, including the ETV director, ETV team, EPA center manager and the EPA center quality manager, to assure mutual understanding and conformance with EPA quality procedures and expectations and ETV policies and procedures;
- managing the oversight and conduct of verification activities;
- assuring that quality procedures are incorporated into all aspects of the each ETV project;
- overseeing the development of verification protocols and test plans;

- overseeing the development and implementation of the WQP Center Quality Management Plan;
- overseeing the development of ETV verification reports for technology evaluations;
- overseeing the development of an ETV verification statement at the completion of each technology verification;
- approving contractual agreements with external parties such as protocol developers, peer-reviewers, and testing organizations; and
- identifying, conducting, and managing Center outreach activities including paper presentations, trade shows, agency visits, etc.

1.2.2.3.   Project Coordinators, WQP Center
Patrick Davison, 734-913-5719
Maren Roush, 734-827-6821

Responsibilities include:

- reporting to Project Manager, WQP Center;
- establishing contact with interested stakeholders and soliciting their participation on Stakeholder Advisory Groups and Technology Panels and with peer-review activities;
- preparing agendas, meeting materials, presentations, and summaries for meetings of Stakeholder Advisory Groups and Technology Panels;
- soliciting vendor applications for verification testing;
- coordinating verification protocol/test plan development;
- soliciting potential field testing organizations/sites for verification activities;
- reviewing qualifications of potential field testing organizations/sites and making recommendations to the Project Manager as to their suitability for conducting testing and preparing reports;
- conducting audits and inspections of verification tests;
- reviewing verification reports and supporting data for completeness and conformance with QA provisions in the verification protocol and test plan;
- preparing and updating the WQP Center Quality Management Plan;
- preparing and maintaining the WQP Center web pages on the NSF web sites and forwarding content to EPA for inclusion on its web sites; and
- ensuring that Center documents are distributed to the proper ETV Program personnel.

1.2.2.4.   Secretary, Federal Programs
Pat Wilkie, 734-913-5740

Responsibilities include:

- maintaining mailing lists for the Stakeholder Advisory Groups, Technology Panels, Contract organizations, and other stakeholders;
- providing administrative support for Center activities such as mailings and faxes; and
- making necessary arrangements for on-site and off-site meetings and conference calls.

1.2.2.5.   Director, Quality Assurance
Bruce DeMaine, 734-769-5143

Responsibilities include:

- ensuring that quality procedures are incorporated into all aspects of the Center;
- ensuring that quality assurance reviews have been performed on all verification protocols, product- and site-specific test plans and verification reports, and that feedback for improvement has been provided and addressed;
- reviewing and approving the WQP QMP; and
- conducting annual audits of the WQP Center for conformance with the WQP QMP.

1.2.3. Center Structure - EPA Personnel

The WQP Center is one of seven centers operating under the EPA's ETV Program. Section 1.2 of the ETV QMP, "Organization Structure", lists the general functional responsibilities of the EPA personnel associated with the ETV program, including the EPA center manager.

1.2.4. WQP Center Stakeholder Advisory Groups

The WQP Center Stakeholder Advisory Groups are comprised of individuals representing organizations concerned with water quality protection. Five Stakeholder Advisory Groups were formed by the WQP Center to address the following technology areas: Ballast Water Treatment, Decentralized Wastewater Treatment, Infrastructure Rehabilitation, Watershed Protection, and Wet Weather Flow. Stakeholder Advisory Group members are selected by NSF and EPA and include users of technologies, technology vendors, consultants, financial institutions, state and local permitters and regulators, EPA regional personnel, and federal agency officials. Many members represent professional and trade organizations in addition to their specific employer. Members of a Stakeholder Advisory Group:

- assist in prioritizing the types of technologies to be verified;
- assist in the development and review of verification protocols, as requested;
- review verification reports and statements, as requested;
- assist in definition and conduct of outreach activities appropriate to the technology area and customer groups;
- exchange information with the organizations represented; and
- provide general guidance to Center, especially with respect to Center policies and procedures.

For more information on the roles and responsibilities of WQP Center Stakeholder Advisory Groups, refer to NSF SOP No. AA-394-0001, which is included in Appendix A.

1.2.5. WQP Center Technology Panels

Technology Panels consist of individuals who have expertise in a particular technology area. Whereas Stakeholder Advisory Group members provide policy-related input to the Center and assist with prioritization of technology areas to be addressed by the Center, Technology Panels are formed, as needed, to assist with the development and review/revision of Verification Protocols and Test Plans for specific technologies or technology areas.

For more information on the roles and responsibilities of WQP Center Technology Panels, refer to NSF SOP No. AA-394-0001, which is included in Appendix A.

All stakeholders in the WQP Center, in addition to those serving on Stakeholder Advisory Groups and Technology Panels, are encouraged to participate in Center activities, including meetings and review of documents that have been released for public comment.

2. Quality System and Description

2.1. Corporate

NSF has a company-wide quality system to assure that the NSF quality policy is upheld and the NSF quality objectives are achieved. The quality system is described in the CQAM and related standard operating procedures (SOPs). Corporate quality systems are reviewed and their description updated annually to reflect changes in the organization and in policy.

Table 2-1 highlights the key elements of the NSF quality system and identifies the NSF Document, by Document Control Number and Title, in which the element is addressed. The procedures and policies contained in the referenced NSF document apply to the Federal Programs area of the Engineering and Research Services Department and the WQP Center.

