

Peconic Program Quality Management Plan for Water Quality Monitoring

Prepared by:

Peconic Estuary Protection Committee, Peconic Estuary Partnership, and
Cornell Cooperative Extension of Suffolk County

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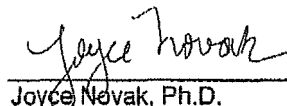


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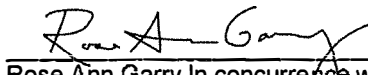
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Attachment. Quality Assurance Project Plan Template

ACRONYMS

ANSI	American National Standards Institute
ASQ	American Society for Quality
ASQC	American Society for Quality Control
CFR	Code of Federal Regulations
DUAR	Data Useability Assessment Report
DCN	document control number
DCS	Document Control Specialist
DQA	data quality assessment
DQI	data quality indicator
DQO	data quality objective
FAR	Federal Acquisition Regulations
NYSDEC	New York State Department of Environmental Conservation
NYSDOH	New York State Department of Health
OSHA	Occupational Safety and Health Administration
PDF	portable document format
PEPC	Peconic Estuary Protection Committee
PWS	performance work statement
QA	quality assurance
QAPP	Quality Assurance Project Plan
QC	quality control
QMP	Quality Management Plan
RFP	request for proposal
SAP	Sampling and Analysis Plan
SOP	standard operating procedure
SOW	statement of work
USEPA	U.S. Environmental Protection Agency

Plan Coverage

This *Peconic Program Quality Management Plan* (QMP) applies to products and services supported by the Peconic Estuary Protection Committee (PEPC), including its members and collaborators; the Peconic Estuary Partnership; and Cornell Cooperative Extension of Suffolk County.

The Peconic Estuary Protection Committee is an intermunicipal affiliation dedicated to restoring and improving water quality in the Peconic Estuary. The members of the Committee as of January 2021 are Suffolk County, Town of Brookhaven, Town of Riverhead, Town of Southold, Town of Shelter Island, Village of Greenport, Village of North Haven, Village of Sag Harbor and the NYS Department of Transportation.

The Peconic Estuary Partnership (PEP) is a ~~Suffolk County Program~~ that acts as a backbone organization, bringing together partners from different sectors around common goals. PEP staff and our partners support monitoring, research, collaboration and education to address priority issues within the Peconic Estuary Watershed.

These entities, Peconic Estuary Protection Committee, Peconic Estuary Partnership together with Cornell Cooperation Extension of Suffolk County, will be herein referred to collectively as the “Peconic Program” in this document.

This QMP provides the basic quality assurance (QA) and quality control (QC) procedures and activities that will be implemented to ensure the quality of products and services provided by Peconic Program.

Work performed by the Peconic Program members might include the following tasks:

- Developing program and project planning (work plans, quality assurance project plans, standard operating procedures), and implementing plans
- Performing field investigations and laboratory analyses
- Preparing assessments, technical reports, studies, methodologies, and other products
- Evaluating assessments, studies, methodologies, policies, and other reports or materials
- Collecting, compiling, generating, and managing data; conducting assessments and analyses; and preparing technical information and information reports based on those data

The Peconic Program will perform these activities in accordance with U.S. Environmental Protection Agency’s (USEPA’s) quality requirements to ensure that the data collected by the Peconic Program are scientifically valid, defensible, and of known quality. Peconic Program members also may receive funding from USEPA through financial assistance agreements or interagency agreements; the Peconic Program will comply with this QMP and other quality planning documents (e.g., quality assurance project plans [QAPPs]), as required by those agreements.

Introduction

The objective of this QMP is to ensure that all data and documents generated under a project are scientifically valid, defensible, and of known and adequate precision and accuracy. Products and services provided by contractors and consultants to Peconic Program will also be monitored to ensure that they meet all applicable project standards and requirements.

This QMP has been prepared according to guidance contained in EPA QA/R-2, *Requirements for Quality Management Plans* (EPA/240/B-01/002; U.S. Environmental Protection Agency, Office of Environmental Information, Washington, D.C., March 2001 [Reissued May 2006]), which is based on the ANSI/ASQ standard.

This QMP addresses the application of quality assurance (QA) and quality control (QC) procedures to all aspects of products and services provided by Peconic Program that are not otherwise covered by a project-specific QAPP. The QMP addresses Peconic Program's QA policy; the QA program organization; the authority and responsibilities of staff; and QA and QC policies, procedures, and tools used to maintain the highest standards of quality in all work products and to assess the adequacy of the quality system. The QMP is divided into the following sections based on EPA QA/R-2. Note that Section 9.0 (Assessment and Response) addresses the evaluation of the deliverables prepared by the Peconic Program.

- 1.0 Management and Organization
- 2.0 Quality System Components
- 3.0 Personnel Qualifications and Training
- 4.0 Procurement of Items and Services
- 5.0 Documents and Records
- 6.0 Computer Hardware and Software
- 7.0 Planning
- 8.0 Implementation of Work Process
- 9.0 Assessment and Response
- 10.0 Quality Improvement

The QMP is a tool that documents the Peconic Program's QA system for planning, implementing, documenting, and assessing the effectiveness of activities supporting environmental data operations and other environmental programs. The team members listed above will implement this QMP to ensure that the products developed and services performed by the Peconic Program meet USEPA's quality requirements.

1.0 Management and Organization

This section of the QMP describes the management and organization of the QA program that Peconic Program will implement under the QMP for environmental and water quality monitoring projects. Section 1.1 discusses Peconic Program's QA policy statement in more detail. Section 1.2 describes the QA organizational management structure. Section 1.3 describes the roles and responsibilities of each member of the QA team and Section 1.4 discusses dispute resolution for quality system policies, procedures, or requirements.

1.1 Quality Assurance Policy Statement

The Peconic Program QMP for Water Quality Monitoring's mission is to establish the framework for QAPPs that the Peconic Program can utilize to develop water quality and sediment monitoring programs that will guide scientifically valid, defensible, and of known quality data collection. The data collected under the QMP and QAPPs is intended to be used to accurately identify and prioritize subwatersheds in the Peconic Estuary that should be targeted for water quality improvement activities, and help the PEPC members and partners assess the current baseline in water quality, and effectiveness of water quality improvement interventions over time.

Consistent with the goals of the QA policies of the USEPA and the NYSDEC, the goal of the Peconic Program QA program is to ensure that all environmental data obtained from environmental monitoring projects are scientifically valid, defensible, and of known quality. This goal can be achieved by (1) ensuring that planning for QA and allocation of adequate resources are part of the initial planning for data collection or analysis efforts and (2) incorporating specified QA procedures into the entire process (from initial study planning through data use). Therefore, the Peconic Program QA policy includes the following objectives:

- Develop, incorporate into each work plan, and implement an acceptable and cost-effective program of QA and QC activities at the onset of each project effort involving data collection and deliverable preparation to ensure the adequacy of the technical product specified by the project.
- Ensure that technical work products generated for each project are complete, accurate, and delivered on time and that the work products are focused, are suitable for the intended purpose, and meet the standards of quality required for the results of the project, as well as professional standards established by technical and scientific disciplines.
- Ensure that any analytical data generated in the course of a project are of a quality and quantity sufficient to support defensible scientific conclusions; that data, when appropriate, will support sound statistical analyses; that generated data can, if necessary, withstand the rigors of legal scrutiny and can effectively support administrative and judicial proceedings; and that quality work products are delivered.
- Ensure that reports, graphical summaries, and other presentation materials accurately and clearly communicate our work.
- Identify deficiencies, coordinate expeditious resolutions, and revise QA/QC procedures in a timely and systematic manner, as needed.
- Use the results of QA/QC reviews to identify and implement quality improvement for future work products.

Peconic Program recognizes that technical problems might occur at any point during the planning, execution, review, and reporting phases of a project. Potential problems can often be avoided or minimized by carefully planning and scheduling the work; assigning the most qualified and appropriate staff; and, most important, clearly communicating objectives and monitoring the progress of the required effort.

1.2 Quality Assurance Staff Organization

All personnel share responsibility for producing quality products. This section describes the lines of authority and communication established among those staff members. The next section describes the responsibilities mentioned here in more detail.

Exhibit 1 shows the organization for the QA program and project management for Peconic Program. As shown in Exhibit 1, the Peconic Program's QA program is independent from project management and from the functional groups that produce deliverables and generate measurement data.

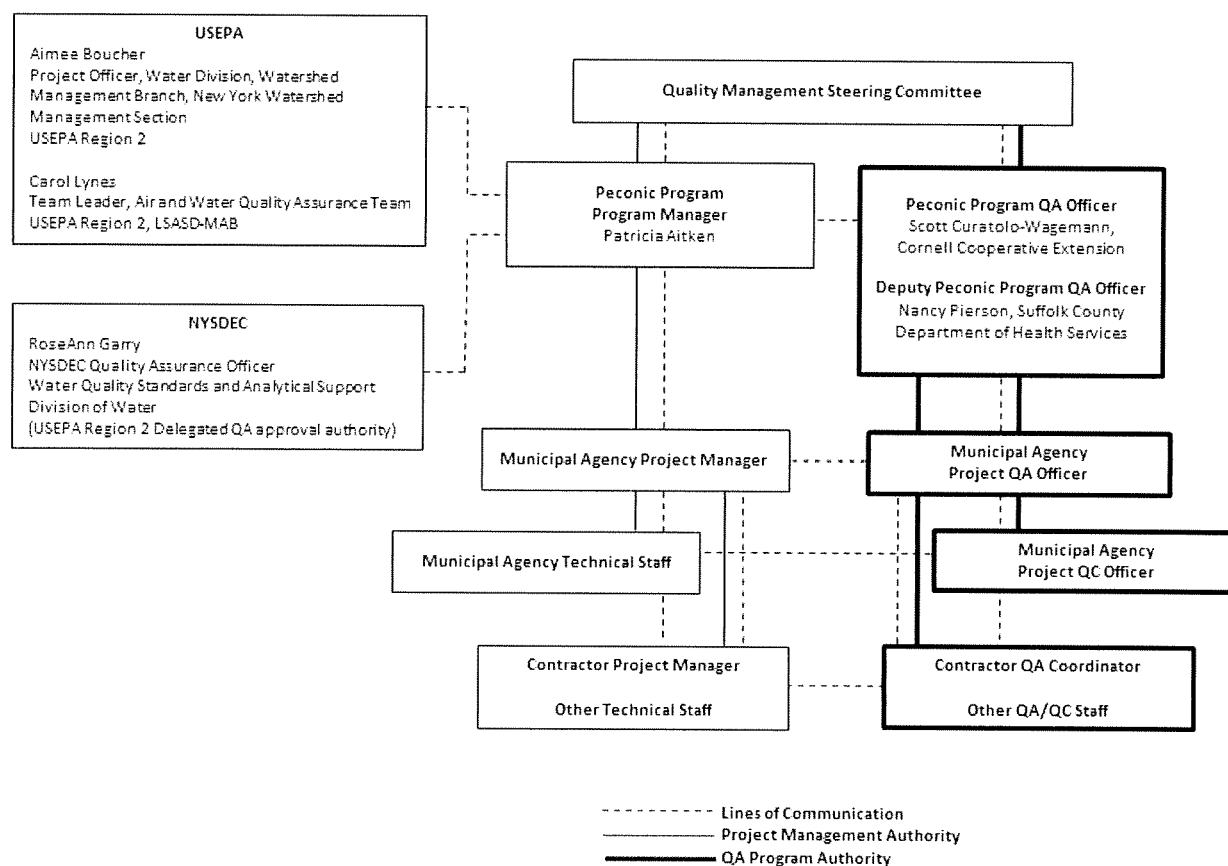


Exhibit 1. Peconic Program Staff Organization

1.3 Quality Assurance Staff Responsibilities

Each Peconic Program employee is responsible for planning the work that is done, documenting the work, and ensuring the quality of work completed meets or exceeds the quality objectives for the activity. This section describes specific responsibilities of the key QA and management personnel. In addition to the roles defined below, the role of senior personnel in the QA program is to share their experience and provide quality review of project deliverables, as appropriate.

A Quality Management Steering Committee will conduct an annual review of the activities conducted under the QMP. The Steering Committee will consist of members of the Peconic Program. A representative from another of the Protection Committees, such as the Hempstead Harbor Protection Committee or Oyster Bay/Cold Spring Harbor Protection Committee, and a municipal official from a municipality who is not a member of the Peconic Program will be invited to participate on the Steering Committee.

When the Peconic Program receives grant funds from New York State Department of Environmental Conservation (NYSDEC), the Peconic Program QA Officer provides all QA documentation and reports to the NYSDEC's QA Officer. When the Peconic Program receives grant funds from the U.S. Environmental Protection Agency (USEPA), the Peconic Program QA Officer provides all QA documentation and reports to the USEPA Project Officer, with a copy provided to the USEPA's QA Officer. The Peconic Program must adhere to the prime organization's specified QA program.

When project funds are directed by USEPA or NYSDEC, the corresponding QA official will provide QA oversight of the project. When requested by USEPA or NYSDEC in a grant, the Peconic Program or municipality overseen by the Peconic Program will develop a project-specific quality assurance project plan (QAPP) (refer to Sections 2.5 and 7.3 of this QMP for additional details). The **USEPA Air and Water Quality Assurance Team Leader** or the **NYSDEC QA Officer** will review and approve the corresponding QAPP before the work begins, as described further in this Section of the QMP.

The **Peconic Program Manager** (Patricia Aitken) and the **Peconic Program QA Officer** (Scott Curatolo-Wagemann), will be responsible for ensuring that the QA program is implemented by the Peconic Program staff. If a **Deputy QA Officer** (Nancy Pierson) is required, the Deputy QA Officer will assume responsibility for ensuring that the QA program is implemented by the Peconic Program staff. Both the Peconic Program Manager and the Peconic Program QA Officer and Deputy QA Officer report directly to the Peconic Program Steering Committee. The Peconic Program Manager and Peconic Program QA Officer will review and approve QAPPs required to be prepared by the Peconic Program to meet USEPA or NYSDEC grant requirements. The Peconic Program Manager and Peconic Program QA Officer will also review and approve QAPPs required to be prepared by municipalities overseen by the Peconic Program. QAPPs must be reviewed and approved before the corresponding work begins.

The **Project Manager** directs the day-to-day operations of a project and is responsible for implementing quality procedures and producing all project deliverables. **QC Officers** are independent from the professionals who are conducting the technical work for the Peconic Program. When projects require **contractors**, each contractor that provides products or services for a project agrees to abide by the terms and conditions of its project agreement when performing work for Peconic Program. Descriptions of the Peconic Program Manager, QA Officer, Project Manager, QC Officers, and contractor QA Coordinators are provided below.

The Peconic **Program Manager's** responsibilities include the following:

- Review and approve the QMP.

- Ensure that municipalities, agencies and contractors assign qualified personnel and equipment to each project to ensure that the quality objectives addressed in the work plan are attained.
- Work with the appropriate organizational managers to determine compliance with procurement regulations.
- Review work plans.
- Provide senior-level direction and review of project deliverables, as needed.
- Assist the QA Officer in resolving issues that cannot be handled by Project Managers and in resolving issues with contractors, if necessary.
- Participate in annual management system reviews, identifying specific weaknesses or areas for improvement, as appropriate.
- Monitor compliance with orders and recommendations to Project Managers regarding corrective action and project-specific quality improvement opportunities.
- Ensure agency satisfaction on all projects by maintaining regular contact with the agency and resolving any agency concerns.
- Allocate resources and provides management support for project-specific quality management system implementation and training.

The Peconic Program **QA Officer** serves as a resource for information on all QA matters pertaining to the design and implementation of the quality systems for projects. The QA Officer is responsible for ensuring that the QA program is implemented by the Peconic Program and provides direction and guidance to the QA/QC staff and contractor QA Coordinators. The QA Officer is organizationally independent from groups generating, compiling, and evaluating the environmental data. A Deputy QA Officer can also be appointed as needed and is responsible for overseeing the quality of work performed by the QA Officer when the QA Officer manages a project. The QA Officer's responsibilities include the following:

- Oversee that QA plans are followed or updated to reflect current direction.
- Compile and maintain a QA reference library.
- Serve as QA Officer on environmental and water quality monitoring grants and projects.
- Act as the official point of contact for all QA matters and coordinate with USEPA, NYSDEC and other state and federal agencies.
- As needed, communicate with QA Coordinators (with appropriate notification of Peconic Program and contractor management) to ensure that contractor QC activities and QA procedures are consistent with contract or project requirements.
- For any contractor that does not have dedicated QA staff or independence of the QA function (whether on the overall organizational level or on a project- or task-specific basis), provide QA oversight for the specific tasks and projects to which the partner is assigned from within the team.