Table 2-1. NSF Quality System Summary and References to Control Documents

Key Elements of the NSF Quality System	Control Document Reference
Established quality policy and objectives focused on meeting customer and stakeholder needs applicable to all of NSF's operations	AF-700-0002: SECTIONS 2.0 AND 2.1 IN CQAM AA-700-0188: CONTINUOUS IMPROVEMENT REPORT AC-700-0007: CONTINUOUS IMPROVEMENT REPORT FORM
Training of NSF personnel	AF-700-0003: CORPORATE TRAINING MANUAL AF-700-0001: HUMAN RESOURSES HANDBOOK AA-700-0001: PERFORMANCE APPRAISALS
Documentation of procedures, policies and processes used in NSF's operations	SEE THE LIST OF CONTROL DOCUMENTS WHICH BEGIN WITH THE LETTERS "AA". THESE LETTERS SIGNIFY THAT THE DOCUMENT IS A PROCEDURE. OTHER LETTER DESIGNATIONS INCLUDE FORMS (AC), ETC.
Process to control the distribution and dissemination of documents such as processes, procedures and contracts for all operations	AA-759-0006: SUBMITTAL AND ISSUANCE OF CONTROLLED DOCUMENTS AA-700-0008: PROCEDURAL MODIFICATION DOCUMENTATION
Addressing customer feed back and comments	AA-700-0191: CLIENT FEEDBACK MANAGEMENT SYSTEM AF-700-0002: SECTION 13 IN CQAM
Internal and external audits and inspections of operations	AF-700-0002: SECTION 14 IN CQAM AA-700-0187: CORPORATE QUALITY ASSURANCE AUDITS
Record retention	AF-700-0002: SECTION 15 IN CQAM

2.2.   Federal Programs

The Engineering and Research Services (ERS) Department consists of two main groups of staff: Federal Programs employees, who are ETV personnel (NSF staff who work for the Drinking Water Systems Center and the Water Quality Protection Center) and other Engineering and Research Services personnel. The ERS staff typically respond to and manage research projects, one-time evaluations and special studies.

The highly qualified and credentialed members of the ERS Department have years of experience in developing and performing test protocols for "non-routine" commercial, municipal, and government projects of all sizes. In addition to operating under the company-wide quality system outlined in Table 2-1, the ERS Department develops, documents and implements procedures as needed for its specific operations. SOPs for ERS operations, including those specific to the Federal Programs personnel, are maintained in the NSF Document Control System.

2.3.   WQP Center

In order to achieve the technical and quality goals of the WQP Center and the ETV Program, the WQP Center operates in accordance with written procedures and guidelines. The procedures and guidelines specific to the Center include the following documents:

AA-394-0001   *Procedures for the Formation, Maintenance, and Role of Stakeholder Advisory Groups and Technology Panels*
AA-394-0002   *Verification Protocol, Test Plan, and Verification Report Development Procedures*
AK-394-0001   *Guidelines for the Conduct of Meetings of the Stakeholder Advisory Groups and Technology Panels*

2.4.   Laboratories

NSF operates several laboratories for the purpose of conducting chemical, engineering, and microbiological assessments. NSF's laboratories are accredited by more than 20 organizations at the state, national, and international levels. The laboratories operate in accordance with the corporate quality system as described in the CQAM, and in accordance with the laboratories' quality system, as described in the NSF Laboratories Quality Assurance Manual (LQAM), Document Control #AF-840-0001. Analyses performed on behalf of the ETV Program are done in accordance with the QA/QC procedures established in the LQAM and the relevant Test Plan(s).

3. Assessments

3.1. Quality Management Systems Review

Periodic reviews of NSF Corporate and WQP Center quality systems are necessary to establish that the Center's quality management structure, policies, practices and procedures are adequate for ensuring the quality of results demanded by its customers.

3.1.1. Assessment of Corporate Quality Assurance

An independent audit of the NSF Corporate Quality Assurance Systems is conducted annually as prescribed in Section 14 of the CQAM.

Independent accreditation bodies periodically audit NSF's Quality Assurance Systems. This is done as necessary to obtain and maintain NSF's multiple accreditations.

3.1.2. Center Quality Systems Audits

3.1.2.1.   Independent Assessment - EPA

The EPA Center Quality Manager will perform a quality systems audit of the WQP Center, using the WQP QMP as a basis, to assess the quality management practices of the WQP Center. The quality systems audit will take place once in the first year after approval of the WQP QMP, and thereafter as requested. The quality systems audit follows the guidelines presented in Part A: Section 2.7 and Table 9.1 of the ETV QMP. The audit report will be forwarded for review to the EPA Director of Quality Assurance, EPA Center Manager, the appropriate Project Manager(s) (NSF), and the ETV Director.

3.1.2.2.   Self Assessment - NSF

The NSF Director, Quality Assurance, will perform a quality systems audit of the WQP Center, using the WQP QMP as a basis, as specified in Part A: Section 2.7 and Table 9.1 of the ETV QMP. The quality systems audit will take place once in the first year after approval of the WQP QMP, and thereafter as requested. The audit report will be forwarded to the Project Manager of the WQP Center for review and final copies of the report will be distributed to the EPA Center Manager.

3.1.3. Other Assessments

NSF is also responsible for conducting quality assessments related to the collection and evaluation of data under the WQP Center. Additional required assessments include Technical Systems Audits, Performance Evaluation Audits, and Audits of Data Quality, the purpose and frequency of which are described in 5.4.

4. Conformance to E4

The ETV Water Quality Protection Center is committed to conforming to the relevant provisions of E4 and EPA QMP Requirements.

4.1. Water Quality Protection Center QMP

The WQP QMP is organized so that it can be compared to E4 and EPA QMP Requirements. Attachment A addresses NSF's quality management system (Part A of E4) and the Center's processes for collecting and evaluating environmental data (Part B of E4).

4.2. Quality Management System (Part A of E4)

The requirements in Part A of E4 for a quality management system are met by two NSF documents:

- AF-700-0002: *Corporate Quality Assurance Manual*
- AF-840-0001: *Laboratory Quality Assurance Manual*

The locations of the specific E4 requirements in these NSF documents are shown in Attachment A. The two referenced documents are attached to this QMP.

4.3. Collection and Evaluation of Data (Part B of E4)

The requirements in Part B of E4 for the collection and evaluation of test data are met by the following NSF documents:

- AA-394-0002: *Verification Protocol, Test Plan, and Verification Report Development Procedures*
- Individual protocols and test plans developed for technology evaluations under the ETV Water Quality Protection Center

5. Collection and Evaluation of Data

5.1. Planning and Design

Verification Protocols have been and will continue to be developed for various categories of water quality protection technologies identified as priorities by NSF, EPA, and the relevant Stakeholder Advisory Groups. Verification Protocols outline the scope, data quality objectives, and the generic experimental design for verification. These protocols are developed in accordance with NSF Document AA-394-0002, *Verification Protocol, Test Plan, and Verification Report Development Procedures*, which conforms to the guidelines established in the ETV QMP Part B: Section 2.0 *Design of Technology Verification Tests*. The Verification Protocols provide the framework for the development of Test Plans, which are also addressed in NSF Document AA-394-0002. Test Plans describe the procedures to be followed when evaluating vendor-specific technologies at site-specific locations.

Each Verification Protocol contains a QA/QC section that provides guidelines for the quality assurance elements to be included in the technology- and site-specific Test Plans. The QA/QC section of the Verification Protocol addresses QA responsibilities, data quality indicators, QC checks, data handling, corrective action plans, and other items necessary to verify the quality and consistency of the work.

Each Test Plan contains a Quality Assurance Project Plan that describes the specific QA/QC methods and procedures to be followed during all phases of equipment operation, sample collection, handling and analysis, instrument calibration, and data handling. The Quality Assurance Project Plans contain written procedures for planning and conducting audits.

5.2. Implementation

Most verification tests are conducted at off-site facilities by organizations under contract with NSF. Procedures for NSF subcontracting are explained in NSF SOP AA-840-0001. The subcontract testing organization, if any, is responsible for conducting the testing in accordance with the approved Verification Protocol and Test Plan(s). The subcontract organization must demonstrate its ability to implement the Verification Protocol and Test Plan(s) as written and operate in accordance with the WQP QMP. If the subcontract organization is to draft the test plan and/or verification report, it must also demonstrate its ability to meet the requirements outlined in AA-394-0002 *Verification Protocol, Test Plan, and Verification Report Development Procedures*.

Due to unforeseen occurrences it is sometimes necessary for a subcontract testing organization to propose deletions, additions, or modifications to an approved Test Plan in order to complete the verification testing. Any changes or additions to the Test Plan deemed necessary by the contract testing organization shall be documented and approved in advance by the Verification Organization.

5.3. Reporting

NSF and EPA are responsible for the issuance of all ETV Verification Reports and ETV Verification Statements developed under the WQP Center.

NSF oversees the development of ETV Verification Reports in accordance with AA-394-0002 *Verification Protocol, Test Plan, and Verification Report Development Procedures* prior to their submission to EPA. The Project Manager (NSF) or designated Project Coordinator is responsible for overseeing the preparation of each verification report. Verification reports are reviewed by the EPA Center Quality Manager, the NSF Director, Quality Assurance, peer-reviewers, and the vendor. The Center Quality Manager and NSF Director, Quality Assurance, are ultimately responsible for the QA review of each verification report, but may choose to designate other staff to perform the review, as needed to expedite the process. The reviewers' comments are considered and the verification report is updated as appropriate. Following the required reviews of the verification report, the Project Manager (NSF) forwards the reviewed reports to the EPA Center Manager for approval, as specified in the ETV QMP. Final verification reports are distributed to the ETV Director and are provided to the ETV Webmaster to post on the Internet.

NSF oversees the development of ETV verification statements in accordance with AA-394-0002 *Verification Protocol, Test Plan, and Verification Report Development Procedures*. A verification statement is included as an "executive summary" of the verification test at the beginning of each verification report, and may also be used as a standalone document. The Project Manager (NSF) is responsible for the preparation of each verification statement. Each verification statement is reviewed by the EPA Center Manager, the EPA Center Quality Manager, the NSF Director, Quality Assurance, peer-reviewers, the vendor and the

ETV Director. The Center Quality Manager and the NSF Director, Quality Assurance, are ultimately responsible for the QA review of each verification statement, but may choose to designate other staff to perform the review, as needed to expedite the process. The reviewers' comments are considered and the verification statement is updated as appropriate. Following the required reviews of the verification statement, the revised verification statements are forwarded to the EPA laboratory directors for approval, as specified in the ETV QMP. Final verification statements are distributed to the ETV Webmaster.

5.4.   Assessments

5.4.1.   Technical Systems Audits

5.4.1.1.   Independent – EPA

The EPA Center Quality Manager will perform a technical systems audit at least once per year, as applicable, in accordance with Part B: Section 4.1.2 of the ETV QMP. The purpose of the technical systems audit is to assess the technical systems of verification tests, including all facilities, maintenance, calibration procedures, reporting requirements, sampling and analytical activities, and quality control procedures, and to ensure their conformance to the approved test plans. Audit reports will be forwarded to the appropriate EPA Center Manager for review.

5.4.1.2.   Self - NSF

The Project Manager (NSF), Project Coordinator, Director, Quality Assurance, or other qualified NSF designee will conduct a technical systems audit at least once during the verification testing period for each technology evaluated through the WQP Center. The purpose of the technical systems audit is to assess the technical systems of verification tests, including all facilities, maintenance, calibration procedures, reporting requirements, sampling and analytical activities, and quality control procedures, and to ensure their conformance to the approved test plans. Technical systems audits are most useful when conducted early in the life cycle of a project, when corrective actions (if necessary) can be performed that will minimize the loss of data. Audit reports will be forwarded to the appropriate Project Manager (NSF), the EPA Center Quality Manager, and the Testing Organization for review.   Subcontract testing organizations will conduct self-assessments of technical systems at a frequency specified in the relevant Test Plan.

5.4.2.   Performance Evaluation Audits

5.4.2.1.   Independent – EPA

The EPA Center Quality Manager will conduct a performance evaluation audit of the measurement systems used in testing, as applicable, according to Part A: Table 9.1 and Part B: Section 4.1.4 of the ETV QMP. 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 material 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. The audit report will be forwarded to the EPA Center Manager for review.