- The QA Officer will work with technical staff to define specific QC activities associated with project tasks, develop project-specific quality planning documents, and develop or adapt documentation systems to be used to monitor QC activities and the reporting mechanism to support the feedback loop for interim and final reviews of work products from inception to delivery.
- Conduct training programs and seminars for project staff on pertinent QA/QC matters.
- Serve as management staff advisor to the Peconic Program and partner leadership teams.
- Review and approve all QAPPs and QA related sections of procurement packages.
- Implement QA policy and guidelines for project activities.
- Ensure that all Project Managers are informed about the QMP and the quality system under which their projects will operate.
- Direct and oversee the project QA program to ensure the quality of all data and reports generated under the project, which includes helping Project Managers identify appropriate technical and editorial reviewers or other specialists who might be required.
- Review and approve project-specific QAPPs and standard operating procedures (SOPs) (see sections 2.2.5 and 2.2.6).
- Provide technical direction on QA procedures to staff and contractors.
- Audit project activities, including QA reviews, documentation procedures, and technical operations, as required.
- Conduct or assist in annual QMP review and assessments and management system reviews.
- Report nonconformance situations to the Program Manager and, as appropriate and with notification of Peconic Program contractor management, to contractor QA Coordinators.
- Initiate, review, and verify compliance with orders and recommendations to the appropriate project management staff (e.g., Program Manager, Project Managers, and contractor QA Coordinators) on corrective actions for all aspects of work that do not meet project standards.
- Communicate regularly with QA/QC staff, overseeing their QA assignments and compiling quality improvement opportunities for review with the Program Manager; communicate quality improvement opportunities to contractor QA Coordinators by appropriate notification of Peconic Program management; and assist all project staff in implementing such improvements to benefit the overall QA program.
- Communicate with external QA official(s) to resolve any problems.

The **Project Manager** is responsible for implementing quality procedures and producing all project deliverables. (Contractor Project Managers have similar roles and responsibilities within their organizations, and they interact with the Project Manager to address the planned tasks.) The Project Manager's responsibilities include the following:

- Prepare and execute the work plan and QAPP (if required). Ensure that funding for QA activities is included in the work plan and that the project is completed in conformance with all QA requirements of the QMP and QAPP.
- Keep informed of any changes made in any NYS DOH Environmental Laboratory Accreditation Program (ELAP) accreditations or certifications.
- Assign staff and contractors to tasks.
- Provide or facilitate project-specific training relative to procedures or address specific project goals and objectives, as required.
- Monitor the budget and project schedule.
- Verify that document control procedures specified for the project are followed and maintain pertinent documentation for the project; assign a Document Control Specialist (DCS), if needed, to compile and organize large quantities of materials so that they are accessible to staff and submitted to the agency when required.
- Ensure that QC activities (e.g., technical reviews, proofreading and technical editing, QC checks of field operations and analyses) are conducted as specified for the project.
- Ensure that all suggested quality improvements (e.g., comments, corrections, revisions, deletions, additions) are incorporated into the deliverables.
- Ensure that products have received appropriate QA review (data validation, software operational review, final evaluation) as specified in the work plan before they are delivered to the end agency.
- Approve all data and documentation before transmittal to the end agency.
- Discuss any concerns about deliverable quality with the end agency and work with the QA Officer to resolve problems.
- Work with the Program Manager and QA Officer (or Contractor Program Manager and Contractor QA Coordinator in the case of a Contractor Project Manager) to identify and implement quality improvements.
- Identify specific repetitive procedures for which SOPs might be appropriate.

QC Officers are appointed, as needed, for projects involving field sampling, laboratory analysis¹, and data processing. The QC Officer works closely with the person responsible for doing the work as it is completed. The QC Officer has sufficient technical background to

¹ Although a local municipality QC Officer would not be able to directly check the work being performed in a laboratory, he or she would be able to check whether laboratory results indicate that project data quality objectives for precision, accuracy, representativeness, completeness and comparability are met. Laboratory data quality objectives would be specified in the QAPP.

understand the tasks to be done as described in the QAPP and SOPs and to reliably perform the checks required. The QC Officer's responsibilities include the following:

- Provide oversight and ensure that work is conducted according to plan and completed; that measurements are taken properly; and that samples are analyzed, data are entered, and calculations are performed correctly.
- Conduct or oversee, and document procedural reviews incorporated into work plans and processes. Procedural reviews might consist of demonstrations of equipment use, training in a specific technique, or introduction to new or modified procedures. Procedural reviews might also be conducted by witnessing a team or teams in the process of conducting specific project operations and discussing any apparent or perceived departures from documented procedures.
- Provide written and signed documentation that the work or information has been checked, as directed by the QA Officer (e.g., prepare short reports, complete checklists, sign logs, initial calculations).
- Oversee the data logging activities of field personnel.
- Conduct laboratory audits and field operations audits.
- Monitoring corrective action implementation within the laboratory and in the field.

The responsibilities of the **USEPA Region 2 Project Officer** (Aimee Boucher) and **Air and Water Quality Assurance Team Leader** (Carol Lynes) include reviewing and approving this QMP. In addition, they will participate in quality reviews of relevant QAPPs developed for projects for which the Peconic Program receives USEPA grant funds.

NYSDEC DOW has USEPA Region 2 QA approval authority. The responsibilities of the **NYSDEC Water Quality Standards and Analytical Support Division of Water Quality Assurance Officer** (RoseAnn Garry) include courtesy review of this QMP. She also will provide ongoing support and technical advice to the Peconic Program. In addition, she will participate in quality review and approval of relevant QAPPs developed for projects for which the Peconic Program receives NYSDEC grant funds.

The QMP has been designed so that it can be tailored to all Peconic Program projects and clients, including USEPA, other federal programs, states, and municipalities. Not all aspects of the QMP are appropriate for certain projects, but some aspects, particularly the quality policy and standards, are applicable to all. The client and/or specific requirements of the project or program will usually determine the required QA and QC levels, including for secondary data and work performed by other organizations that fall under the quality management of the Peconic Program Manager and QA Officer. Absent specific quality guidance, the QA Officer will determine the required project-specific quality program.

The QMP is also designed to incorporate our contractors. The Peconic Program will require that all work conducted by our contractors is conducted in compliance with our QMP and appropriate QAPPs.

When projects require **contractors**, each contractor that provides products or services for a project agrees to abide by the terms and conditions of its project agreement when performing work for Peconic Program. Statements of work (SOWs) are prepared and attached to each project agreement describing the minimum standards of performance for compliance with municipality or agency requirements or this QMP, or the standards of quality for the specific discipline being outsourced. When appropriate, the contractor appoints a QA Coordinator, who is responsible for all QA/QC requirements of each project for which the contractor's services are required. The QA Coordinator reports directly to the Peconic Program QA Officer and must adhere to the specified QA program to ensure that rigorous QA/QC standards are met.

The QA Coordinator's responsibilities include the following:

- Provide the QA Officer with contractor-specific QA policies and procedures or a written QMP when requested.
- Review the team agreement and ensure that all project personnel are following all QA/QC requirements and applying other sound engineering and scientific practices.
- Prepare QAPPs for projects on which the contractor has primary responsibility for sampling, analysis, measurement, or data collection efforts.
- Review and approve QAPPs for projects on which the contractor has secondary responsibility for sampling, analysis, measurement, or data collection efforts.
- Verify that all data collection activities are covered by approved QAPPs.
- Ensure that all routinely used sampling and analysis procedures are described in approved SOPs.
- Ensure that no deviations from approved QAPPs, SOPs, or other relevant project documents occur without proper authorization and documentation.
- Observe control procedures for quality-related documents, as indicated.
- Conduct audits of work performed by the contractor.
- Assist management in solving QA problems, as needed, and ensure that any corrective action resulting from a performance or system audit conducted under the project or any quality improvement communicated by the Peconic Program Project Manager to contractor management is carried out and documented.

The Peconic Program recognizes the importance of ensuring the quality of its work products and has developed and implemented QA/QC policies and controls for all its work. Implementing QA/QC procedures is necessary to ensure that all work completed is of the highest caliber, and that all data collected and analyzed are verifiable, reproducible, and reliable. The Peconic Program is committed to ensuring that all members of its team, including its contractors, meet the highest standards in designing and implementing their QC procedures.

The Peconic Program Quality Management Steering Committee will annually assess and document the adequacy and effectiveness of the quality system. As appropriate, assessments of internal organizations, contractors, technical programs, and specific projects might be conducted.

Those assessments could be conducted by internal staff, under the direction of the QA Officer, or by independent outside reviewers. Both types of assessments should determine the effectiveness of management controls that are in place and the adequacy of resources to ensure quality. Criteria for performing audits are described in Section 9.

The Peconic Program QA Officer and assigned QC staff will be independent from the Project Managers and individuals generating, compiling, and evaluating environmental data, and will review all final documents and products, including technical reports and data analyses, before their submission to USEPA. Additionally, they are instructed to access the appropriate level of Peconic Program management, when and if necessary, to ensure the integrity of the quality program. The division of QA responsibility allows the Peconic Program to focus the most appropriately trained and experienced personnel on tasks of different emphasis, thereby attaining a higher degree of QA while also providing a greater degree of flexibility of work force than would be available when dedicating all QA responsibility to one employee.

1.4 Communication and Dispute Resolution

Critical to any quality system's implementation is promoting and retaining a work environment conducive to open and frank communication among members of the quality and technical staff. To that end, QC and QA responsibilities and authority are distributed throughout the various functional contribution teams composed of project technical staff and with the quality team. When disputes regarding quality system policies, procedures, or requirements arise that are not readily resolved at the lowest management level possible (closest to the issue), senior-level staff will be notified to ensure objectivity and to preserve the independence of the quality management organization in the resolution of those issues. For example, in the unlikely event that a dispute were to arise (e.g., with regard to handling of specific information or data, with the documentation of specific field observations between the task or field QC Officer and the project technical or sampling staff), and that dispute remained unresolved following consultation with the appropriate task or field supervisor, the Project Manager or contractor Project Manager is responsible for resolving the use of that information with the assistance of the QC Officer or QA Coordinator, respectively. This approach incorporates the project management hierarchy at the level closest to the issue, ensuring that the needs of the project team are included in the consideration of the satisfaction and compliance with quality policy or requirements. In this regard, escalation of disputes to the Program Manager are minimized, as is the potential for issuing stop work orders in dispute resolution. Final authority to resolve disputes involving Peconic Program quality system issues lies with the Peconic Program's Program Manager with the assistance of the QA Officer. Note that dispute resolution entails engagement of the Assessment and Response processes described in section 9.0 of the QMP, specifically the corrective action process detailed in section 9.3. Responses to disputes are based on the corrective action investigation and findings, as well as remedy options. Escalation level and recurrence rate dictate whether significant corrective actions should include modifying policies described in this QMP, specific procedures or work practices (SOPs), or project-specific quality guidance (QAPPs).

2.0 Quality System Components

A quality system is a management system that specifies the level of quality to be achieved; the responsibilities of personnel; the required demonstration of analytical laboratory competency

(i.e., ELAP laboratory certification is required for parameters for which ELAP certification is offered); and the procedures, activities, and tools needed to plan, implement, and assess the quality of products prepared and services provided by an organization to ensure that this level of quality is attained. The multi-tiered quality system includes:

1. the organization-wide QMP, which supports
2. QAPPs that describe the applicability of the quality system to specific activities and projects,
3. SOPs and other QC tools, such as review checklists.

The Peconic Program QA Officer is responsible for designing the Peconic Program quality system, preparing the QMP that explains that system, and updating the QMP when reviews of the system indicate that changes are necessary. The Project QA Officer(s) is responsible for designing the quality system for work performed for projects under the Peconic Program in accordance with the Peconic Program's quality system and assisting with monitoring QC activities to determine conformance with quality system requirements. Although the QMP is valid for five years, the Peconic Program QA Officer and Program Manager perform annual reviews to ensure its effectiveness and that it is representative of current practice.

Laboratories used to analyze samples collected under a project will be NYS DOH ELAP-certified, as specified in Article 5, Title 1 of the New York State Public Health Law § 502. If the project is collecting samples for which there is no ELAP certification, quality of analysis will be demonstrated through the QA/QC and audit process.

The Peconic Program's quality system follows the basic quality paradigm, the *plan-do-check-act* cycle. It encompasses the concept of continuous improvement. Because of the diversity of projects undertaken, the types of work performed, and the deliverables submitted to an agency, the procedures and practices used to ensure that Peconic Program's products and services meet or exceed project quality specifications must be flexible to meet different needs (referred to as the *graded approach* [USEPA 2018]).

The Peconic Program's QAPP will address the tasks to be completed for the project and the proposed technical approach, the deliverables to be prepared, and project-specific QA/QC procedures to be executed during the work. Additional planning documents, such as a standard operating procedures (SOPs) or other documents that discuss quality requirements and procedures, may also be completed and submitted to the agency for review and approval before work begins on the project so that all parties have a clear understanding of the project goals, the deliverables and schedule for their submission, and the established quality standards that must be met.

Senior-level personnel are responsible for assigning staff to projects, reviewing plans, and overseeing the work as it is performed. As needed, the QA Officer provides training in the QA responsibilities and requirements for the project to all staff. The Project Manager provides supervision and guidance to staff during the execution of the plan(s). Periodic assessments or audits (e.g., assessments of data quality, technical and editorial reviews of draft and final deliverables, surveillance, technical assessments, and technical systems audits) are conducted by senior-level staff and documented in writing to ensure that project requirements are attained.

Corrective actions, based on assessment or audit results, will be implemented for continuous quality improvement responsive to the needs of the project throughout the term of the project. The quality system is formally reviewed annually through a management system review to determine whether changes are needed to improve the processes guiding the preparation and assessment of work products or services. During development of formal responses, the QMP is reviewed for applicability and relevance to the current scope and discussed or attached as evidence of the quality system. These responses reflect a review of the QMP and its representativeness of current work practices and quality system implementation procedures.

The following sections discuss the basic quality tools that will use to implement the quality system (plan-do-check-act). Other sections in this QMP discuss the tools in greater detail.

2.1 Quality Management Plan

The QMP describes the overall QA policies and procedures that Peconic Program will follow in conducting work for projects. Following approval by the QA Officers, this QMP will be distributed to Peconic Program staff working on projects. While this QMP is valid for five years, QA staff and Program Managers will perform annual reviews to assess its effectiveness and ensure that it is representative of current practice. If revisions are not substantive, additional detail in annual reauthorization or revision might not be required.

The Peconic Program will notify EPA Region 2 of any changes in its QA personnel on an annual basis through email. The QMP will not be revised simply to reflect changes in QA personnel, but it could be revised as a result of any of the following circumstances:

- Changes suggested following management system reviews
- Changes in the procedures as a result of the implementation of corrective actions
- Feedback received from a municipality or agency regarding the quality of any aspect of performance
- Major changes in mission and responsibilities, such as changes in the delegation status of a program
- Reorganization of existing functions that affect programs covered by the QMP

The Program Manager will solicit agency feedback regarding responsiveness, presentation of deliverables, and general level of satisfaction with the Peconic Program's performance. Peconic Program will respond to this feedback by implementing quality improvements and incorporating changes, as necessary, into the QMP. The Peconic Program envisions this QMP as a *living* document that will be continually improved to ensure high-quality performance (section 10.0).

2.2 Training and Certificates

Refresher training can be conducted if significant revision to the QMP occurs in response to deficiencies observed in surveillance or at the request of an employee's supervisor to ensure a comprehensive understanding of the quality system's requirements. The QA Officer provides periodic informal reminders about key aspects of program implementation, and formal notifications of changes to the quality system when the QMP is revised either through regular

review, or as a product of a corrective action or other continuous quality improvement process. Peconic Program also ensures that staff members are kept up-to-date with the latest developments in their professional fields to provide USEPA with the most relevant expertise for each project. Section 3.0 provides more information on training.

2.3 Work Plan

The Project Manager writes a work plan in response for each project received to clarify the objective(s), task(s), schedule, staffing requirements, and budget and to inform the project technical staff and the municipality or agency. The work plan also addresses administrative procedures; format and content of the deliverable(s); resources and contacts; and, if contractors are involved, their roles and responsibilities. The work plan incorporates QA/QC procedures for preparing deliverables based on the QMP (for example, technical and editorial reviews) or as specified in the task order. Section 7.1 presents additional information regarding the work plan.

2.4 The Data Quality Objectives (Technical Planning) Process

For those projects that require the collection and analysis of monitoring data or data generation, an important part of the QA effort is the establishment of Data Quality Objectives (DQOs). DQOs are specific, integrated statements and goals developed for each data or information collection activity to ensure that the data, once collected, are of the required type, quality, and quantity and meet the intended uses for a project, and they should be developed for all environmental data operations. Section 7.2 discusses DQOs in more detail. They are incorporated into the project-specific QAPP or equivalent documentation. The DQOs can apply to primary data (measurements or analyses of monitoring samples or other data) to be collected for a specific purpose or application to a decision to be made or to secondary data (existing environmental data that were collected by the municipality or agency or other organizations for other purposes).

Quality requirements, including performance criteria for newly collected or generated data or acceptance criteria for existing data from other sources—such as the data quality indicators (DQIs) accuracy, bias, precision, representativeness, completeness, and comparability—must be appropriate for the intended use of the data.

2.5 Quality Assurance Project Plan or Equivalent Documentation

A QAPP is a document that describes specific procedures and responsibilities needed to meet the data collection or generation goals of the project (see also section 7.3). When requested by an agency in a grant, the Peconic Program will develop a project-specific QAPP and submit it to the agency's representative for approval before the work begins. The Peconic Program will review and approve QAPPs required to be prepared by municipalities overseen by the Peconic Program (refer to the QAPP template in the Attachment to this QMP).