5.4.2.2.   Self – NSF

As applicable, NSF's Director, Quality Assurance, or another qualified NSF designee, will conduct a performance evaluation audit of the measurement systems used in testing at least once during the verification testing period for each technology evaluated under the WQP Center, as specified in Part A: Table 9.1 and Part B: Section 4.1.4 of the ETV QMP. 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 material 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. Audit reports will be forwarded to the Project Manager (NSF) and the EPA Center Quality Manager for review. Contract testing organizations will conduct self-assessments of measurements performance at a frequency specified in the relevant Test Plan.

Laboratories conducting sample analyses for the WQP Center shall be accredited by:

- The state in which the laboratory operates, if an accreditation program is offered;
- The American Association for Laboratory Accreditation;
- NSF International (according to the LQAM); or
- An equivalent program deemed acceptable by NSF.

Subcontract laboratories shall have documented quality control procedures that include participation in approved, independent performance audits.

5.4.3. Audits of Data Quality

5.4.3.1. Independent – EPA

To determine the accuracy and usability of data calculations and reporting, the EPA Center Quality Manager will conduct an audit of data quality for the WQP Center, as applicable. The audit of data quality will be performed on raw data and summary data. Findings will be documented in a data quality audit report, which will be provided to the EPA Center Manager for review.

5.4.3.2. Self - NSF

To determine the accuracy and usability of data calculations and reporting, NSF's Director, Quality Assurance, or another qualified NSF designee, will conduct an audit of data quality for each verification test conducted under the WQP Center using raw data and summary data. Audits of Data Quality are performed on at least 10% of the test data ("10% of the test data" means a random selection of 10% of the data from all of the measured parameters") that have already been 100% verified by project personnel, as possible (i.e. it may not be feasible to verify every data point generated by a monitor that measures flow every five seconds over the course of a verification test). Findings are documented in a data quality audit report, which is signed by NSF's Director, Quality Assurance, and is provided to the appropriate NSF Project Manager and to the EPA Center Quality Manager for review. Data quality audit reports will document that NSF's Quality Assurance Department reviewed the data associated with the verification test for the data quality indicators and that they were found to be acceptable. The data quality audit report will outline any deficiencies in 1) the data set and 2) the way in which the data were presented in the draft verification report. The data quality report will note any data quality deficiencies, along with corrective actions taken.

6. Use of Existing Data

The use of existing data (i.e., data collected outside of the ETV Program) toward the ETV Verification of a water quality protection technology is considered in accordance with the guidelines established in the ETV QMP Appendix C – *Environmental Technology Verification Program Existing Data: Policy and Process.*

Attachment A: Location of E4 Requirements in NSF Reference Documents

E4: PART A

ITEM	E4 REFERENCE NO.	E4 SECTION	SPECIFICATION	NSF REFERENCE DOCUMENT AND SECTION
001	2.01.1.001	mgt	quality policy	2.0-2.1 in CQAM
002	2.01.1.002	mgt	quality system resp. authority, mgt appr	4.0-4.3 in CQAM
003	2.01.1.003	mgt	ID of customers and suppliers	2.0-2.1 in CQAM, Protocols
004	2.01.1.004	mgt	ID their needs/expectations, est. work objectives	3.0-3.4 in CQAM, Protocols
005	2.01.1.005	mgt	negotiation for quality when problems/constraints	3.0-3.4 in CQAM, AA 700-0191
006	2.01.1.006	mgt	ensure E4 understood and implemented	5.1.1 in CQAM
007	2.01.1.007	mgt	provide adequate resources	1.2 in CQAM
008	2.01.1.008	mgt	stop unsafe work or delegate authority	Technology-Specific Test Plans
009	2.01.1.009	mgt	assess and document adequacy of Q system	3.0-3.4 and 14.0-14.4 in CQAM
010	2.01.1.010	mgt	define assessment objectives, determine Q system, impl. meas.	3.0-3.4 and 14.0-14.4 in CQAM
011	2.01.1.011	mgt	determine response actions, implement in a timely manner	3.0-3.4 and 14.0-14.4 in CQAM
012	2.02.1.001	Qsyst	Qsys plan, established, documented, implemented, and assessed	3.0-3.5 in CQAM
013	2.02.1.002	Qsys	include as org, policy, requi., guidance necessary	3.0-3.5 and 4 in CQAM
014	2.02.1.003	Qsys	shall ensure product/results of type needed	3.0-3.5 in CQAM
015	2.02.1.004	Qsys	no initiation of work until Qsys approved	3.0-3.5 and 5.1.1 in CQAM
016	2.02.1.005	Qsys	Qsys in QMP approved by mgt for implementation	3.5 and 14.4 in CQAM
017	2.02.1.006	Qsys	controls for projects and how projects are plan/impl/assess	3.0-3.5 in CQAM
018	2.02.1.007	Qsys	address all applicable part of E4	3.0-3.5 and 5.11 in CQAM
019	2.02.1.008	Qsys	general descr. items/prog/activities Qsys applies to	3.0-3.5 in CQAM
020	2.02.1.009.00	Qsys	ID/document activities affecting Q	3.0-3.5 in CQAM
021	2.02.1.009.01	Qsys	.........mgt. resp.	4.0-4.3 in CQAM
022	2.02.1.009.02	Qsys	.... technic. act. resp.	4.0-4.3 in CQAM
023	2.02.1.009.03	Qsys	.... required interfaces	3.2 and 4.0-4.3 in CQAM
024	2.02.1.010	Qsys	Qsys update, at least annual	3.5 and 14.0 in CQAM

ITEM	E4 REFERENCE NO.	E4 SECTION	SPECIFICATION	NSF REFERENCE DOCUMENT AND SECTION
025	2.03.1.001	Per/Tr	trained for project before starting the work	8.0-8.3 in CQAM, AF-700-0003, AA-759-0006
026	2.03.1.002	Per/Tr	need for training evaluated and impl.	8.0-8.3 in CQAM, AF-700-0003
027	2.03.1.003	Per/Tr	documentation of training	8.0-8.3 in CQAM, AF-700-0003, AA-700-0001
028	2.03.1.004	Per/Tr	ensure training when job reqs change	8.0-8.3 in CQAM, AA-759-0006
029	2.03.1.005	Per/Tr	doc/maintain evidence of job proficiency	8.0-8.3 in CQAM, AA-700-0001
030	2.03.1.006	Per/Tr	training resources	8.0-8.3 in CQAM, AF-700-0003
031	2.04.1.001	Procur	planned/controlled/documented to meet client needs	CQAM 9.0-9.3, LQAM 5.11-5.13
032	2.04.1.002	Procur	docs describe item/service needed & associated technical reqs/crit.	CQAM 9.0-9.3, LQAM 5.11-5.13; AA-840-0001
033	2.04.1.003	Procur	specify parts of E4 supplier resp. for	NA
034	2.04.1.004	Procur	docs reviewed for accuracy before release	CQAM 9.0-9.3, LQAM 5.11-5.13
035	2.04.1.005	Procur	changes to docs subject to same review	CQAM 9.0-9.3, LQAM 5.11-5.13
036	2.04.1.006	Procur	procedures to ensure procured items meet requirements	CQAM 9.0-9.3, LQAM 5.11-5.13; AA-840-0001
037	2.04.1.007	Procur	if stated, demonstrated capability needed from suppliers	CQAM 9.0-9.3, LQAM 5.11-5.13; AA-840-0001
038	2.05.1.001	Doc/Rec	records mgt. procedures required	10.0-10.5 in CQAM, AF-700-0002
039	2.05.1.002	Doc/Rec	must be applicable to all, including electronic media	NA
040	2.05.1.003	Doc/Rec	ID need for control of any specified documents	10.0-10.5 in CQAM, AF-700-0002, AA-759-0006
041	2.05.1.004	Doc/Rec	must be reviewed for conformance before release by authoriz.	10.0-10.5 in CQAM, AF-700-0002, AA-759-0006
042	2.05.1.005	Doc/Rec	if used for work, must be kept current	10.0-10.5 in CQAM, AF-700-0002, AA-759-0006
043	2.05.1.006	Doc/Rec	ensure all users understand docs	10.0-10.5 in CQAM, AF-700-0002, AA-759-0006
044	2.05.1.007	Doc/Rec	ID obsolete/superseded docs/ remove from workplace	10.0-10.5 in CQAM, AF-700-0002, AA-759-0006
045	2.05.1.008	Doc/Rec	maintain docs to show quality of work or conformance to regs.	10.0-10.5 in CQAM, AF-700-0002, AA-759-0006
046	2.05.1.009	Doc/Rec	maintenance to include retention/prot/pres/trac/retr	10.0-10.5 in CQAM, AF-700-0002, AA-759-0006
047	2.05.1.010	Doc/Rec	if evid. records, COC for records and confidentiality proc.	10.0-10.5 in CQAM, AF-700-0002, AA-759-0006
048	2.05.1.011	Doc/Rec	retention times based on contract/stat requirements	10.0-10.5 in CQAM, AF-700-0002, AA-759-0006
049	2.05.1.012	Doc/Rec	storage, protection from damage, loss, deterioration	10.0-10.5 in CQAM

ITEM	E4 REFERENCE NO.	E4 SECTION	SPECIFICATION	NSF REFERENCE DOCUMENT AND SECTION
050	2.06.1.001	Comput	all aspects to meets user reqs & conform to appl. conc. stds.	CQAM 7.0-7.3, LQAM 5.8
051	2.06.1.002	Comput	test hardware/software before use	CQAM 7.0-7.3, LQAM 5.8
052	2.06.1.003.00	Comput	further testing of configs not req. unless:	NA
053	2.06.1.003.01	Comput	........software usage scope changes	NA
054	2.06.1.003.02	Comput	........mods to hard/software configs.	NA
056	2.06.1.004	Comput	assess changes to configs re: impact on technical & Q obj.	NA
057	2.06.1.005	Comput	change components (& config), must retest	NA
058	2.06.1.006	Comput	program changes, check (& test) config as needed	NA
059	2.06.1.007.00	Comput	configs covered include:	NA
060	2.06.1.007.01	Comput	........experimental design	NA
061	2.06.1.007.02	Comput	........design analysis	NA
062	2.06.1.007.03	Comput	........environmental modeling	NA
063	2.06.1.007.04	Comput	........process control systems (LIMS, auto data acquisition, etc.)	NA
064	2.06.1.007.05	Comput	........environmental data bases	NA
065	2.07.1.001.00	Planning	establ./imple/control/ and docu planning process to:	5.0-5.6 in CQAM
066	2.07.1.001.01	Planning	........ID customers, needs, work results expected	5.0-5.6 in CQAM, Protocols
067	2.07.1.001.02	Planning	........ID tech and Q goals to meet needs	5.0-5.6 in CQAM, Protocols
068	2.07.1.001.03	Planning	........translate goals to tech. specs.	5.0-5.6 in CQAM, Test Plans
069	2.07.1.001.04	Planning	........address cost/schedule constraints	5.0-5.6 in CQAM, Protocols and Test Plans
070	2.07.1.001.05	Planning	........ID acceptance criteria for results	5.0-5.6 in CQAM, Protocols and Test Plans
071	2.07.1.002	Planning	plan. docs approved by authorized person. Before work starts	5.0-5.6 in CQAM, Protocols and Test Plans
072	2.07.1.003	Planning	plan doc include work plans, schedules, and QAPPs	5.0-5.6 in CQAM, Test Plans
073	2.08.1.001	Implement	work accord. to plans and other docs, in the correct order	3.0-3.4 in CQAM, Protocols
074	2.08.1.002	Implement	mgt. oversight commensurate to work importance	3.0-3.4 in CQAM, Protocols
075	2.08.1.003	Implement	SOPs for standard, critical operations	3.0-3.4 in CQAM