The QAPP is developed and implemented to ensure that data collected, and analytical data generated are complete, accurate, and suitable for the intended purpose and to ensure that data meets the project specific data quality objectives. In some cases, the Peconic Program might prepare other kinds of documents that serve some of the same goals as a QAPP and require submission to the agency for approval before work proceeds. As QAPPs are highly project- and

task-specific, they are routinely developed to cover the period of performance for a specific project and are only subject to review or revision based on developments in project conditions, additional technical directives from the agency, or significant revisions to work practices. However, QAPPs are routinely reviewed at the change in project option period (generally on an annual basis), or when specific technical directives or amendments are received which may alter QA, QC, or documentation requirements. For other projects, a generic QAPP might be prepared for an entire data collection effort; then the Peconic Program would prepare site-specific sampling and analysis plans (SAPs) to describe specific samples to be collected, sampling procedures, shipping requirements, and analyses to be conducted at multiple sites. Any revisions to QAPPs or QAPP-equivalent documentation are distributed to the signatory personnel and those identified in project distribution lists. These representatives are expected to ensure that all persons engaged in the project receive access to, or copies of, revised plans.

Municipalities or entities engaged in sample collection activities recognize that these activities may present the need for a health and safety plan. These activities should be conducted in accordance with the municipality's or entity's health and safety plans that have been developed by the municipality or entity. Development of such plans will not be the responsibility of the Peconic Program.

2.6 Standard Operating Procedure

An SOP is a document that explains how activities must be conducted; for example, field or laboratory data collection operations, operating and maintaining equipment, calibrating instruments, analyzing environmental samples, analyzing data, tracking samples, record keeping, and other activities. For program-wide activities (e.g., statistical analyses, data management), a technical staff member with expertise in the corresponding subject matter develops the SOPs for review and approval by the Program Manager and QA Officer. For project-specific activities, the Project Manager will develop the project-specific procedure for agency review and approval. SOPs and project-specific procedures describe the step-by-step procedure for the activity so that it can be repeated consistently over time, thus minimizing problems. SOPs and project-specific procedures are referenced in the QAPP or equivalent documentation, as necessary. The Peconic Program updates or develops new SOPs or project-specific procedures, as needed (See also section 7.4.).

2.7 Technical Review

A technical review is a documented critical review of a work product that is performed by a technically qualified reviewer who did not participate in producing the work. A technical reviewer will have expertise in the subject matter areas that they review. For example, a technical reviewer evaluating field measurement data will have had prior experience in collecting these types of field measurements. The technical reviewer will also have knowledge of the quality system for the Peconic Program.

The Project Manager selects qualified technical personnel to conduct technical verification, validation, or confirmation of the information or results presented in the work product. Data assessments may be conducted to verify and validate the data and to determine whether the data obtained from environmental data operations are of the right type, quality, and quantity to

support the intended use of the data, as specified during the planning phase using the DQO process. Deliverables produced by contractors receive comparable levels of review by the Project Manager or authorized designee. Section 9.2 describes the task review process.

2.8 Final Review

Significant deliverables (those that will be published or distributed widely by the agency) are released after review by the Program Manager or authorized designees.

2.9 Audit

An audit is an evaluation of a process's implementation in relation to the planning of that process. It is conducted to identify and document problems affecting quality and to propose recommendations for quality improvements, as needed (see for example, EPA QA/G-7, *Guidance on Technical Audits and Related Assessments for Environmental Data Operations* [EPA/600/R-99/080; USEPA 2000b]). An audit can be a self-assessment (performed by someone in the offices) or an independent assessment (performed by someone outside the offices). The Peconic Program uses a variety of audits to evaluate work processes and products, as described further below.

A field or laboratory audit would be referred to as a system audit when evaluating the operations involved in a data collection activity and related results to confirm that it is occurring as specified in the QAPP. A technical system audit is a thorough evaluation of a system, including facilities, equipment, personnel, procedures, record keeping, training, data management, and reporting. A management system review or quality system audit is an assessment of an organization's quality system to evaluate whether the prevailing quality management structure, policies, practices, and procedures, as described in the QMP, are adequate for ensuring that the type and quality of data or other work products needed are obtained and that the quality system is operating as designed. Management system reviews are performed annually through informal interviews with Program Manager and Project Manager staff to ascertain how the system is supporting their programs and projects effectively and where the system could be refined or enhanced to better support operations while retaining the requisite standards of performance and quality.

The Peconic Program will use a graded approach to guide planning decisions to ensure the efficient and effective use of resources for activities for which audits are needed most (USEPA 2000b). The level of risk associated with an activity should be taken into consideration when determining whether an audit should be performed and for determining the frequency of audits. For long-term monitoring projects designed to provide information about the waterbody being studied, at least one audit should be performed every 5 years. For shorter-term activities related to collecting monitoring data that could be used to make decisions regarding human health (e.g., opening or closure of shellfish beds), one audit should be scheduled early (i.e., before half of the samples have been collected) in the project to ensure timely implementation of any needed changes in procedures based on the results of the audit. In addition, it is likely that a laboratory audit would be required when a new laboratory performs analyses of parameters for which ELAP-certification is not available.

For parameters for which ELAP laboratory certification is offered, the laboratories performing the corresponding analyses under the Peconic Program must be ELAP certified. Because ELAP conducts audits as part of its laboratory certification process, laboratory audits for analysis of parameters for which ELAP certification is offered are outside the scope of this QMP. Details on laboratory audits for laboratories performing analyses of parameters for which ELAP-certification is not available is provided below.

Laboratory Internal Audit and Data Review

A. Data Review - When manpower and time permits, original observations and calculations are reviewed and evaluated by the supervisor or second analyst. The level of review for a particular data set should be commensurate with the decision that the data will be supporting. The data is reviewed to ensure that calculations are correct and to detect transcription errors.

B. Internal Quality System Audits - The QA Officer will arrange for an internal quality system review annually. The audit will be carried out by trained personnel who are independent of the activity being audited. The results of the audits will be documented in writing. Where audit findings cast doubt on the validity or correctness of the data, the lab will take immediate corrective action. Any corrective actions will be documented. Any authority/client whose work was possibly adversely affected shall be notified in writing. Documented reviews are performed with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity. Allegations are confidentially investigated. All investigations that result in findings of inappropriate activity are documented and shall include any disciplinary actions involved, corrective actions taken, and all appropriate notifications to clients. Documentation is maintained for five years.

C. Managerial Review - The Technical Director shall review the laboratory quality system and its testing and calibration activities annually to introduce any necessary changes or improvements. The review will take into account the outcome of recent internal audits, reports from managerial and supervisory personnel, suitability of policies and procedures, assessments by external bodies (NYS Department of Health [DOH] or Primary Accrediting Authority, NYSDEC, USEPA, or clients), the results of ELAP proficiency tests, any changes in the volume and type of work undertaken, feedback from clients or Authorities, corrective and preventive actions and complaints, and other factors such as quality control activities, resources and staff training. The findings and any corrective actions from this review will be documented.

In all formal audit activities, the auditor examines the procedures by which work plans, QAPPs, or deliverables are prepared, reviewed, and approved for submittal as specified in the QMP to verify that the appropriate plans have been prepared, the plans have been reviewed and approved by responsible personnel, and the work products have been reviewed and approved as required. Management system reviews or quality system audits are conducted by the QA staff to identify areas for improvement in the structure and processes of the quality system described in this QMP. Section 9.2 describes these reviews in more detail.

3.0 Personnel Qualifications and Training

Appropriately qualified technical personnel are selected and used to ensure that the highest standards of QC are maintained for each project and that technical problems are adequately identified and resolved at the lowest management level possible (closest to the issue). The Peconic Program is ultimately responsible for hiring and selecting staff with the qualifications to meet the needs of a project. Section 3.1 discusses personnel qualifications, while section 3.2 describes training requirements and opportunities to enhance the qualifications of personnel. Section 3.3 describes procedures for changing project personnel.

3.1 Personnel Qualifications

Appropriately qualified personnel from the Peconic Program, contractors, or consultants are used to ensure high-quality products for each project. For each project, the corresponding Program Manager is responsible for ensuring that personnel are qualified, have the skills to perform their job functions, and meet the professional standards of their disciplines.

The Peconic Program determines and maintains the classification system for positions needed for the Program based on the employee contract associated with its host county (Suffolk County). Each classification is defined by a minimum set of requirements including experience, education, and/or certification. Personnel hired by the Peconic Program must meet these minimum requirements to qualify for a certain position.

If contract requirements, regulations, or Peconic Program policies require specific certifications and special training for certain types of work, Project Managers are responsible for identifying such requirements for conducting work for each project. For example, a project might require technical staff having health and safety certification. The Program Manager and QA Officer identify personnel with the appropriate certification and training. If the required qualifications are not available within the Peconic Program, the Program Manager will either initiate the procedures to hire or contract for the needed skills or schedule training for Peconic Program staff.

3.2 Training

With regard to personnel qualifications and training, the Peconic Program Manager is responsible for the following:

- Determining the level of education, experience, and training required to ensure that personnel are qualified to perform work within their respective organizations and specific projects. Specialized training requirements needed to accomplish highly technical work activities are identified in work plans, QAPPs, and SOPs.
- Establishing specific requirements for subject matter training, qualification, certification, personnel training records (and their maintenance), and implementation in accordance with project procedures.
- Providing training resources for required education, training, and retraining, including activities such as continuing education, on-the-job training, and training seminars to ensure that personnel demonstrate and maintain proficiency in performing assigned work.

- Ensuring that when job requirements change, the need for retraining is evaluated by Peconic Program management and provided when necessary.
- Ensuring that records of training, qualification, and certifications are maintained.

Training and professional development activities, including those related to QA, are tracked and individual training records kept in staff personnel files and a database by Peconic Program members.

During annual reviews of the QMP, the Peconic Program QA Officer reviews QA training requirements with the QA staff; if it is determined during that any of the QA team members require additional training in QA, the QA Officer will coordinate additional QA training activities.

As described in section 2.2 of this QMP, the QA Officer provides training to all staff on the quality system during their initial orientation to a project and during refresher training, as required. Refresher training can be conducted if significant revision to the QMP occurs in response to deficiencies observed in surveillance or at the request of an employee's supervisor to ensure a comprehensive understanding of the quality system's requirements. Additional details are provided in section 2.2 of this QMP.

Through their exposure to this QMP, staff members are introduced to the management organization and key components of the comprehensive quality system: training; DQOs; QAPPs; SOPs; and technical, editorial, and audit system requirements, as appropriate for their specific duties. Staff members are introduced to the highlights and components of each of those subsystems, the requirements established in their underlying industry or agency guidance, and how to engage the quality system for support in developing and reviewing internal QA guidance, where required. Employees are also introduced to the other resources available, including the location of the QMP in electronic form, as well as the locations of SOPs, checklists, which provides access to the documentation that can accompany the many review and approval processes required as part of a comprehensive quality system used in their daily operations. Any future revisions and updates are posted to an identified location, and staff members are notified to review the changes.

As a demonstration of ongoing commitment to the QMP, the Peconic Program also conducts a program of continuing QA refresher training. Refresher training is required when the QMP is subject to significant revision, as a corrective action in response to deficiencies observed in surveillance, or at the request of an employee's supervisor to ensure a comprehensive understanding of the quality system's requirements. Orientation and quality system refresher training include introduction to the key components and principles of the quality system, the QMP, and the continuous improvement process as it relates both to the QMP's components and to its specific implementation organizationally and in specific functional organizations. Refresher training also provides a structured forum that allows Peconic Program to introduce key changes in the QMP as they are adopted through regular updates and reviews. During the refresher training, Peconic Program also discusses modifications to implementation procedures adapted at the office level, if applicable. While the QMP details the basic requirements of the quality system and describes specific implementation tools, promoting continuous quality

improvement (section 10) requires that the technical staff be empowered to develop alternative procedures and documentation systems.

General training in project operations and the quality system is provided to all staff members; advanced understanding of project management and processes, such as budget tracking and QAPP preparation, is required of Project Managers. The Program Manager is responsible for ensuring that personnel on a project have appropriate training and coaching as needed to meet the requirements for the preparation of high-quality materials for every project. Sessions are provided to all personnel involved in the contract to familiarize them with contract and project requirements; the procedures for preparation, review, and approval of work plans, QAPPs, SOPs, and other documents needed for projects; and pertinent QA/QC procedures required before work begins. The amount and type of training required can vary with the project and may change during a project. The Program Manager, Project Managers, and QA Officer will work together to address training issues as they arise.

Other in-house training is provided as needed. Such training can include mentoring, on-the-job training, *brown bag* (lunch hour) presentations, workshops, seminars, formal courses, self-instructional videos and computer software, or courses offered by organizations through the Internet. Informal educational opportunities include email reminders on different aspects of the quality system and distribution of brochures, fact sheets, or other materials.

Supervisors and senior managers conduct assessments of training experience and proficiency when necessary. The QA Officers maintain records of training related to the quality system.

3.3 Changes in Personnel

Throughout the course of executing a project, the Program Manager will work with the municipality or agency and the Project Managers to ensure that qualified personnel participate in the work, relative to the requirements of the tasks. If the requirements for a project change, the Project Manager and Program Manager will determine whether retraining of current staff is necessary or whether asking a staff member who is especially qualified to work on the project would be better.

4.0 Procurement of Items and Services

The Peconic Program procures a variety of items and services for environmental data collection needs through various contractors, including laboratories and technical firms. Procurement of items and services for a project will follow the current standards (at the time of the project implementation) of the agency commissioning a project. These standards will be included or referenced in the procurement documents. The acceptability of purchased items and services will be verified and documented by the individual who has requested the items or services.

The Program Manager and the Project Manager will coordinate with the QA Officer to ensure that appropriate QA/QC requirements are included in all contracts for procurement of services and items that require QA oversight. It is the Peconic Program's goal that all procurement involving environmentally-related measurements or data generation require contractors to have a quality management system that complies with this QMP. Subsequently, the organization must

submit a QAPP for Peconic Program review and approval before any environmental measurements or data collection activities can be performed.

Section 4.1 discusses specific requirements for maintaining equipment and items or services that can directly affect the quality of work performed. Section 4.2 describes procurement of services. Section 4.3 describes procurement of laboratory services. Section 4.4 discusses documentation.

4.1 Maintenance of Equipment and Supplies

The municipality or agency making a purchase is responsible for inventory and maintenance of all equipment and supplies provided, either directly or indirectly, under a project. Inventories of supplies and disposable equipment provided or specifically purchased for the project are maintained and replenished as needed so that work quality or productivity is not compromised.

The Peconic Program's field teams and staff maintain and routinely inspect and verify the performance of sampling and field data collection equipment. Prior to mobilization, teams will evaluate inventory and procure or rent additional equipment as necessary, depending on the size and complexity of the data collection effort. At a minimum in-house and rental equipment are operationally inspected, calibrated and verified prior to mobilization. Equipment from outside vendors or those of which may have been stored long-term, may require additional preparation (supplemental decontamination, solvent or acid rinsing) prior to deployment. Additional preparation will be based on the parameter measurements of sample classes to be collected prior to deployment to the field.

4.2 Procurement of Services

All procurements are defined in writing in one or more procurement documents (purchase orders, requests for proposals, procurement contracts, and other agreement documents). Routine commodity purchases are made through the use of a purchase order. A Request for Proposal (RFP) is sometimes developed for procurement of services and stipulates requirements of the Peconic Program. The nature of the work, the location, and the anticipated cost are factors that contribute to the determination of when an RFP is necessary. QA requirements of all potential contractors are clearly identified within the RFP and are a requirement of all contract documents. The Program Manager and QA Manager determine such QA requirements, with the assistance of QA staff. An RFP has a set of screening criteria that ensure the potential contractors meet the quality requirements. A designated group is responsible for review of proposals, for scoring the proposals by preset criteria, and for selecting the contractor(s).

4.3 Procurement of Laboratory Services

The Peconic Program's procedures for procuring the analytical laboratory services are secured under individual municipal or agency policy. In identifying and selecting analytical laboratory services to support projects, the Peconic Program will first carefully review the requirements specified by the municipality or agency. The Project Manager will then communicate with the municipality or agency to identify all the critical needs of the analysis and any special considerations for the project.

QAPPs developed by or on behalf of the Peconic Program will specify what QC samples (e.g., duplicates, blanks) project personnel will take to provide a check on the validity of laboratory results.

4.4 Documentation for Procurements

The Program Manager (or designee) will retain contracts, SOWs, copies of correspondence, invoices, and other materials pertaining to any procurement of products and services. Contractor information can include correspondence regarding contractor performance, progress reports, and Peconic Program inquiries with regard to compliance with the terms of the contract agreement. In all cases, documentation will follow the requirements of the municipality or agency making the purchase.

5.0 Documents and Records

Documents and records that might require special handling are those pertaining to the quality system and those obtained or generated to support projects. Documents that may require control can be in the form of printed or electronic media, and include QMPs, QAPPs, health and safety plans, work plans, SOPs, checklists, metadata, assessment results and findings, blueprints, chain-of-custody forms, calibration data, field logbooks, materials testing results, sampling and analytical data, inspection results, QC data, design documents, reports, and calculations. Other examples of such records are audit and nonconformance reports, and corrective action requests.