ITEM	E4 REFERENCE NO.	E4 SECTION	SPECIFICATION	NSF REFERENCE DOCUMENT AND SECTION
078	2.08.1.004	Implement	SOPS in good format, sufficient detail	3.0-3.4 in CQAM, AA-759-0006
079	2.08.1.005.00	Implement	following addressed at minimum:	3.4 in CQAM
080	2.08.1.005.01	Implement	........ID of operations needing SOPs	3.4 in CQAM
081	2.08.1.005.02	Implement	........prep process for SOPs- form, content, applicability	3.4 in CQAM
082	2.08.1.005.03	Implement	.... review/approval for SOPs	3.4 in CQAM
083	2.08.1.006	Implement	tech SOPs reviewed/approved by qualified personnel	3.4 in CQAM
084	2.08.1.007	Implement	Impl. to include measurement of performance to tech. Q specs.	3.0-3.4 in CQAM
085	2.08.1.008	Implement	monitor work proc.	3.0-3.4 in CQAM
086	2.08.1.009	Implement	independence of monitor. personnel commensurate with work	3.0-3.4 in CQAM
087	2.09.1.001	Ass/Resp	assess. to be plan/sche/periodically cond.	14.0-14.4 in CQAM
088	2.09.1.002.00	Ass/Resp	four types of assessment:	14.0-14.4 in CQAM
089	2.09.1.002.01	Ass/Resp	........mgt. self-assessment	14.0-14.4 in CQAM, AA-700-0187
090	2.09.1.002.02	Ass/Resp	........mgt. ind.–assessment	14.0-14.4 in CQAM
091	2.09.1.002.03	Ass/Resp	........tech. self-assessment	14.0-14.4 in CQAM; WQP QMP
092	2.09.1.002.04	Ass/Resp	........tech. ind.-assessment	14.0-14.4 in CQAM; WQP QMP
093	2.09.1.003	Ass/Resp	ass. type selected in planning stage of project	14.0-14.4 in CQAM, WQP QMP, Test Plans
094	2.09.1.004	Ass/Resp	must address tech requirement (not just procedural)	14.0-14.4 in CQAM, WQP QMP
095	2.09.1.005	Ass/Resp	ass. performed according to a described process	5.0 and 14.0-14.4 in CQAM, WQP QMP
096	2.09.1.006	Ass/Resp	ass. documented, reported to mgt, reviewed by mgt.	14.0-14.4 in CQAM, WQP QMP
097	2.09.1.007	Ass/Resp	assessors must be qualified	14.0-14.4 in CQAM, WQP QMP
098	2.09.1.008	Ass/Resp	respo. and authority for ass. must be documented/stop work	14.0-14.4 in CQAM, WQP QMP
099	2.09.1.009.00	Ass/Resp	authority must include:	14.0-14.4 in CQAM
100	2.09.1.009.00	Ass/Resp	........ID and document problems	14.0-14.4 in CQAM
101	2.09.1.009.00	Ass/Resp	........ID lessons learned and share them	14.0-14.4 in CQAM
102	2.09.1.009.00	Ass/Resp	........propose recommendations	14.0-14.4 in CQAM

ITEM	E4 REFERENCE NO.	E4 SECTION	SPECIFICATION	NSF REFERENCE DOCUMENT AND SECTION
103	2.09.1.009.00	Ass/Resp	........independently confirm corrective action	14.0-14.4 in CQAM
104	2.09.1.009.00	Ass/Resp	.... document to mgt., monitoring of work where problems	14.0-14.4 in CQAM
105	2.09.1.010	Ass/Resp	resp. to adverse conclusions must be timely	14.0-14.4 in CQAM
106	2.09.1.011	Ass/Resp	condition. needing corrective action ID and responded timely	14.0-14.4 in CQAM
107	2.09.1.012	Ass/Resp	follow-up required to confirm response	14.0-14.4 in CQAM
108	2.10.1.001	Improv.	process to be est. / implemented	14.0-14.4 in CQAM
109	2.10.1.002	Improv.	process to detect and correct problems in all phases	14.0-14.4 in CQAM, AA-700-0188
110	2.10.1.003	Improv.	if big problems, ID cause & effect and root causes	14.0-14.4 in CQAM, AA-700-0188
111	2.10.1.004	Improv.	ID root causes before permanent prev. measures	14.0-14.4 in CQAM, AA-700-0188
112	2.10.1.005	Improv.	plan/doc/imple. appro responses, timely	14.0-14.4 in CQAM, AA-700-0188

Referenced NSF Documents:

CQAM: Corporate Quality Assurance Manual, Issue No. 2 (AF-700-0002)

LQAM: NSF International Laboratories Quality Assurance Manual (AF-840-0001)

WQP QMP: Water Quality Protection Center Quality Management Plan (AA-394-003)

AA-700-0001: Performance Appraisals

AA-700-0008: Procedural Modification Documentation

AA-700-0187: Corporate Quality Assurance Audits

AA-700-0188: Continuous Improvement Report

AA-759-0006: Submittal and Issuance of Controlled Documents

AA-840-0001: Qualifying a Subcontract Laboratory

AF-700-0001: Human Resources Handbook

AF-700-0003: Corporate Training Manual

Water Quality Protection Center Verification Protocols and Test Plans (available at www.epa.gov/etv and www.nsf.org/etv
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E4 - PART B

ITEM	E4 REFERENCE NO.	E4 SECTION	SPECIFICATION	NSF REFERENCE DOCUMENT AND SECTION
113	3.01.1.001	Plan/Scope	all work (involving generation, acquisition, & use of environ. data) planned and documented	AA-394-0002 / Verification Protocols / Test Plans
114	3.01.1.002	Plan/Scope	type & qual. of environ. data, ID and documented using a systematic planning process	ibid.
115	3.01.1.003	Plan/Scope	proj. spec. planning involves key users, customers of data,& tech. staff	AA-394-0001 / AA-394-0002 / Verification Protocols / Test Plans
11 6	3.01.1.004	Plan/Scope	results of planning activities subject to review for conformance to tech. and qual. expectations	ibid.
117	3.01.1.005.00	Plan/Scope	proj. planning coordinated among participating orgs. & include:	AA-394-0001 / AA-394-0002 / AK-394-0001
118	3.01.1.005.01	Plan/Scope	.......definition of proj./task scope & objs. & desired action or result from the work	AA-394-0002