The QA Officer maintains files for all quality system documents for the project. Responsibilities of the QA Officer, as appropriate, include the following:

- Distribute quality system documents and record forms to the Program Manager, Project Managers, and other pertinent staff.
- Maintain a list of personnel who receive controlled documents so that updated documents or portions thereof can be quickly distributed.
- Notify all project staff of changes or updates to these documents and ensure that the latest version of the document is being used.
- Maintain the files for all quality system records under the project to prevent damage and deterioration but provide access to authorized personnel.
- Ensure that the Program Manager and Project Managers are apprised of the existence of these records.

The Project Manager or designee is responsible for incorporating record-keeping practices into project activities. For primary data collection projects, the Project Manager will describe chain-of-custody procedures for sample collection and analysis in the corresponding primary data collection QAPP or SAP. The Project Manager maintains a filing system for all incoming documentation, work plans, records of project activities and staff meetings, completion reports, monthly reports, and technical reports; all documents and deliverables generated as part of the project; and all correspondence. The Project Manager is also responsible for collecting and compiling reference documents and other literature and materials that might use in the preparation of a deliverable. These materials are maintained in accordance with project requirements, as specified in the work plan.

For projects requiring library compilations or specific control of materials used in the preparation of deliverables, the Project Manager can select a qualified DCS to compile and maintain these documents and other materials. The DCS uses an appropriate filing system as a repository for information and data used in the preparation of reports and documents for the project.

Appropriate SOPs cover the preparation of documents and the filing system, including logging receipt of the item in a log book, assigning each piece of information a unique identifying code and sequential number (document control number, or DCN), and storing the material in a labeled filing cabinet or other receptacle, permitting ready access by appropriate staff or the municipality or agency. During preparation of each deliverable, a working copy of any information needed by the project team is prepared and distributed to the staff. The original remains in the file. The DCS is responsible for supervising the use of these specially filed materials.

Other documents which require special handling procedures would include evidentiary records. If a project involves special handling beyond current procedures, they will be addressed in separate, specific SOPs prepared and submitted as part of a project-specific QAPP for review and approval by the municipality or agency before the work begins.

Section 5.1 outlines the procedures used to review and approve these documents and records and Section 5.2 describes record storage and Section 5.3 describes archiving of records.

5.1 Document Review and Approval

The Peconic Program prepares and reviews quality system documents and records as specified in the QMP or according to appropriate SOPs or other guidance to ensure consistency in the type, format, and content of these documents. The QA Officer is responsible for ensuring that these materials are prepared and revised according to specifications. Authorized personnel (including the Program Manager and QA Officer, or their qualified designees identified in written communication to the pertinent parties) review and approve the materials before they are submitted for approval by the agency as required by the project. The QA Officer prepares and revises the QMP, as appropriate, which is reviewed and approved by the Program Manager. Project Managers prepare and revise work plans, QAPPs, and SOPs. The QA Officer reviews and approves these documents following the process described in section 7 of this QMP. The QA Officer ensures that the appropriate personnel approve the quality system documents before they are used and that authorized personnel have signed and dated completed record forms before they are filed. The QA Officer is responsible for removing outdated or obsolete documents. The QA Officer must inform the Program Manager, and Project Managers about changes in documentation and assist in distributing the current documents to staff.

5.2 Documentation and Record Storage

All documents and records associated with grants, contracts, and financial and personnel management are stored and maintained electronically on a secure server at the Peconic Estuary Partnership's office in Riverhead, New York. In addition, some older documents and records are maintained as hard copy documents at the Peconic Estuary Partnership's office in Riverhead, New York. Some individual municipalities also maintain hard copies of these documents. Documentation and record storage at the Peconic Program is the responsibility of individuals charged with performing the tasks associated with this function.

Members of the public are required to schedule an appointment by calling the Peconic Estuary Partnership's office by phone (631-852-5806) or by using the online contact form (<https://www.peconicestuary.org/protect-the-peconic/about-pep/staff-and-contacts>) to review the Peconic Program's files. All files will remain in the possession of the Peconic Program at all times.

Confidential documents are stored in secure areas. Procedures for chain of custody and confidentiality for evidentiary documents and records are documented in relevant QAPPs, SAPs, and other QA documents.

File maintenance is the responsibility of all Peconic Program employees and municipal members. Employees are required to file their own documents or have this task performed by support staff according to Peconic Program policy.

5.3 Archival Storage

All quality system documents and records are maintained for the life of the project and ten years from issuance of the final report.

6.0 Computer Hardware and Software

The Program Manager, and QA Officer are responsible for ensuring that specific requirements for the quality of the products of environmental and water quality monitoring projects are met and that the appropriate staff maintains pertinent documentation for these items, as needed for the particular project. The Peconic Program maintains or secures services for a variety of computing and communications systems to meet the needs of the monitoring projects for efficient and accurate data processing. When specifically required for a project, the Project Manager will maintain records on the computers and software used or developed for that project.

The Peconic Program Manager must approve all hardware and software purchases for a specific project before its purchase. The Project Manager is responsible for ensuring that the installation, testing, use, maintenance, control, and documentation of all computer hardware and software meets the contractual, technical, and quality requirements of the project.

If custom software is needed for a project, the Project Manager will work closely with the programmer to ensure that the final product will meet user requirements. The Project Manager will coordinate with contractors, as needed, to ensure that contractual requirements and standards are met for software development.

Municipal servers are backed up regularly in accordance with their internal protocols. Municipalities provide final versions of project documents, data compilations, and other related files to the Peconic Estuary Partnership which uses Suffolk County computers and servers. The Suffolk County servers are backed up daily. The Suffolk County issued computers and laptops have a local McAfee client installed that provides antivirus protection. Suffolk County computers use the Secure Sockets Layer (SSL) protocol SSL and Virtual Private Network

(VPN), which are checked by multiple Advanced Persistent Threat appliances monitoring for malicious traffic from all Personal Computers and Servers.

7.0 PLANNING

Every project undertaken by the Peconic Program begins with the identification of specific objectives and requirements for the project and the development of one or more documents describing the tasks to be performed and QA/QC procedures and activities to be conducted to ensure the quality of products and services provided for the project. The Project Manager is responsible for preparing, or having the appropriate staff member prepare, these planning documents and distributing them to the project team to ensure that goals and expectations are effectively communicated to project management and staff. Sections 7.1 and 7.3 describe the formal planning documents that might be prepared. Section 7.2 describes the development of DQOs. Sections 7.4 and 7.5 describe the development of SOPs and guidance to implement the plans. Section 7.6 discusses documentation.

7.1 Work Plan

When starting the planning phase of a project, the Program Manager will work closely with the project team and the municipality or agency to ensure clear, mutual understanding of the goals and objectives of the assignment, the desired work products, and the type and level (and location) of expertise required to meet the objectives, schedule, and budget. In many cases, the scope of work is similar to the scopes of work of other projects conducted by one or more of the team members. Such experience can be invaluable in helping the Program Manager select the Project Manager for the project and in anticipating and avoiding potential technical problems. The Project Manager also helps to identify any special requirements for the project; for example, field investigations, laboratory analyses, or data processing that require preparation of a QAPP. The Project Manager reviews available background information and data, including work plans and reports from similar projects, to assist in designing the work plan and determining the tasks that must be performed to complete the project.

The Project Manager writes a work plan to succinctly address why the project is needed, what specific tasks are necessary to achieve the goals and objectives and the technical approach, the personnel who are to perform the work and their responsibilities, contracting arrangements, the level of effort required, QA/QC procedures that are to be performed, the schedule of project activities and deliverable due dates, and a detailed cost estimate. The work plan might also address the type and amount of coordination required with other federal and state agencies and the public, the type of sampling program to be conducted, specific steps to be accomplished in environmental sampling or field investigations, procedures for managing the data obtained, analyses to be performed, reports to be prepared, and special requirements. Each work plan prepared for a particular project follows a similar format to provide continuity and consistency between projects.

7.2 Data Quality Objectives

For projects requiring data collection or use, the DQO process is a planning tool that usually consists of seven iterative steps to define the decision to be made, clarify the information needed for this decision, and design the data collection program on the basis of the decision rule and the tolerable limits of decision error. Peconic Program follows USEPA's Data Quality Objectives

Process, as described in EPA QA/G-4, *Guidance on Systematic Planning Using the Data Quality Objectives Process* (EPA/240/B-06/001; USEPA 2006), unless the municipality or agency provides other guidance.

The Project Manager works with the municipality or agency and others identified as members of the planning team (such as those who collect and analyze the samples, community representatives, statisticians, users of the data, and decision makers) to develop the DQOs. This process includes:

1. preparing a clear statement of the problem;
2. identifying the decision(s) to be made using the data;
3. identifying the information needed to make the decision(s) (e.g., previously collected data, new environmental measurements);
4. defining the spatial and temporal boundaries of the study;
5. developing a decision rule that describes a logical basis for choosing an appropriate action based on study results;
6. specifying the limits on decision errors; and
7. optimizing the design for obtaining data.

Several iterations might be needed to specify the DQOs for a project.

If all seven steps of the DQO process are not applicable to an environmental data collection activity (e.g., specific decisions cannot be identified or the study is exploratory in nature), only applicable steps are used to help plan the data collection effort.

As noted in Section 2.4, the DQOs may apply to primary use of data (collection of measurements or other data during the project for a specific purpose) or to secondary use of data (use of existing environmental data collected by the municipality or agency or other organizations for other purposes). Quality requirements are known as performance criteria for newly collected or generated data or as acceptance criteria for existing data from other sources. Standards of quality that must be met for the data to be used in a project may be qualitative statements or quantitative DQIs such as accuracy, bias, precision, representativeness, completeness, and comparability.

The agency, as the ultimate user of the data, is responsible for establishing and approving the DQOs, although the Project Manager and QA Officer may assist in this process. To ensure that the data or information collected are of the type and quality needed to satisfy the DQOs, a QAPP or other type of quality planning document is developed for collecting the data consistent with available resources and data quality requirements, according to specific activities and procedures. Because DQOs are continually reviewed during data collection activities, any needed corrective action can be planned and executed to minimize problems before they become significant.

7.3 Quality Assurance Project Plan or Equivalent Documentation

A QAPP specific to the needs of a project involving environmental data operations, including the acquisition, analysis, and evaluation of environmental data is developed to ensure that the

work is performed by fully trained and qualified technical staff and supported by sufficient resources to achieve the planned DQOs. The need for a QAPP or other quality planning document that requires municipality or agency approval before work begins is identified during the development of the work plan. When requested by an agency in a grant, the Peconic Program will develop a project-specific QAPP and submit it to the agency's representative for approval before the work begins. The Peconic Program will review and approve QAPPs required to be prepared by municipalities overseen by the Peconic Program (refer to the QAPP template in the Attachment to this QMP).

The Project Manager and QA Officer (and contractor Project Manager and QA Coordinator if another firm is conducting the work) are responsible for ensuring that the QAPP or other quality planning documentation is implemented throughout the duration of the project. The final responsibility resides with the Project Manager.

The Project Manager or a qualified staff member prepares and implements the QAPP. The QAPP defines the DQOs for a project and the roles and responsibilities of project staff; identifies the critical measurements, analyses, or modeling to be performed and the procedures for doing so (in SOPs; see section 7.4); and discusses the various QA/QC activities to be conducted. Unless otherwise specified by the agency, QAPPs for projects conducted by Peconic Program are controlled documents, prepared in accordance with the specifications for format and content in EPA QA/R-5, *Requirements for Quality Assurance Project Plans* and subject to review and approval (section 5.1) (USEPA 2001b). When necessary, the Project Manager ensures that a separate health and safety plan is prepared to ensure that collection of field samples by Peconic Program personnel complies with all company health and safety policies and applicable OSHA standards.

The Project QA Officer and Project Manager review and approve the QAPP and submit the QAPP to the Program QA Officer and Program Manager for review. The Program QA Officer and Program Manager review the QAPP and return it with comments and requested revisions or specifies that the draft plan meets their requirements. The approved QAPP is distributed to the Program Manager, QA Officer, Project Manager, project staff, contractor(s), and other appropriate staff.

All projects or studies conducted to generate environmental data that are funded by or conducted in cooperation with the NYSDEC Division of Water (DOW) are to have QAPPs reviewed and approved by NYSDEC DOW prior to the start of any data collection effort.

7.4 Standard Operating Procedures

An SOP presents in detail the method for a given operation, analysis, or action in sequential steps. It includes specific facilities, equipment, materials and methods, QA/QC procedures, and other factors required to perform the operation, analysis, or action. An SOP is prepared for those activities which need to be performed the same way every time (i.e., it is standardized). The Project Manager is responsible for utilizing the most up to date SOPs which have been prepared and which are provided in an appendix to this document. SOPs will be located at the PEPC google drive: <https://drive.google.com/open?id=1wR-KZcxGUQc4zuxKDOABkxZGzKvYmMjF>.

Any technical staff with the permission of the Project Manager and the employee's supervisor can prepare an SOP. Most effective SOPs are developed by staff involved in conducting the procedure being documented. The format and content of SOPs are based on EPA QA/G-6, *Guidance for Preparing Standard Operating Procedures* (EPA/600/B-07/001), unless otherwise specified (USEPA 2007a). Additional information on implementation of SOPs and work processes is provided in section 8 of this QMP.

7.5 Guidance

The Program Manager, key technical personnel, Project Manager, or other staff may issue additional information that is important for the execution of a project in the form of guidance documents, notes, or memoranda. The Project Manager ensures that project team members are using the most recent versions of any guidance required for the project.

7.6 Documentation for Planning

As noted in the above sections, planning and implementation documents such as work plans, DQOs, QAPPs, SOPs, and task order or project-specific guidance will be developed and maintained by the Project Manager, Program Manager, QA Officer, or other staff member, as appropriate. These documents will be distributed to all staff involved in the task order or project. Adherence to the plans and guidance is discussed with the task order team, as needed, throughout the project. Draft planning documents can be submitted either in hard copy or electronic format for review. Final delivery of planning documents for approval requires approval signatures; therefore, final documents must be submitted as hard copy. A single signed hard copy of the approval page can be submitted to the municipality or agency for approval by mail with an electronic PDF file for review, if the final approval sheet is either returned to or scanned with the municipality or agency approval signatures along with those of the Project Manager and QA Officer. When a fully signed approval page, or a scan of the approval page, is received, the corresponding pages of the original document PDF can be replaced, affording a full electronic copy of the approved plan for distribution.

8.0 IMPLEMENTATION OF WORK PROCESSES

Peconic Program follows specific procedures to ensure that work is performed as required under each project, as detailed in the work plan (Section 7.1), the QAPP (Section 7.3), and SOPs (Section 7.4). Those procedures apply to all projects that the Peconic Program conducts, unless otherwise specified in writing for the contract or project. The Program Manager, Project Managers, and QA Officer are responsible for implementing the procedures. Section 8.1 discusses the process of how and by whom work is implemented, including the process for confirming that work is performed according to the plans and the process for changing plans when required. Section 8.2 details the level of management oversight usually indicated for work conducted in Peconic Program offices.

8.1 Procedures to Ensure that Work Is Performed According to Plan

The Project Manager informs project staff members and contractors of (1) the purpose and goals of the project, (2) the schedule, (3) their responsibilities, and (4) the person(s) to whom they are accountable for their performance. That information is included in the work plan (section 7.1,

description of tasks, schedule, and deliverables) and QAPP or equivalent documentation (section 7.3) prepared for each project. Staff members use the municipality or agency-approved work plan and QAPP or equivalent documentation, if any, to guide the work. The Project Manager is responsible for ensuring that staff and contractors have access to the latest versions of these documents and that previous versions are disposed of properly.

The Project Manager oversees the day-to-day operations of the project and communicates frequently with staff and contractors as a work product is developed. The Project Manager also continually monitors technical progress and budgetary performance. This approach provides early identification of problems so they can be quickly resolved. Frequent communication between the Project Manager and the Program Manager are essential to determine progress. Any technical or schedule difficulties are immediately addressed. If the plans (work plan, QAPP, or other documentation) require significant changes, the Project Manager is responsible for preparing the revised documentation and ensuring that the municipality or agency representative and other pertinent parties (e.g., QA Officer, contractor) receive, review, and approve the changes. The Project Manager is also responsible for ensuring that all project staff members are informed of the changes and that they follow the most recent version of these documents.

The Project Manager is responsible for determining whether training or written procedures are required by staff or contractors to execute particular processes during the project. Repetitive or complex operations might require the development of written procedures or formal SOPs to be carefully followed by staff performing the operations (e.g., data entry checks, software application development, water quality sampling). The Project Manager, with assistance from the QA Officer or other QA/QC staff, is responsible for preparing procedures, securing DCNs, taking them through the review process, revising the documents, and obtaining approvals (section 5.1), if required (on formal SOPs or when requested by the municipality or agency).

SOPs are developed as Peconic Program staff need them to cover specific operations and standardize new activities. SOPs are referenced or attached to the QAPP if project-specific. If SOPs require modification for a project, the modifications will be discussed in the QAPP. SOPs are effective until revised or retired and are reviewed at least annually. Existing SOPs are reviewed and revised as necessary when new equipment is used, when comments by personnel indicate that the directions are not clear, or when a problem occurs. Project-specific procedures are developed by the Project Manager and submitted as project deliverables for review and approval by the municipality or agency. Project-specific procedures are effective for the duration of a project and are reviewed and revised at least annually or if new equipment is used, when comments by personnel indicate that the directions are not clear, or when a problem occurs.

The QA Officer or contractor QA Coordinator reviews and approves revised SOPs (to verify that changes are made as prescribed) and new SOPs as appropriate, before implementation (section 5.1). The QA Officer or contractor QA Coordinator, as appropriate, ensures that obsolete documents are removed and that the revised SOPs are used in subsequent tasks.

All SOPs are reviewed by personnel responsible for the tasks that they describe. This review focuses on consistency with current practices and compliance with prevailing requirements

(analytical methods). The review also focuses on ensuring that references and citations are up-to-date and consistent with the most current guidance or procedures.

Contractors are required to prepare SOPs based on specified methods, protocols, or guidance; the Peconic Program reviews contractors' SOPs to ensure that they can meet the municipality or agency's requirements. The Project Manager is also responsible for distributing the procedures (or providing access to electronic files) to staff who must follow them, and for providing training in the procedures, as needed. Review and revision procedures for contractor SOPs and project-specific procedures are the same as those for (SOPs are effective until revised or retired and are reviewed at least annually). Existing SOPs are reviewed and revised as necessary when new equipment is used, when comments by personnel indicate that the directions are not clear, or when a problem occurs. Project-specific procedures are effective for the duration of a project and are reviewed and revised at least annually or if new equipment is used, when comments by personnel indicate that the directions are not clear, or when a problem occurs. The Project Manager must verify that staff are using the latest version(s) of the procedure(s) and have discarded or eliminated access to earlier versions. Project staff members are responsible for consistently implementing the procedures as they conduct the work. They must document any problems encountered in using the procedures and report such problems to the Project Manager or contractor Project Manager so that corrective action can occur, if necessary. Project staff meetings or teleconferences are held when necessary to review project status, report on activities, and describe planned activities. Newly available information is distributed so that technical personnel are informed of all new developments. Significant events, decisions, and issues that affect the project are documented and distributed to the team members as the project proceeds. Notes are kept of project staff meetings and distributed in memorandum form to the meeting attendees, as needed. Action items generated as a result of the meetings are included in the memoranda.

Laboratory analyses are conducted according to the specifications of the QAPP and the contracting agreement with Peconic Program. As a final step to ensure that technical QC of work products is achieved and any problems are adequately addressed, the Project Manager ensures that appropriate reviews have been conducted on final deliverables prepared for a project and that all revisions have been made before submitting the deliverables to the agency (see section 9.0).

8.2 Level of Management Oversight and Inspection to Be Provided

The Peconic Program will provide the level of management oversight and inspection that is appropriate to the work being performed under a particular project. Levels of inspection are discussed in section 9.1. The Program Manager, in consultation with the QA Officer, determine an appropriate level of management oversight and inspection for each task or project, in accordance with budgetary constraints and anticipated difficulties that might be encountered; however, the routine management and inspection activities described in section 8.1 will be implemented by the Project Manager without fail.

9.0 Assessment and Response

Assessments provide a basis for improving the Peconic Program's QA Program by identifying problems, revealing areas of strength and weakness, and allowing management to evaluate the Peconic Program's processes and performance. Assessments include project task reviews and formal audits.

9.1 Project Task Reviews

The Project Manager is responsible for ensuring that all data generated are appropriate for their intended use and are of the required level of precision and accuracy. The Project Manager will assess the data collection methods and examine the data for adherence to QA standards, including

- The **desired degree of precision**, defined as the degree of dispersion of the data;
- The **required accuracy**, defined as agreement of the collected data with prior measurements;
- The **degree of completeness**, which indicates the amount of data obtained in comparison to the amount expected to be collected under normal conditions;
- The **representativeness of the data**, which expresses the degree to which the data accurately represent the population from which they are drawn; and
- The **comparability of the data**, indicating the confidence with which one data set can be compared to another.

The components for data QA oversight for projects are as follows:

- Specification of the hypotheses, goals, issues of concern or problems to be addressed;
- Justification of the expertise represented in the expert investigators team;
- Specification of the methods to be used for identification of relevant studies, assessment of evidence of the individual studies, and interpretation of the entire body of available evidence;
- Review of the process; and
- Communication of findings.

Project task reviews are conducted by project QC Officers throughout the duration of a project. The level of QC checks and reviews should be based on the DQOs of the project. Collection and analysis of field blanks is often performed once per every 10 samples collected and analyzed. Because of the diversity of projects undertaken by the Peconic Program, the level of review for a particular task should be commensurate with the decision that the data will be supporting. For example, a more extensive review should be applied for data used to support regulatory decisions, while a lower level of review should be applied for data used for educational purposes.

9.2 Audits

An audit is a systematic assessment or evaluation to measure the performance or effectiveness of a process, to determine whether QC procedures have been implemented effectively, and to examine whether the results of the activity have achieved the desired objective. Audits are typically used to assess the overall quality of data collected during a measurement program. In addition, audits are useful in evaluating the procedures used in collecting and analyzing samples, how data are handled, and how a program or project is managed. Often an audit detects problems that might otherwise have gone undetected until the end of the activity. The results of such audits also serve as learning and teaching tools to assist staff in improving their abilities to produce quality products for all work performed.

Audits will be performed based on the following criteria:

- 1) Each newly initiated project will be audited at the end of its first season or cycle of monitoring;
- 2) Projects that have operated continuously for a period of three years;
- 3) Projects with a duration of more than three years or with a cost of monitoring in excess of \$80,000

Two classes of audit may be conducted: Technical System Audit (program-level assessment) and Management System Review or Quality System Audit (performed annually, the review generally coincides with the review of the QMP). These classes of audits can be further classified into *internal* or *external* audits. An audit is internal when a qualified staff member evaluates a process implemented by other staff in relation to the planning of that process. An external audit is conducted by someone outside of the Peconic Program, usually working for a contractor or another organization. Internal audits are conducted to identify and document problems affecting quality and to propose recommendations for improvements.

A primary qualification of auditors or audit staff is that they be independent of the work being reviewed, and that not be engaged in the primary project performance. Contractor audits are conducted by the QA Officer or other designated auditor as needed. The QA Officer selects an independent auditor and audit team, if needed, based on the activities to be audited and their complexity. The auditor's responsibilities include preparing the audit plan, coordinating the audit process, communicating with the project team or organization being audited, participation in the audit, coordinating the preparation and issuance of audit reports, and evaluating the audit process. Audits are conducted by personnel who remain independent of the project or systems under review. Auditors, as designees of the QA Officer, or senior program or project management personnel, are staff members who have not been engaged in the primary work processes that are being evaluated. As members of, or as extensions to, the quality management team, auditors have the full authority of the QA Officer with regard to access of project records and files in order to complete their assigned review procedures. Audits, announced or unannounced, serve at least six purposes:

- Ensuring that performance is responsive to the municipality or agency's needs and objectives and that appropriate information is available in a time frame adequate to meet the deadlines of the project

- Determining whether the work is being performed in a systematic, easily understood, and professional manner
- Verifying that the QMP, work plan, and project-specific QAPPs are being executed and that SOPs are being followed
- Detecting and defining problems so that immediate corrective action can begin
- Verifying implementation and effectiveness of major corrective actions, where required by previous audit, or in response to an agency complaint
- Identifying and exploiting quality improvement opportunities in the project execution process and operations

The audits might not cover all tasks and activities performed by Peconic Program under all projects, but they involve sufficient activities to allow an evaluation of the quality of the work and compliance with the QMP, work plan, QAPP, and/or SOP(s), as appropriate. Specific areas to examine include, but are not limited to, the following:

- Qualifications of technical and management staff
- Quality of performance of administrative and technical personnel, including contractors
- Sample collection procedures, chain-of-custody records, and document control systems
- Procedures for analysis, documentation of data sources, and storage and retrieval of data
- Validation of analytical data, calibration procedures, and detection limits of test equipment
- Identification and reporting of nonconformance
- Completion of corrective actions
- Procedures for document review and resolution and incorporation of review comments
- Documentation of technical/editorial reviews and DQAs

The auditor prepares a formal Audit Report (Exhibit 2) describing the extent of the audit, audit results, nonconformance observed, and any corrective actions required. The auditor also identifies quality improvement opportunities. The report is submitted to the Program Manager and QA Officer, if the QA Officer is not directly involved in the audit, and the Project Manager, as appropriate. The QA Officer, following consultation with the Program Manager, has authority to suspend the performance of any activities determined to be deviating from the established QMP, work plan, or QAPP until appropriate corrective actions can be instituted. The QA Officer may issue periodic audit reports to the Program Manager, environmental scientist and Project Managers to provide an overview of performance of QA activities, including the status of action items for resolving nonconformance and recommendations for improvements (see section 10.0).

The QA Officer or an authorized designee conducts management system reviews or quality system audits. The results of the quality system reviews are reported by the QA Officer to the Program Manager. Any deficiencies noted during the review are subject to management review, coordinated by the Program Manager.

AUDIT REPORT

Contract (name) _____

Date of Assessment _____

Request No. _____

Title (of project or other) _____

Project Leader _____ TC# _____

Other Responsible Personnel _____

Auditor _____ Title _____

Site Name and Location _____

Description of Activity Audited:

Summary of Audit: (Attach additional sheets or reports if necessary or applicable)

Corrective Action Identified? (Circle one) Yes No

If yes, complete Corrective Action Request and Response Verification form and describe briefly here:

Other Comments or Notes:

Signature of Auditor:

Signature _____

Date _____

Original form to be filed in QAO File; one copy to be filed in Project File and one copy in Contract File (if audit was conducted on a project), or one copy to be filed in Contract File (if audit was conducted on a contract).

Exhibit 2. Example Audit Report form

9.3 Response

When errors, omissions, or other revisions are identified during technical, editorial, or final reviews, the Project Manager compiles the comments received from internal or external technical reviewers and editors. The Project Manager is responsible for ensuring that all comments, corrections, additions, deletions, or other revisions are incorporated into the deliverable. If there are conflicts in the quality improvements that have been indicated by two or more reviewers, the Project Manager should seek additional professional guidance and document how the conflicts were resolved. Observations of incompleteness, as well as technical or editorial inconsistencies, require corrective action. Any member of a project team can initiate corrective action, often resulting in immediate resolution of inconsistencies in performance or work products, but sometimes requiring additional investigation and analysis by the project team prior to development and implementation of adequate corrective action plans.

During project operations, many of the technical problems that might occur can be solved on the spot by the staff members involved; for example, by modifying the technical approach, repairing instrumentation that is not working properly, or correcting errors or deficiencies in documentation. Also, for example, when there are conflicts in the quality improvements that have been indicated by the technical editor and the lead author of a document, the Project Manager will resolve the conflict (if qualified in the corresponding topic area) or seek additional professional guidance from a technical expert to resolve the conflict. Problems that cannot be solved in this way are brought to the immediate attention of the Program Manager and the QA Officer or the contractor QA Coordinator. The QA Officer works with the Program Manager, or each of them to determine whether major corrective actions are needed.

Modifications to a technical approach may only add an additional review step or change the order in which data are collected or recorded. Where these modifications do not affect SOP or QAPP specifications they can be resolved without significant documentation. A simple manual correction of notes, records, or files including a single straight-line strikeout with the initials of the reviewer and the date of the correction, or a simple entry in a maintenance log can be the final outcome of a minor corrective action. When errors are repeated sequentially, or a trend is observed, a formalized corrective action investigation may be necessary. The corrective action process presented graphically in Exhibit 3 starts with the observation of deficiency. Deficiencies are corrected and recorded in project files, notes, and review documents. The QA Officer, or Program Manager may interpret the deficiencies as indicative of a trend, deficiency, or some other weakness in the process or technical approach, and initiate the corrective action process.

The formal corrective action process includes investigation into the root cause of the deficiency or failure. Investigation may include a full retrospective assessment of the activity throughout the project, or may focus on a recent procedural modification or revision in project documentation.

The investigation results in identification of the factor(s) most likely to have contributed to or caused the deficiency. After the root cause or contributing factors are identified, the project technical staff and QA Officer compile and evaluate alternatives to correct the situation (corrective measures) in order to assess the completeness of the actions, to ensure that the corrective action recommendations are practical, and to define their overall effect on project schedule and budget. The Program Manager and QA Officer collaborate on which alternatives

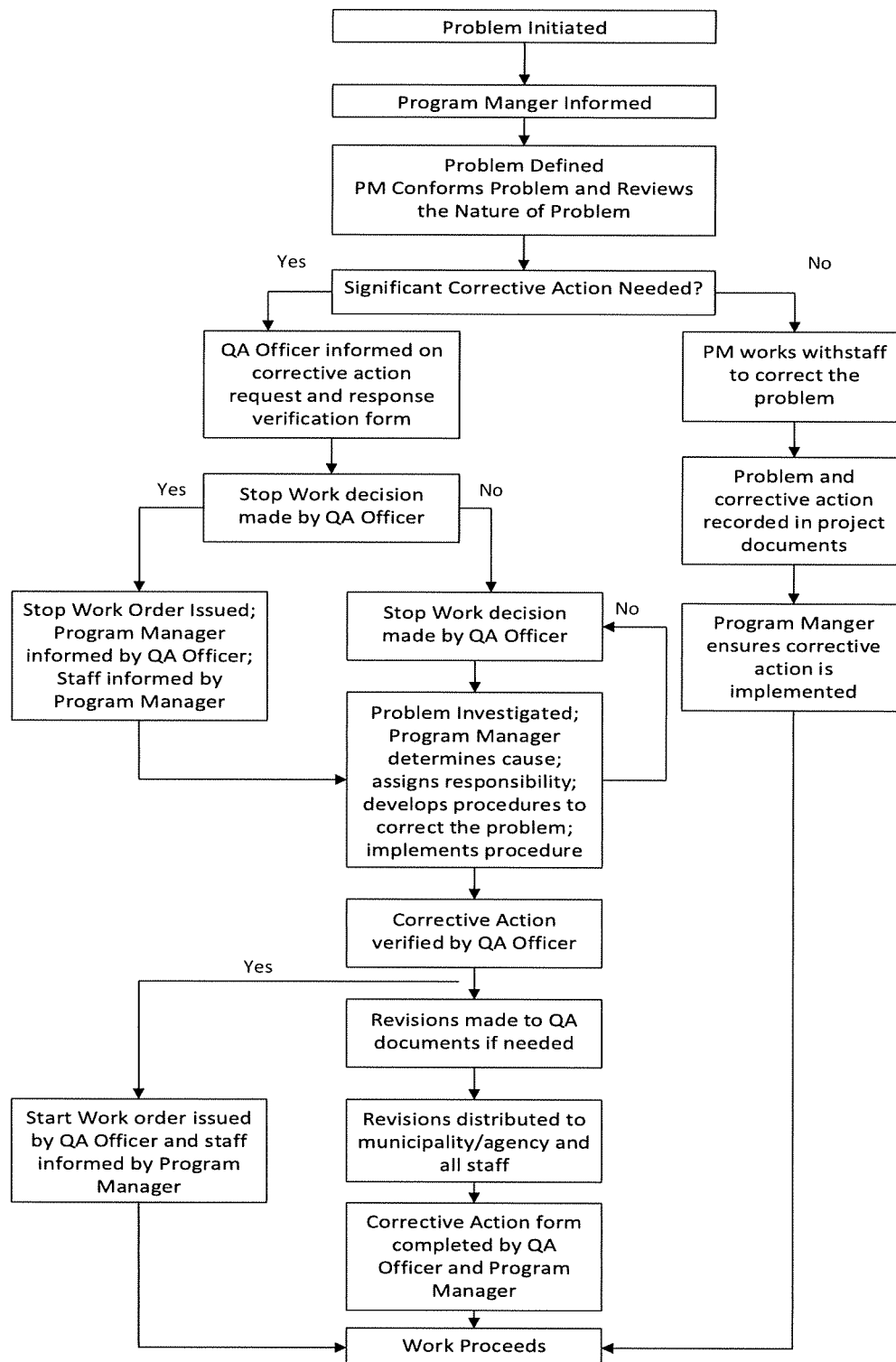


Exhibit 3. Corrective Action Process

are most appropriate, given the scope and impact of the problem and the cost and reasonableness of the corrective actions. They determine the schedule for implementation or a completion date for the corrective action(s).

Results from the following QA activities might initiate a corrective action: technical and editorial reviews, DQAs, audits, and management system reviews. In particular, failure to adhere to the QMP, work plan, QAPP, or SOP, as well as identification of a nonconformance (not meeting predetermined specifications), requires that corrective action be taken. In addition, the Program Manager queries the municipality or agency regarding any concerns about deliverable quality. The emphasis of long-term corrective actions is on building quality into the conduct of procedures rather than relying on QC reviews and audits to identify and correct errors and deficiencies on a case-by-case basis. Corrective actions may include the following:

- Reemphasizing to project staff and their supervisors the project directives, the limitations in scope, the need to adhere to the agreed-upon schedule, and the need to document QA/QC procedures
- Securing additional commitment of staff time to devote to the project
- Retaining outside consultants to review problems in specialized technical areas
- Changing procedures

The Program Manager might exercise his or her authority to replace a Project Manager or staff member if it is in the best interest of the project to do so. If a contractor is performing the project, such replacement takes place only after discussion with the contractor QA Coordinator and management staff.