119	3.01.1.005.02	Plan/Scope	........ID of orgs. (e.g., sampling groups & anal. labs) that need to
			       participate in proj. & their role in planning/imp/ass.
			          activities
				AA-394-0001

120	3.01.1.005.03	Plan/Scope	........ID of environ. data required to achieve desired action or result	AA-394-0002
121	3.01.1.005.04.00	Plan/Scope	ID of QA/QC requirements to establish qual. of data collected or produced including:	AA-394-0002 / Verification Protocols / Test Plans
122	3.01.1.005.04.01	Plan/Scope	........data qual. indicator (e.g., precision, bias) goals	ibid.
123	3.01.1.005.04.02	Plan/Scope	........acceptable level of confidence (or statistical uncertainty)	ibid.
124	3.01.1.005.04.03	Plan/Scope	........level of data valid. & verif. needed	ibid.
125	3.01.1.005.05	Plan/Scope	ID of documentation to describe qual. of results	ibid.
126	3.01.1.005.06	Plan/Scope	ID of personnel, their skills & required equipment.	WQP QMP
127	3.01.1.005.07	Plan/Scope	ID of applicable regulatory requirements & other constraints (e.g., time & budget)	AA-394-0002
128	3.01.1.005.08	Plan/Scope	ID of conditions under which suspension of work is necessary	AA-394-0002
129	3.01.1.005.09	Plan/Scope	determination of assessment tools (e.g., prog. tech. reviews, peer reviews, surveillances, readiness reviews, & tech. audits)	AA-394-0002 / Verification Protocols / Test Plans

ITEM	E4 REFERENCE NO.	E4 SECTION	SPECIFICATION	NSF REFERENCE DOCUMENT AND SECTION
130	3.01.1.005.10	Plan/Scope	ID of methods/procedures for storing, retrieving, analyzing, & reporting data produced	AA-394-0002 / Verification Protocols / Test Plans
131	3.01.1.005.11	Plan/Scope	ID of possible methods/procedures (including waste minimization objs) for char. & disp. of cont. sample material accumulated during the proj.	Verification Protocols / Test Plans
132	3.02.1.001	Design Ops	Define, control, verify, & document the design of data collection operation	AA-394-0002
133	3.02.1.002	Design Ops	ID all relevant activities pertaining to environ. data operations, establish performance specs, ID appropriate ctrls	AA-394-0002
134	3.02.1.003.00	Design Ops	design process includes detailed specs for:	
135	3.02.1.003.01	Design Ops	assessments during proj. (e.g., surveillance, audits, performance evaluations).	4 in WQP QMP / AA-394-0002 / Verification Protocols
136	3.02.1.003.02	Design Ops	data reporting requirements.	AA-394-0002 / Verification Protocols
137	3.02.1.003.03	Design Ops	data validation & verification methods	Verification Protocols
138	3.02.1.003.04	Design Ops	integrating cost or schedule constraints into design	AA-394-0002 / Verification Protocols
139	3.02.1.003.05	Design Ops	protection of health & safety of workers & the public	Verification Protocols
140	3.02.1.003.06	Design Ops	readiness reviews prior to data collection	AA-394-0002 / Test Plans
141	3.02.1.003.07	Design Ops	reqs. for calibration & perf. eval. samples for anal. methods	Verification Protocols / Test Plans
142	3.02.1.003.08	Design Ops	requirements for data (and data base) security, archival, & retention	Verification Protocols / Test Plans
143	3.02.1.003.09	Design Ops	requirements for field & lab QA/QC activities	Verification Protocols / Test Plans
144	3.02.1.003.10	Design Ops	requirements & qualifications for sampling & analysis personnel	Verification Protocols / Test Plans
145	3.02.1.003.11	Design Ops	sample handling, packaging, shipping & custody requirements	Verification Protocols / Test Plans
146	3.02.1.003.12	Design Ops	selection of analytical methods & their quality performance expectations	Verification Protocols / Test Plans
147	3.02.1.003.13	Design Ops	selection of analytical facility or lab	AA-394-0003 /Test Plans

ITEM	E4 REFERENCE NO.	E4 SECTION	SPECIFICATION	NSF REFERENCE DOCUMENT AND SECTION
148	3.02.1.003.14	Design Ops	selection of field sampling or testing methodology (specific sampling or field analytical instrumentation & other analytical testing requirements)	Verification Protocols / Test Plans
149	3.02.1.003.15	Design Ops	techniques for assessing limitations on data use	Verification Protocols / Test Plans
150	3.02.1.003.16	Design Ops	disp. or min. proc. for wastes prod. during sampling & analy. operations	Verification Protocols / Test Plans
151	3.02.1.004	Design Ops	ID & control (accord. specs determined during design) key variables that det. or directly affect qual. of results	Verification Protocols
152	3.02.1.005	Design Ops	ensure that data are traceable to the proc. (incl. revisios) used to produce data & to the persons generating or coll. data	AA-394-0002 / Verification Protocols / Test Plans
153	3.02.1.006	Design Ops	deter. & document data transfer, red., verif. , and valid. reqs	AA-394-0002 / Verification Protocols / Test Plans
154	3.02.1.007	Design Ops	deter. & spec. in the design data interpretation and analysis needs, such as the use of specific statist. methods	AA-394-0002 / Verification Protocols / Test Plans
155	3.02.1.008	Design Ops	ID & doc. reports to manag. re: work status, interim work results, & ass. results	AA-394-0002 / Verification Protocols / Test Plans
156	3.02.1.009	Design Ops	ID & state restrictions on using interim results (and data) - defines restriction & the specific data to which it applies	AA-394-0002 / Verification Protocols / Test Plans
157	3.02.1.010	Design Ops	(if the data are stored in magnetic media) Encode restrictions with the data and report in accompanying documentation	AA-394-0002 / Verification Protocols / Test Plans
158	3.02.1.011	Design Ops	document results of the environ. data collection design process in QAPP & other plan docs according to reqs. of QA system & line mgmt	AA-394-0002 / Verification Protocols / Test Plans
159	3.02.1.012	Design Ops	review/approve QAPP &/or other plann documents by designated persons - tech. capable of eval. the proj.	AA-394-0002 / Verification Protocols / Test Plans
160	3.02.1.013	Design Ops	organizations qual. system ID who must review & approve proj.-specific QAPP & explain process for conducting the review	AA-394-0002 / Verification Protocols / Test Plans