If major corrective action is required, the QA Officer or an auditor documents the problem on a Corrective Action Request and Response Verification form (Exhibit 4). If more than one problem is involved, each is documented on a separate form. The QA Officer documents the schedule for implementation or a completion date for the corrective action(s) on this form.

Extreme cases might call for the QA Officer to issue a stop work order recommendation. In such cases, the QA Officer communicates with the Program Manager the deficiencies observed and their effect on project outcomes, as well as whether the municipality or agency QA Officer/Coordinator needs to be engaged to effect resolution. If the municipality or agency QA Officer/Coordinator is critical to the resolution of the deficiencies, they are contacted by the QA Officer.

In the event of a stop work order, the Project Manager contacts the municipality or agency project representative, while the Program Manager might contact the municipality or agency's Contracting Officer. The decisions to communicate specific deficiencies are based on their impact to project work products and schedules. Stop work recommendations are extremely rare, but their issuance must be considered in the overall quality system as an avenue to address significant issues which may arise during project execution. The QA Officer acts with the authority of the Program Manager when invoking a stop work order, but does not generally do so without sufficient discussion with management staff.

CORRECTIVE ACTION REQUEST AND RESPONSE VERIFICATION

Contract (name) _____

Date of Assessment _____ Request No. _____

Title (of project or other) _____

Project Manager _____ TC# _____

Other Responsible Personnel _____

Auditor or Initiator of This Corrective Action Request _____

Problem Description:

Corrective Action(s) (attach extra sheets as necessary):

Schedule for Implementation:

Quality Assurance Officer

Date

Operations Manager or Regional Manager

Date

Corrective Action(s) Taken:

Completion Date:

Verification of Completion of Corrective Action:

Quality Assurance Officer

Date

Operations Manager or Regional Manager

Date

Original form to be filed in QAO File; one copy to be filed in Project File and one copy in Contract File (if corrective action pertains to a project), or one copy to be filed in Contract File (if corrective action pertains to a contract).

Exhibit 4. Example Corrective Action Request and Response Verification Form

The QA Officer is responsible for verifying and documenting that the corrective action has eliminated the problem within the agreed-upon time frame. The QA Officer and the Program Manager or Program Manager, as appropriate, sign and date the form, verifying that the corrective action has been implemented. The QA Officer monitors the status of all corrective actions to ensure that problems remain corrected and reports to the Program Manager, as needed.

The Program Manager and QA Officer work with the Program Manager to resolve all QA issues arising under the project. In the event of a stop work order, final resolution and continuance of work (start work order) is communicated through the same channels as the initial stop work order.

9.4 Documentation for Assessment and Response

Each formal assessment requires its own form of documentation, such as technical, editorial, or final review forms or correspondence and edited review documents, procedural review checklists, audit plans and reports, corrective action requests, or reports to management. Each should be submitted to the Program Manager or the QA Officer, as appropriate, on completion. During development of formal proposals, responses to solicitations, or consideration of technical approaches for bid response requests, it is common for the QMP to be reviewed for applicability and discussed or attached as evidence of the quality system. At other times interviews are conducted with the operations management to describe evolving needs or municipality or agency requirements, explore potential solutions, or simply recommend refinements to enhance the applicability of the quality system within a group or in support of a specific project or project requirement.

10.0 Quality Improvement

The Peconic Program's QA Program includes procedures for identifying and implementing quality improvements. In addition to carrying out plans and assessing work products, the quality system must be flexible and change as deficiencies in the work process become apparent. The project staff might identify such deficiencies, or they might be revealed during a formal quality system audit. The QA Officer and Program Manager are responsible for resolving quality system issues and determining whether corrective actions are needed. Section 10.1 reviews how deficiencies are identified, and section 10.2 provides information on activities that might be implemented to improve the system. Other options might become apparent as the issues are discussed with staff; thus, flexibility in how quality can be improved and how the system should be revised is important for Peconic Program. Section 10.3 discusses documentation.

10.1 Identifying Deficiencies

A quality system can be established with the best of intentions and with support from management and staff, but as the system is implemented over time it might become apparent that something is amiss—perhaps the work plan is confusing or training insufficient—and the quality goals and objectives cannot be met. For example, an agency might identify that some data were submitted to respond quickly to his or her request and turned out to be inaccurate; however, the Project Manager had considered the data to be preliminary and had not conducted an independent review because it was not required. The need for frequent and open communication with the agency and appropriate documentation of project activities has been emphasized to

Project Managers, and the system review policies have been revised to ensure that independent reviews are conducted or, if not, that the agency is informed that such reviews have not taken place. As noted in section 2.2, Peconic Program will continue improving the system, change the QMP as needed, and offer training to ensure the highest quality performance.

As described in section 9 of this QMP, during project operations, many of the technical problems that might occur can be solved on the spot by the staff members involved; for example, by modifying the technical approach, repairing instrumentation that is not working properly, or correcting errors or deficiencies in documentation. Problems that cannot be solved in this way are brought to the immediate attention of the Program Manager and the QA Officer or the contractor QA Coordinator. The QA Officer works with the Program Manager, or each of them to determine whether major corrective actions are needed.

Modifications to a technical approach may only add an additional review step or change the order in which data are collected or recorded. Where these modifications do not affect SOP or QAPP specifications they can be resolved without significant documentation. A simple manual correction of notes, records, or files including a single straight-line strikeout with the initials of the reviewer and the date of the correction, or a simple entry in a maintenance log can be the final outcome of a minor corrective action. When errors are repeated sequentially, or a trend is observed, a formalized corrective action investigation with additional tracking/documentation of actions taken toward prevention or remediation may be necessary, as described in further detail in section 9.

The Peconic Program senior staff, including the Program Manager, and QA Officer, obtain information on how the overall quality system is working from verbal or written correspondence from a municipality or agency representative, during meetings with project officers and administrators, or through reports prepared by the agency representatives rating project quality performance.

10.2 Improvement Options

Continuous improvement of the quality system may be carried out by individuals as well as the entire Peconic Program Team. In either case, it is important to analyze the work processes and determine how errors that affected the quality of the product or service occurred. As noted in section 9.3, many corrective actions might be implemented informally on a daily basis to fix problems as they occur. It is also important to consider how changing overall work processes can prevent these problems in the future, decreasing project costs and improving municipality or agency's confidence in the Peconic Program. When process changes are needed, the Program Manager and QA Officer will brainstorm with staff to understand the issues and recommend preventive actions to improve the system. These discussions include consideration of whether and on what level a process must be changed and the potential costs involved in implementing the change versus not implementing the change.

Selected staff might test proposed processes and procedures prior to their office-wide implementation, including promising ways to perform particular tasks, conduct assessments, or document reviews. Results of the testing are examined to determine success or whether additional changes are necessary.

When it is certain that new work processes should be implemented office-wide, managers and staff are informed of the changes through distribution of written materials and participation in training sessions. As the changes take place, agency satisfaction is monitored and staff are rewarded appropriately. The adoption of changes might go through a number of iterations. As more staff become involved, additional insights might contribute to further improvement in the processes.

10.3 Documentation for Quality Improvement

The Program Manager and QA Officer maintain quality system audit reports, memoranda, correspondence with Peconic Program staff, correspondence with the agency, notes taken during annual project review meetings, and other written documentation. When significant changes to the quality system have been recognized, they are documented in a revised QMP. Formal QMP evaluation documentation is prepared concurrent only with the annual management system reviews. The QMP is, however, continually evaluated and assessed between the management reviews every time a response to an agency solicitation is prepared. During development of formal proposals, responses to solicitations, or consideration of technical approaches for bid response requests, it is common for the QMP to be reviewed for applicability and discussed or attached as evidence of the quality system. These responses reflect a review of the QMP and its representativeness of current work practices and quality system implementation procedures.

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Attachment

Quality Assurance Project Plan Template

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1.0 TITLE AND APPROVAL SHEET

Quality Assurance Project Plan for Peconic Program Water Quality Monitoring [by Municipality Name]

[Instructions to municipal authors: Example text is provided throughout this QAPP. This text should be updated to address the needs of the project.]

Prepared by:

Peconic Estuary Protection Committee
300 Center Drive, Room 204N
Riverhead, NY 11901

Peconic Estuary Partnership
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Cornell Cooperative Extension of Suffolk County
Extension Education Center
423 Griffing Avenue, Suite 100
Riverhead, NY 11901

Month XX, 2021

QAPP-2021-V1

This quality assurance project plan (QAPP) has been prepared according to guidance provided in the following documents to ensure that environmental and related data collected, compiled, and/or generated for this project are complete, accurate, and of the type, quantity, and quality required for their intended use:

- *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5, EPA/240/B-01/003, U.S. Environmental Protection Agency, Office of Environmental Information, Washington DC, March 2001 [Reissued May 2006])
- *Guidance for Quality Assurance Project Plans* (EPA QA/G-5, EPA/240/R-02/009, U.S. Environmental Protection Agency, Office of Environmental Information, Washington DC, December 2002.
- *USEPA Region 2 Guidance for the Development of Quality Assurance Project Plans* (U.S. Environmental Protection Agency Region 2, Air and Water Quality Assurance Team, Edison, NJ, April 2004).

The Peconic Program and municipalities performing sampling will conduct work in conformance with the quality assurance program described in this QAPP.

This publication was fully funded by the County of Suffolk Department of Economic Development and Planning, Division of Water Quality Improvement, through the Water Quality Protection and Restoration Program.

Approvals:

Patricia Aitken
Program Manager
Peconic Program

Date

Scott Curatolo-Wagemann
Quality Assurance Officer
Peconic Program

Date

Nancy Pierson
Deputy Quality Assurance Officer
Peconic Program

Date

[Municipality Name]
Project Manager
Peconic Program

Date

[Municipality Name]
Quality Assurance Coordinator
Peconic Program

Date

[* If providing grant funding, include signature lines for the New York State Department of Environmental Conservation Project Officer and Quality Assurance Officer, and/or the U.S. Environmental Protection Agency Region 2 Air and Water Quality Assurance Team Leader. When a separate approval sheet is provided by the funding agency, it will be inserted into the final QAPP document after the signature page.]

Document Revision History

QAPP Submittal	Summary of Edits Received/Changes Made
Draft QAPP submitted to the Peconic Program* for Review on [Date]	

[* If providing grant funding, submit QAPP to the New York State Department of Environmental Conservation Project Officer and Quality Assurance Officer, and/or the U.S. Environmental Protection Agency Region 2 Air and Water Quality Assurance Team Leader.]

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Acronyms and Abbreviations

DQI	data quality indicator
DQO	data quality objective
EPA	U.S. Environmental Protection Agency
GPS	global positioning system
IDC	initial demonstration of capability
IDP	initial demonstration of proficiency
NELAC	National Environmental Laboratory Accreditation Conference
NELAP	National Environmental Laboratory Accreditation Program
PDF	portable document format
PEPC	Peconic Estuary Protection Committee
QA	quality assurance
QAPP	quality assurance project plan
QC	quality control
QL	quantitation limit
RL	reporting limit
RPD	relative percent difference
SM	Standard Methods for the Examination of Water and Wastewater
SOP	standard operating procedure

3.0 DISTRIBUTION LIST

This document will be distributed to the following U.S. Environmental Protection Agency (EPA), Peconic Estuary Protection Committee, Peconic Estuary Partnership, and Cornell Cooperative Extension of Suffolk County staff involved in this project.

[Please add names of staff who will be responsible for sampling, as well as other collaborators and stakeholders.]

Name	Contact Information	Mailing address or regional office
U.S. Environmental Protection Agency (EPA) Region 2 [include if agency is providing grant funding for your project]		
Aimee Boucher Project Officer	212-637-3837 boucher.aimee@epa.gov	U.S. Environmental Protection Agency Region 2 Water Division, Watershed Management Branch, New York Water Management Section 290 Broadway, 24th Floor New York, NY 10007
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New York State Department of Environmental Conservation [include if agency is providing grant funding for your project]		
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Name	Contact Information	Mailing address or regional office
		360 Yaphank Avenue, Suite 2B Yaphank, NY 11980
Municipality Name		
[Name] Project Manager	Phone # Email	Address
[Name] Quality Assurance Officer	Phone # Email	Address

The purpose of the project organization is to provide involved parties with a clear understanding of the role that each play in the project and to provide lines of authority and reporting for the project. This section describes the overall organization of the water and sediment quality monitoring program for the Peconic Estuary Protection Committee (PEPC), including its members and collaborators; the Peconic Estuary Partnership; and Cornell Cooperative Extension of Suffolk County (herein referred to collectively as the Peconic Program).

The organizational chart for the Peconic Program is structured as follows:

- Quality Management Steering Committee** (top level)
- Peconic Program Program Manager** (Patricia Aitken)
 - Municipal Agency Project Manager**
 - Municipal Agency Technical Staff**
 - Contractor Project Manager**
 - Other Technical Staff**
- Peconic Program QA Officer** (Scott Curatolo-Wagemann, Cornell Cooperative Extension)
 - Deputy Peconic Program QA Officer** (Nancy Pierson, Suffolk County Department of Health Services)
 - Municipal Agency Project QA Officer**
 - Municipal Agency Project QC Officer**
 - Contractor QA Coordinator**
 - Other QA/QC Staff**

External entities and their roles are listed in separate boxes:

- USEPA**
 - Aimee Boucher: Project Officer, Water Division, Watershed Management Branch, New York Watershed Management Section, USEPA Region 2
 - Carol Lynes: Team Leader, Air and Water Quality Assurance Team, USEPA Region 2, LSASD-MAB
- NYSDEC**
 - RoseAnn Garry: NYSDEC Quality Assurance Officer, Water Quality Standards and Analytical Support Division of Water (USEPA Region 2 Delegated QA approval authority)

Legend:

- Lines of Communication
- Project Management Authority
- QA Program Authority

Figure 5. Project Organization

Table 1. Key Personnel Titles and Areas of Responsibility [Example text is provided in this table. Please update titles and descriptions, as needed.]

Title	Description of Duties/Responsibilities
USEPA Region 2 Project Officer	If grant funding is being provided by EPA, the EPA Region 2 Project Officer will review and approve the QAPP and will provide overall project oversight.
USEPA Region 2 QA Officer	If grant funding is being provided by EPA, the EPA Region 2 QA Officer will review and approve the QAPP and participate in any Agency quality reviews of the project.
New York State Department of Environmental Conservation (NYSDEC) QA Officer	If grant funding is being provided by NYSDEC, the NYSDEC QA Officer will review and approve the QAPP and participate in any NYSDEC quality reviews of the project.
Peconic Program Manager	The Peconic Program Manager will provide overall project and program oversight. She will review and approve materials developed to support the project. The Peconic Program Manager will provide oversight for all technical aspects of this project and adherence to project objectives. She will also coordinate with stakeholders, collaborators, reviewers, and others to ensure technical quality in all work products.
Peconic Program Estuary QA Officer	Before field sampling begins, the Peconic Program QA Officer reviews the QAPP to make sure it specifies appropriate field procedures, proper analytical methods, and quality requirements that are consistent with project objectives and subsequently approve the QAPP. He trains field personnel if necessary. The Peconic Program QA Officer maintains the official approved QAPP. After each field sampling event, the he reviews field data sheets, calibration records, laboratory reports, and other documentation to see if quality criteria specified in the QAPP were achieved.
Municipal Agency Project Managers	The Municipal Agency Project Managers directly supervise all field activities and are responsible for ensuring that field activities are carried out and documented in a manner that is consistent with the procedures and quality requirements specified in the QAPP.
Municipal Agency Project QA Officers and QC Officers	The Municipal Agency Project QA Officers work with the Municipal Agency Project Managers to identify and correct deficiencies in protocols, techniques, or documentation and to ensure compliance with the QAPP. The Municipal Agency QC Officers are responsible for performing evaluations to ensure that QC is maintained throughout the sampling process, that the data collected will be of optimal validity and usability, and that limitations of the data set are minimized as much as is possible. The Municipal Agency Project QC Officers will provide a second-level review of all documentation and records developed during the sample and data collection process. The QC evaluations will include doublechecking work as it is completed and providing written documentation of these reviews (minimally initialing and dating documents as they are reviewed) to ensure that the standards set forth in the QAPP are met or exceeded.
Contractor Laboratory Manager	The Contractor Laboratory Manager will oversee water quality analyses for this project. He or she oversees the preparation of the necessary field sampling kits. The Contractor Laboratory Manager oversees the receipt, inspection, test assignment, sample logging, and distribution of samples to laboratory departments. The Contractor Laboratory Manager serves as the primary point of contact for water quality analyses for this project.

Title	Description of Duties/Responsibilities
Contractor Laboratory QA Coordinator	The Contractor Laboratory QA Coordinator will review and approve the project QAPP and oversee its implementation. He or she will work with the analytical staff to ensure QC activities and quality assessments are conducted during sample preparation and analysis. The Contractor QA Coordinator communicates QC deficiencies, if appropriate, and oversees any necessary corrective action investigation, remedy selection, implementation and verification in collaboration with the Contractor Laboratory Manager and Peconic Program QA Officers, where appropriate. He or she will work closely with analytical laboratory staff to ensure implementation of the approved QAPP, conduct internal and project-specific QC reviews, and provide input into QA status as appropriate for QA reports while samples are being analyzed.

The technical and project management teams and their quality systems support staff will communicate regularly, as may be appropriate throughout the period of performance. Some tasks will require broader engagement of the project team, while more specific tasks will engage a more focused management and communication organization

5.0 SPECIAL TRAINING OR CERTIFICATION

All sample collectors must be trained by a competent training program. Sampling collector training records will be stored in the project files at the Peconic Estuary Partnership's Office in Riverhead, New York.

[Please include a description of any safety training that is required for field personnel here.]

Under the current NELAC standards, all laboratory assessments include reviews of staff training and proficiency demonstration records. As such, training and proficiency demonstration are part of the routine laboratory quality system and are not considered special or outside of the normal laboratory operations. No additional training or certification is required for performing analysis of water and sediment samples in support of the Peconic Program's water quality monitoring program.

6.0 PROBLEM DEFINITION/BACKGROUND

6.1 Problem Definition

The overall goals and objectives of this project are to conduct water and sediment sampling and analyses of samples collected from the Peconic Estuary. The results of this sampling and analysis effort will be used to accurately identify and prioritize subwatersheds in the Peconic Estuary that should be targeted for water quality improvement activities, and help the PEPC members and partners assess the current baseline in water quality, and effectiveness of water quality improvement interventions over time. The following field measurements will be collected at marine stations:

A. In situ:

- Temperature

- Salinity/conductivity
 - Dissolved oxygen
 - pH
- B. Collection and handling of water samples for laboratory analysis by others:
- Fecal coliform
 - Nitrogen (total nitrogen, ammonia, nitrate, nitrite, total Kjeldahl nitrogen)
- C. Collection and handling of sediment samples for laboratory analysis by others
- Nitrogen
 - Sediment organic matter
- D. Additional parameters will include, but not necessarily be limited to:
- Continuous measurements and collection of water samples at 2-3 depths (if possible) for in situ parameters

6.2 Background

Water quality and sediment monitoring is essential to assess the health of the Peconic Estuary and to help determine if management goals are being reached. The Peconic Program supports a year-round long-term periodic sampling program conducted by the Peconic Estuary Partnership. The Peconic Estuary Partnership's water quality sampling provides excellent spatial coverage of the estuary and its freshwater tributaries

A continuous sampling program is also conducted by the United States Geological Survey (USGS). The two water quality sampling programs complement each other and together provide a great resource for understanding the Peconic Estuary.

Monitoring data are essential to assess the health of the Peconic Estuary and to help determine if management goals are being reached.

Suffolk County Bureau of Marine Resources Water Quality Sampling

Suffolk County Bureau of Marine Resources has routinely monitored the water quality of surface and marine waters in the Peconic Estuary since 1977. On a monthly basis, 38 marine locations in main bays and peripheral embayments, and an additional 26 stream and point source sites in the Peconic Estuary are sampled from boats or from shore to assess status of the Peconic Estuary. Field measurements are collected to document seasonal variability and trends in the waterbodies being measured.

- Depth (feet)
- Secchi (feet)
- Temperature (°C)
- Dissolved oxygen (mg/L)
- Salinity (psu) / Conductivity (µS/cm)
- Light attenuation
- pH

- Tide
- Weather
- Water color
- General phytoplankton

Water samples are collected at the marine stations for analyses of the parameters, including the following:

- Coliform (MPN/100 mL)
- Nitrogen (NH₃, NO₂, NO₃, TKN, TN) (mg/L)

USGS Continuous Water Quality Sampling

In 2012, the Peconic Program and Suffolk County partnered with USGS to install two continuous monitoring stations in the Peconic Estuary, one located at the mouth of the Peconic River under the County Road 105 bridge in Riverhead and one in Orient Harbor. At 6-minute intervals, ocean and estuary elevation, water temperature, specific conductivity, salinity, dissolved oxygen, turbidity, chlorophyll, sampling depth and pH are measured. A nitrate analyzer measures nitrate in the water column every 30 minutes.

Additional Monitoring

Since 1997, the Cornell Cooperative Extension (CCE) of Suffolk County has monitored eelgrass survival and bed expansion resulting from previous habitat restoration efforts. Currently, the CCE conducts long-term monitoring at thirteen sites within the Peconic Estuary. Nine of those sites are monitored annually and four of those sites (that no longer support eelgrass) are monitored every 2-3 years.

Since 2003, the Peconic Estuary Partnership has been monitoring the atmospheric deposition of nitrogen in the Peconic Estuary watershed through its participation in the National Atmospheric Deposition Program (NADP). This monitoring is essential to understanding the amount of nitrogen entering the estuary through atmospheric deposition and helps inform nitrogen management policies and goals. The Suffolk County Department of Health Services Bureau of Marine Resources conducts weekly monitoring at the NADP rain and atmospheric deposition gage at Cedar Beach, Southold, New York.

The Peconic Estuary Partnership measures surface elevation of the salt marsh at Indian Island County Park. There are six surface elevation tables at the site to measure marsh accretion or subsidence, natural processes that may be influenced by sea-level rise, changes in sediment loading, increasing temperatures, and other consequences of climate change. Monitoring is conducted twice annually, once in the spring and once in the fall.

7.0 PROJECT/TASK DESCRIPTION

The purpose of this project is to collect and analyze water and sediment quality samples in the Peconic Estuary. The results of this sampling and analysis effort will be used to accurately identify and prioritize subwatersheds in the Peconic Estuary that should be targeted for water quality improvement activities, and help the PEPC members and partners assess the current

baseline in water quality, and effectiveness of water quality improvement interventions over time.

The study area is shown in Figure 2 and coordinates are provided in Table 2. [Please provide a description and map of the sampling locations and a table of coordinates]

Placeholder Figure 2

Table 2. Placeholder for sample location coordinates

Sample Location Identifier	Latitude	Longitude

[Please provide a detailed description of tasks to be performed for this project; some examples of tasks are provided below.]

Task 1. Develop Quality Assurance Project Plan (QAPP)

The [municipality name] has developed this QAPP in accordance with *EPA Requirements for Quality Assurance Project Plans* (USEPA 2001), *USEPA's Guidance for Quality Assurance Project Plans* (USEPA 2002), and *USEPA Region 2 Guidance for the Development of Quality Assurance Project Plans* (USEPA 2004). The [municipality name] will submit a draft version of the QAPP to the Peconic Program for review. After addressing comments on the draft QAPP, the [municipality name] will submit the final version of the QAPP to the Peconic Program for approval.

When grant funding is provided, the Peconic Program will submit the QAPP to the appropriate funding agency (NYSDEC and/or USEPA Region 2) for review. After addressing comments on the draft QAPP, the Peconic Program will submit the final version of the QAPP to the funding agency for approval.

Task 2. Preparation for Field Sampling

The Municipal Samplers will obtain all needed sampling equipment and supplies by one week before each sample event. The Municipal Samplers will inspect and organize the sampling equipment and supplies before the sampling event begins. In addition, the Municipal Samplers will contact the laboratory several days before the sampling event regarding the anticipated sample delivery schedule.

Task 3. Collection of Water and Sediment Samples

The Municipal Samplers will collect in situ measurements, as well as water and sediment samples at the locations shown in Figure 2 and provided in Table 2. Field teams will be staffed by at least two trained sampling personnel. Water quality samples will be collected directly into pre-labeled sample bottles at [0.X] meters below the surface. Municipal Samplers will collect surficial sediment samples (top 5 cm) at the index site using the supplied gravity corer. A corer is

used to collect two intact sediment core samples at the index site, crews will slice off the top 5 cm from these two sediment cores and composite them for analysis. The laboratory will analyze this composite sample for all forms of nitrogen and sediment organic matter. Duplicates will be collected at [10%] of sites.

All sampling will be performed in accordance with the [municipality name's] protocols and the analytical laboratory's requirements.

Task 4. Analysis of Water and Sediment Samples

After collecting water quality samples, the Municipal Samplers will ensure they are preserved as needed (refer to Section 12.0 of this QAPP for details) and will place them in coolers on ice. Sediment cores will be transferred to clean glass bottles and placed in coolers. The Peconic Program will prepare chain-of-custody forms and ensure that the samples are delivered to the analytical laboratory within holding times and kept within temperature requirements until delivery to the laboratory. Analysis of water and sediment samples will be conducted according to the laboratory methods described in Section 11.1 of this QAPP.

Task 5: Reports

Summary reports will be prepared. The report will include the scope, procedures, and findings of data quality assessments in addition to summary tables of qualified analytical results, as appropriate. The reports will provide data for use in accurately identifying and prioritizing subwatersheds in the Peconic Estuary that should be targeted for water quality improvement, and help the PEPC members and partners assess the current baseline in water quality, and effectiveness of water quality improvement interventions over time.

The general time schedule for project deliverables is presented in Table 3. Project activities include determining the sample locations; producing and then finalizing the QAPP; conducting the sampling events; and writing draft, draft final, and final sampling event reports.

Table 3. Example Schedule of Sampling Support Tasks

Action/Deliverable	Due Date
Draft QAPP	Date
Final QAPP	2 weeks after receiving comments from the Peconic Program*
Obtain sampling equipment and supplies	One week before each sampling event
Contact analytical laboratory regarding anticipated sample delivery schedule	Two days before each sampling event
Conduct sampling events	As required by the sampling program
Deliver samples to analytical laboratory	Within required holding times
Prepare sampling reports	Date

*Note: When grant funding is received, the Peconic Program will submit the final QAPP to the corresponding funding agency (NYSDEC and/or EPA Region 2) in 2 weeks after receiving comments from the funding agency.

8.0 QUALITY OBJECTIVES AND CRITERIA FOR MEASUREMENT DATA

8.1 Project Quality Objectives

Data of known and documented quality are essential to the success of any monitoring or surveying program. Data quality objectives (DQOs) are qualitative and quantitative statements that clarify the intended use of the data, define the type of data needed to support the decision, identify the conditions under which the data should be collected, and specify tolerable limits on the probability of making a decision error due to uncertainty in the data (USEPA 2006). DQOs are developed by data users to specify the data quality needed to support specific decisions. Sources of error or uncertainty for surveying and analysis activities include the following:

- Survey error: The difference between survey values and *in situ* true values from unknown biases due to collection methods and survey design,
- Measurement error: The difference between survey values and *in situ* true values associated with the measurement process,

Discussion of data quality indicators (DQIs) is provided in Section 8.2. Methods and procedures described in this document are intended to reduce the magnitude of the sources of uncertainty (and their frequency of occurrence) by applying the following approaches:

- Use of demonstrated, standardized analytical techniques, procedures, and methods for physical and chemical analysis.
- Use of trained field staff and laboratory microbiologists to perform the investigation.
- Use of global positioning system (GPS) coordinates to record the actual sampling locations for future reference purposes and to ensure that the correct locations are sampled.
- Use of appropriate calibrated equipment to obtain data.
- Use of QC samples (field duplicates, 10 percent of the total samples)

Municipal Samplers will adhere closely to laboratory custody requirements. Scientific staff collecting and processing samples in the field will initiate custody records during collection that will accompany samples to the laboratories and be maintained throughout the preparation and analysis processes.

8.2 Measurement Performance Criteria

Measurement performance criteria are quantitative statistics that are used to interpret the degree of acceptability or utility of the data to the user. These criteria, also known as DQIs, include the following:

- precision,
- accuracy (bias),
- representativeness,
- completeness, and
- comparability.

In accordance with project requirements, field and laboratory standard operating procedures (SOPs; Attachments 1 and 2), and basic good laboratory practice, a series of QA/QC assessments will be performed throughout the analytical process. These tests include negative controls, as well as field duplicates. Further discussion of quality characteristics is included in the following section of this plan, as well as the summarized QC activities that support their assessment.

8.2.1 Precision

Precision is a measure of internal method consistency. It is demonstrated by the degree of agreement between individual measurements (or values) of the same property, pollutant or indicator, measured under similar conditions. Precision of laboratory analyses is estimated by splitting an individual field sample for analysis. Precision of field sampling methods is estimated by taking duplicate samples for analysis. This QC calculation for field duplicates also addresses uncertainty due to natural variation and sampling error.

Precision is assessed by calculation of relative percent difference (RPD) between two measurements using the following equation:

$$RPD = \frac{(\text{sample result} - \text{duplicate result})}{(\text{sample result} + \text{duplicate result})/2} \times 100$$

The equation is readily described as the absolute difference between two measurements divided by the mean.

Precision of laboratory analyses will be assessed by performing duplicate analyses on 10 percent of all water and sediment samples submitted to the laboratory for each field survey.

8.2.2 Accuracy (Bias)

Accuracy is defined as the degree of agreement between an observed value and an accepted reference or true value. Negative controls (i.e., laboratory dilution blanks, field [bottle] blanks), are analyzed with each batch of samples received.

Negative controls (field and laboratory blanks) demonstrate bias (contamination) associated with sample bottles or technique, and analytical process, and their potential effect on sample measurements. If positive controls are used, results are evaluated through calculation of percent recovery (%R) computed using the following formula:

$$\%R = \frac{\text{analytical result}}{\text{true value}} \times 100\%$$

Where *analytical result* is the measured value and *true value* is the known concentration of constituent in the positive control sample.

Acceptance criteria for the constituents for this project are included in Table 7.

Precision and accuracy are key indicators of laboratory performance, and laboratories include a number of additional QC checks and analyses in their routine operations. Laboratory method SOPs (Placeholder - include laboratory SOPs in Attachment 2) and specific laboratory implementation may include more frequent blank analyses in its routine operation or prepare control samples at multiple levels as part of their quality system implementation, but minimum requirements for positive and negative controls and spiked samples, laboratory duplicates or duplicate spiked samples are generally defined at the batch level, and most methods define a batch as 20 field samples or less.

8.2.3 Representativeness

Data representativeness is defined as the degree to which data accurately and precisely represent a characteristic of a population, parameter, and variations at a sampling point; a process condition; or an environmental condition. It therefore addresses the natural variability or the spatial and temporal heterogeneity of a population. The Peconic Program will compare results of measured environmental concentrations. Detailed knowledge of the area based on Peconic Estuary monitoring data collected since 1977 was used to select appropriate sites and stations for monitoring.

8.2.4 Comparability

Comparability is an expression of the confidence with which one data set can be compared with another. For the current data collection activities, comparability is dependent on the proper design of the survey program and on adherence to accepted sampling and analytical techniques, SOPs (Placeholder – include field and laboratory SOPs in Attachments 1 and 2, respectively), and QA guidelines, to allow comparisons of water quality data at different sites. Additional comparability of data can be achieved through similarity in geographic, seasonal, and sampling method characteristics. Comparability for analysis of samples will be accomplished by utilizing demonstrated and documented techniques and procedures in the laboratory SOPs, and adherence to the program QA guidelines.

8.2.5 Completeness

Completeness ensures the statistical power supporting the sample design. To optimize completeness for this data collection project, every effort will be made to avoid data loss. Data loss is managed through consistent use of standardized, documented procedures, incorporation of appropriate QC activities and analyses, and implementation of the approved quality guidance. Completeness (%C) is evaluated by dividing the total number of valid measurements taken (v) by the total number of measurements planned (T):

$$\%C = \frac{v}{T} \times 100$$

A completeness goal of no less than 95% [some studies use 90%] is recommended for results to for use in accurately identifying and prioritizing subwatersheds in the Peconic Estuary that should be targeted for water quality improvement activities, and helping the PEPC members and partners assess the current baseline in water quality, and effectiveness of water quality improvement interventions over time.

8.2.6 Sensitivity

Sensitivity is essentially the lowest detection limit of the method or instruments for each of the measurement parameters of interest. Technically, sensitivity is the capability of a method or instrument to discriminate between measurement responses representing different levels of the variable of interest (USEPA 2004).

The minimum detection limits for this project are provided in Table 6. The detection limit will allow results to be compared to the corresponding water quality standards or limits [add detection limits to Table 6 – these limits should be provided by the analytical laboratory].

8.3 DQOs for In Situ Measurements

For in situ measurements, the DQOs will consist of successful instrument calibration, instrument stability during the sampling period, and agreement between the initial calibration and post-event calibration verification. For instruments used for instantaneous in situ measurements, calibration will be checked either on site or in the office at the beginning of each day's field measurements with the current day's reading being the calibration check for the end of the previous day. If multiple instruments are used for instantaneous in situ measurements, agreement among separate instruments will be checked by comparing concurrent readings taken from the same sample of water using each instrument. Concurrent readings will be taken at the beginning of each day. Example DQOs for instrument stability and agreement are shown in Table 4.

Table 4. DQOs for In Situ Measurement Stability and Agreement [Use information from user manuals to update this table]

In Situ Parameter	Performance Criteria	
	Instrument Stability	Instrument Agreement
Temperature	No calibration performed	All instruments agree within 0.5 C
Salinity / conductivity		
Dissolved oxygen	Post-sampling DO measurements in water-saturated air are within 1.0 mg/L of theoretical value	All instruments agree within 1.0 mg/L
pH		

An additional DQO for in situ measurements is that they must be reasonable. The Municipal Sampling Team Leader will review in situ measurements for reasonableness at the time the data are collected (i.e., before moving on to the next site). In situ data must be the right order of magnitude and within believable ranges.