ITEM	E4 REFERENCE NO.	E4 SECTION	SPECIFICATION	NSF REFERENCE DOCUMENT AND SECTION
161	3.02.1.014	Design Ops	changes to data collection designs or procedures (including field changes) subject to same review/approval protocols as the original document	AA-394-0002 / Verification Protocols / Test Plans
162	3.03.1.001	Implement	environ. data operations implemented according to approved planning docs - by qual. persons Doc. and report deviations to mgmt.	4.3.2 in WQP QMP / Verification Protocols / Test Plans
163	3.03.1.002	Implement	determine impact & significance of the deviation on planned operations & make adjustments to such operations	4.3.2 in WQP QMP / Verification Protocols / Test Plans
164	3.03.1.003	Implement	make approved changes to planning documents, operating guides & manuals and distribute to proj. personnel	4.3.2 in WQP QMP / Verification Protocols / Test Plans
165	3.03.1.004	Implement	data collected during impl. shall be traceable to plans used & persons collecting data	Verification Protocols /Test Plans
166	3.03.1.005	Implement	use qual. and accepted services/items in environ. data operations. Accept. shall be ID on the items &/or in docs traceable to the items.	Verification Protocols /Test Plans
167	3.03.1.006	Implement	perform inspections/accept. test. of samp. meas., anal. instr. (or other meas. systems) and their components to confirm intended use of items	Verification Protocols / Test Plans
168	3.03.1.007	Implement	when accept. criteria are not met, defic. resolved & re-inspection performed	Verification Protocols / Test Plans
169	3.03.1.008	Implement	ctrl tools, gauges, instruments, & other sampling, measuring, & testing equipment for activites affecting qual. as required & at specified intervals, calibrated to maintain accuracy within specified limits. ID unsuitable equipment	Verification Protocols / Test Plans
170	3.03.1.009	Implement	eval. the valid. of measure./ tests performed with out-of-calibr. equipment - measurements and tests will be repeated	Verification Protocols / Test Plans
171	3.03.1.010	Implement	document basis for the calib. Maintain docs of calibr. - shall be traceable to the equipment	Verification Protocols / Test Plans
172	3.03.1.011	Implement	perform periodic preventive and corrective maint. of meas./test equipment - ensure avail. and satisfactory perf. of the systems	AA-394-0002 / Verification Protocols / Test Plans
173	3.03.1.012	Implement	re-calibrate all equipment subj. to maintenance or repair, before the equipment is used	Verification Protocols / Test Plans

ITEM	E4 REFERENCE NO.	E4 SECTION	SPECIFICATION	NSF REFERENCE DOCUMENT AND SECTION
174	3.03.1.013	Implement	perform hand., stor., cleaning, pack., ship., and pres. of field and lab samples accord. to req. specs, protocols, or proc. to prevent damage, loss, deter., artifacts, or interfer. Track and document sample chain of custody	Verification Protocols / Test Plans
175	3.03.1.014	Implement	perform data or info. mgmt., incl. trans., storage, valid., assess., process., & retrieval, accord. to approved instr., methods, procs.	Verification Protocols / Test Plans
176	3.04.1.001	Ass/Resp	assess activities perf. during environ. data ops. that affect the qual. of the data & the find. reported to mgmt. to ensure that the reqs stated in planni docss (e.g., QAPPs, work & sampling plans) are being implemented	Verification Protocols / Test Plans
177	3.04.1.002	Ass/Resp	take appropriate corr. actions and verify/ document the ass. findings	AA-394-0002 / Verification Protocols / Test Plans
178	3.04.1.003	Ass/Resp	eval. data obtained prev. from a method or instrument found to be nonconforming to specs to determine impact of a nonconform. on qual. of data. Doc. impact and the approp. action taken	Verification Protocols / Test Plans
179	3.05.1.001	Ass/Verif	assess, verify, and qualify data obtained from environ. data operations according to their intended use	Verification Protocols / Test Plans
180	3.05.1.002	Ass/Verif	express limitations on this intended data use (quantitatively) and doc. reporting of the data in print or electronically	AA-394-0002
181	3.05.1.003	Ass/Verif	assess data obtained from sources that did not use a qual. system equiv. to this Standard according to approved/documented proc.	3.5 in WQP QMP
182	3.05.1.004	Ass/Verif	independ. review of proj. reports w/ data, OR report results of environ. data ops to confirm that data/r results are presented correctly.	AA-394-0002
183	3.05.1.005	Ass/Verif	reports shall be approved by mgmt. prior to release, publ., or dist.	AA-394-0002

Referenced NSF Documents:

WQP QMP: Water Quality Protection Center Quality Management Plan (AA-394-003)

AA-394-0001: Procedures for the Formation, Maintenance, and Roles of Stakeholder Advisory Groups and Technology Panels
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AA-394-0002: Verification Protocol, Test Plan, and Verification Report Developmental Procedures
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AK-394-0001: Guidelines for the Conduct of Meetings of the Stakeholder Advisory Groups and Technology Panels
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Appendix A: NSF International SOPs

NSF considers all Controlled Documents, including SOPs, forms or laboratory manuals as Proprietary Business Information. Therefore, NSF will provide EPA any Controlled Documents referenced in this QMP upon request. NSF requests that EPA refrain from sharing these documents with any other party.