9.0 NON-DIRECT MEASUREMENTS (SECONDARY DATA)

No non-direct measurements are anticipated as part of this data collection program; however, it is expected that available data from previous sampling events will be important to assessing results and informing the potential for trends. Secondary data will be limited to those collected by the Peconic Program during previous sampling events, thus it is assumed that those data were subject to the same quality rigor as those in this collection, that they have been evaluated for

quality, and that they have been accepted with documentation of any existing limitations on their use described in narrative reports.

10.0 FIELD MONITORING REQUIREMENTS

10.1 Monitoring Process Design

This section describes the strategy and procedures to be used to collect site information as well as water and sediment quality data. Samples will be collected at the XX sites listed previously in Table 2. Samples will be collected [describe frequency, duration]. The following field measurements will be collected at Peconic Estuary stations:

- A. In situ:
 - Temperature
 - Salinity/conductivity
 - Dissolved oxygen (including membrane-based and optical sensors)
 - pH
- B. Collection and handling of water samples for laboratory analysis by others:
 - Nitrogen (total nitrogen, ammonia, nitrate, nitrite, total Kjeldahl nitrogen)
 - Fecal coliform
- C. Collection and handling of sediment samples for laboratory analysis by others
 - Nitrogen (all forms)
 - Sediment organic matter
- D. Additional parameters will include, but not necessarily be limited to:
 - Continuous measurements and collection of water samples at 2-3 depths (if possible) for in situ parameters

10.2 Monitoring Methods

SOPs for the following field collection activities are provided in Attachment 1 [these are placeholder SOPs – please include the SOPs that should be followed for this project in Attachment 1]:

- Protocol for Measuring Water Quality Parameters Using a Multi-Parameter Water Quality Meter
- Protocol for Collecting Surface Water Samples for Analysis of Fecal Coliform
- Protocol for the Collecting Surface Water Quality Samples for Nitrogen Analysis
- Protocol for Collecting Sediment Samples

Information for collection of additional sample types that might be performed for the Peconic Program will be provided by the corresponding analytical laboratory or municipality.

10.3 Field Quality Control

Municipal Samplers will ensure that replacement bottles and backup equipment are available for field sample collection. Pre-cleaned, laboratory-certified sample collection bottles will be used to collect water samples. Field bottle blanks will be collected for analysis at the frequency designated by the lab or in the field sampling SOP. Table 5 includes some examples of routine QC samples and frequency.

Table 5. Examples of Routine Field QC Samples and Frequencies

Analyte(s)	DQI	Field QC Check	Frequency of Collection	Acceptance Criteria	Corrective Action(s)
	Precision	Field Duplicate	1 per 20 environmental samples analyzed	Describe method requirements	Laboratory to reanalyze; action taken per validation protocols
	Accuracy	Field Blank	1 per 20 environmental samples analyzed	Describe method requirements	Compare to sample results. Laboratory must reanalyze if detection is within 5 times sample values.
	Representativeness, Comparability	Temperature Blank	1 per cooler	Describe method requirements	Action taken per validation protocols

The Municipal Samplers will maintain a record of sample custody and copies of chain-of-custody forms. In addition, Municipal Samplers will ensure the proper labeling of all samples. The distribution of each bottle from each location must be documented on the custody forms. Before sampling visits, Field Forms and Labels (placeholder – please include a copy of the blank field forms and labels in Attachment 3) and chain-of-custody forms (placeholder – please include a copy of the chain-of-custody form in Attachment 4) will be printed by a member of the Municipal Sampling Team. The location, date, and actual collection time, and information about all samples to be collected during that visit will be entered on the forms, by hand (or electronically, before printing). Each cooler used to transport samples from the site to the lab will have a copy of the appropriately completed collection/custody form(s) in it or securely attached to it.

The Municipal Samplers will know in advance how many samples can fit in a cooler and should, therefore, prepare each cooler with space for adequate addition of clean wet ice before going to the field. Additional columns on the chain-of-custody forms include the actual collection time and the time samples arrive at the laboratory. Arrival time at the laboratory can be indicated by

entering a time for the first sample on a custody sheet and drawing a down arrow in the lab arrival time column for the rest of the samples.

A different form (or forms) will be used by the laboratory to record the dates and times of analysis for all methods, steps within methods (when applicable), the dates and time plates or tubes are placed in the water bath or incubator, the dates and time samples are removed from incubation, and the analysis results. There will be spaces for associated initials for each of the sequential steps.

Sample containers will be labeled with water-resistant sample labels (e.g., laboratory tape and a Sharpie). Sample containers may be reused after proper cleaning and reesterilization, or bottles, presterilized by the manufacturer, may be used. If containers are to be reused, labeling should not be permanent but must be able to withstand the rigors of field and laboratory activities. The sample bottles will have IDs that incorporate the sample date and location.

11.0 ANALYTICAL REQUIREMENTS

Laboratory staff will analyze samples in this data collection effort by the methods described in this QAPP and its attachments. Analysts will be proficient in the methods or receive appropriate training. Laboratory staff will provide suitable laboratory facilities for performing the analytical methods in this data collection effort, including facilities for sample storage. Laboratories involved in this project follow all the applicable QA/QC procedures required by NELAC and the methods used for analysis. The laboratory is accredited by NELAC.

11.1 Analytical Methods

The analytical methods to be used and corresponding project action levels and detection limits are presented in Table 6.

Table 6. Example Analytical Method Information [Please update this table with information from the laboratory]

Analyte	Sample Matrix	Analytical Method	Method Detection Limit	Laboratory Reporting Limit
Total nitrogen	Estuarine water			
- Ammonia	Estuarine water			
- Nitrate	Estuarine water			
- Nitrite	Estuarine water			
- Total Kjeldahl nitrogen	Estuarine water			
Total coliform	Estuarine water			
Fecal coliform	Estuarine water			
Total Nitrogen	Sediment			
- Inorganic nitrogen	Sediment			
- Ammonia	Sediment			
- Nitrate	Sediment			
- Nitrite	Sediment			

Analyte	Sample Matrix	Analytical Method	Method Detection Limit	Laboratory Reporting Limit
- Total Kjeldahl nitrogen	Sediment			
Organic Matter	Sediment			

11.2 Analytical Quality Control

For this study, laboratory method blanks will be analyzed at a frequency designated by the laboratory or described in the field sampling SOP. Table 7 includes some examples of QC acceptance criteria. The laboratory staff will maintain a dedicated sample record book that is used to record all sample IDs as samples are checked into the laboratory. The record book will also have columns for date and time of check-in, initials of the person logging in the samples, storage locations, and disposal dates. The laboratory staff will also note in the record book any leaking containers or other irregularities in the samples.

Table 7. Examples of QC Acceptance Criteria [Please update this table with information provided by the laboratory]

Analyte(s)	DQI	Lab QC Check	Frequency of Collection	Acceptance Criteria	Corrective Action(s)
Nitrogen analytes	Accuracy	Laboratory blank	1 per 20 environmental samples analyzed	Describe method requirements	
Nitrogen analytes	Precision	Laboratory duplicate	1 per 10 environmental samples analyzed	30% RSD	
Microbiological indicator	Accuracy	Laboratory Method Blank	1 per 20 environmental samples analyzed	Describe method requirements	Laboratory to reanalyze; action taken per validation protocols
Microbiological indicator	Accuracy	Positive Control	1 per 20 environmental samples analyzed	Describe method requirements	Laboratory to reanalyze; action taken per validation protocols
Microbiological indicator	Precision	Laboratory duplicate	1 per 10 environmental samples analyzed	30% RSD	
Organic matter	Accuracy	Positive Control	1 per 20 environmental samples analyzed	Describe method requirements	Laboratory to reanalyze; action taken per validation protocols
Organic matter	Precision	Laboratory duplicate	1 per 10 environmental samples analyzed	30% RSD	

12.0 SAMPLE HANDLING AND CUSTODY REQUIREMENTS

Sample handling and custody requirements are presented in Table 8 and described further in the laboratory SOPs (placeholder – please include laboratory SOPs in Attachment 2).

Table 8. Examples of Sample Handling and Custody Requirements [Please update/populate this table after receiving method information from the laboratory]

Sample Matrix	Analyte(s)/Parameter(s)	Total # Samples	Sample Volume	Type Container	Sample Preservation	Maximum Allowable Holding Time
Estuarine water	Total nitrogen					
Estuarine water	Ammonia					
Estuarine water	Nitrate					
Estuarine water	Nitrite					
Estuarine water	Total Kjeldahl nitrogen					
Estuarine water	Total coliform					
Estuarine water	Fecal coliform					
Sediment	Total Nitrogen					
Sediment	Inorganic nitrogen					
Sediment	Ammonia					
Sediment	Nitrate					
Sediment	Nitrite					
Sediment	Total Kjeldahl nitrogen					
Sediment	Organic Matter					

Water samples will be collected during daylight hours and the Municipal Samplers will deliver the samples on ice to the analytical laboratory within holding times. Sample custody will be supervised by the Municipal Sampling Team Leader and the analytical laboratory sample custodian. The Municipal Sampling Team Leader will be responsible for assigning personnel for getting the samples delivered on ice to the laboratory. The laboratory sample custodian will be responsible for entry of the sample into the Laboratory Information Management System (LIMS) (sample log-in and analysis system).

Sample Numbering System

Prior to the field survey, the sample bottles will be labeled by the laboratory to indicate which bottles to use for different analyses. At the time of sampling, Municipal Samplers will mark each sample bottle with the site number, date, and time. Samples with a corresponding field duplicate will be identified by taking the site number in Table 2 and appending “A” for the original sample and “B” for the duplicate sample.

Sample Integrity

Sample integrity will be maintained by ensuring that samples remain on ice at all times after collection. The Municipal Samplers will deliver water samples to the analytical laboratory to allow for analysis within prescribed holding times.

Sample Log-in Documents

An example of the sample chain-of-custody form that will be used for the project is provided in Attachment 4 (Placeholder – please add chain-of-custody form to Attachment 4). The laboratory will receive the original chain-of-custody form with the samples arriving from the Municipal Samplers. The laboratory will send a copy of each chain-of-custody form (either a hard copy or an electronic scanned image) to the [Municipal Agency] Project Managers at the same time as the analytical results are reported.

Chain-of-Custody Documents During Sample Transfer

Chain-of-custody forms will be filled out by the Municipal Samplers and one form will accompany each ice chest of samples. The form for the samples in the ice chest will be placed in the ice chest in a sealed plastic bag affixed to the inside lid of the ice chest.

Archiving of Shipping Documents

Copies of chain-of-custody forms will be maintained by the Municipal Sampling Team Leader or designee by placing them in a folder designated for the purpose. In addition, a copy of the original chain-of-custody form received by the laboratory will be included with the laboratory report.

Sample Security

Samples will remain in the possession of sampling personnel or laboratory personnel at all times. The chain-of-custody forms will indicate operator and site number, analyses to be performed, and date and time of sampling. It constitutes the official analysis request for the laboratory. Any special instructions for the laboratory must be included on the form.

All sample containers will be labeled with the parameters to be analyzed (labeled by the laboratory beforehand), site number, and sampling time and date (filled in by the Municipal Samplers). Samples will be placed in the dark, on ice, immediately when collected.

The chain-of-custody documents will include the following information:

1. Sample identification number corresponding to sample identification number on sample containers
2. Date and time of sample collection
3. Method of collection (Grab or composite [presume these will be grabs but this is an option for some samples])
4. Type of sample preservative (sodium thiosulfate can be used for microbiological samples if needed).
5. Type of container for each analyses

6. Requested analyses
7. Chain-of-custody signatures with date and time

13.0 TESTING, INSPECTION, MAINTENANCE AND CALIBRATION REQUIREMENTS

13.1 Instrument/Equipment Testing, Inspection, Maintenance

[Some example text has been included here; it will need to be updated to make it relevant to this project.]

The purpose of this element of the QAPP is to describe procedures used to verify that all instruments are maintained in sound operating condition and are capable of operating at acceptable performance levels. Periodic regular inspection of equipment and instruments is needed to ensure the satisfactory performance of the systems.

Routine operations of instrumentation will produce acceptable calibration and QC results, where frequent failures are observed, or sequential, continuous failures are observed laboratory instrumentation may need to be taken off-line for routine or major maintenance depending on the magnitude and duration of failure. Field SOPs (placeholder – please include them in Attachment 1) include QC criteria for continued use of equipment and often include troubleshooting or regular maintenance procedures that resolve performance issues. Other sources of troubleshooting guidance are included in laboratory QA and instrument user manuals. Because of critical holding time requirements and stringent project deadlines, most analytical laboratories maintain service agreements for their key instruments to ensure limited “down time” and optimize regular operation. Instrumentation that is not meeting performance specification must be taken off-line and marked “DO NOT USE” until it can be demonstrated to perform reliably. After major maintenance, a demonstration of capability including precision and accuracy and MDL studies may need to be repeated before the instrument can be put back into routine use. These requirements are generally set forth in laboratory QA Manuals or Quality Management Plans.

Work for this project involving the acquisition or processing of data and the generation of reports and documents will require the maintenance of computer resources. [Suggest discussing how computers are serviced, how they are protected from viruses, and how files are backed up].

13.2 Instrument/Equipment Calibration and Frequency

Temperature measurement devices will be National Institute of Standards and Technology (NIST) certified or will be verified against and calibrated to an NIST thermometer. If a non-NIST device is used, any variability between the deployed measurement device and the NIST thermometer will be marked on laboratory tape and affixed to the device at the ranges anticipated during use.

Field observations and other notes pertaining to the environmental settings will be recorded in a field log or notebook. These ancillary observations and measurements are included to gain an understanding of the condition and variability in the current data collection effort framework.

All the requirements included in the approved laboratory methodology are implicit. Laboratory measurement systems must be calibrated, verified stable, and continually assessed for measurement system performance. Analytical measurement system requirements, including demonstrations of capability or performance (IDC or IDP), annual method detection limit demonstration, ongoing precision and recovery through analysis of laboratory control samples, and routine blank, duplicate, and spike sample analyses are required at the frequency and within the specifications of the reference methods and laboratory SOPs (Attachment 2 – placeholder – please add laboratory SOPs to Attachment 2).

13.3 Inspection/Acceptance of Supplies and Consumables

Supplies and consumables are those items necessary to support the sampling and analytical operation, including sample containers, decontamination supplies, and various types of growth media. The responsible receiving laboratory will order and store all supplies and consumables. Upon delivery of supplies, the laboratory staff will ensure that the type and quantities of supplies received are consistent with what was ordered and with what is indicated on the packing list and invoice for the material. The staff will contact the supplier immediately if they find any discrepancies.

While preparing for sampling, the Municipal Samplers will be responsible for acquiring and inspecting materials that will be used in obtaining the samples and field measurements. Sample containers containing visible traces of water will not be used to collect samples. Other materials must also meet specific requirements as indicated by the appropriate manufacturer.

All media and reagents prepared will be routinely tested for sterility. The goal is to have a clear association of all microbiological data with specific lots of all materials employed in performing analyses.

14.0 DATA MANAGEMENT

Samples will be documented and tracked via field data sheets, sample identification labels, and chain-of-custody records from collection through analysis. Samples will be retained by the laboratory following analyses pending review and acceptance of laboratory results. Municipal Samplers will be responsible for completing custody records and field data sheets and providing activity-specific metadata to the Peconic Program Manager.

Sample custodians in the receiving laboratory will be responsible for ensuring completion and accuracy of custody records for samples generated in the laboratory and for bench sheets completed during the various assessments. Copies of these forms will be maintained by the [Municipal Agency] Project Managers in the project files. Data entered into any spreadsheet or other format will be manually checked by another person against the original source to ensure accurate data entry. If there is any indication that requirements for sample integrity or data quality have not been met, the Peconic Program QA Officers will be notified immediately (with an accompanying explanation of the problems encountered).

Laboratory data will be managed in accordance with established protocols and will be submitted to the Peconic Program in electronic database format as well as scanned hardcopy data packages

either transmitted electronically or made accessible through on-line data access from the laboratory data system. The electronic data will be submitted in a format to be negotiated with the lab, but will follow a generalized minimum file specification, as listed below [these are commonly used fields below, but please updated as needed].

- Project
- Site ID
- Field Sample ID
- Lab Sample ID
- Matrix
- Method
- Sample Date and Time
- Preparation Date and Time
- Analysis Date and Time
- Percent Solids
- Result
- Units
- Dilution Factor
- Reporting Limit
- Dilution Qualifier
- Laboratory Qualifier
- Comments

All data reported will be qualified by the laboratory in a manner consistent with the guidance established in their standard procedures.

Electronic data packages will be submitted by the analytical laboratory to the [municipality name] in a timely manner. The [municipality name] will provide a copy of the electronic data packages to the Peconic Program in a timely manner. All reports will be paginated, fully validatable raw data packages including an analytical narrative with a signed certification of compliance with this QAPP and all method requirements; copies of chain-of-custody forms; sample inspection records; laboratory sample and QC results; calibration summaries; example calculations by parameter; and copies of all sample preparation, analysis, and standards logs adequate to reconstruct the entire analysis. The on-line electronic copy of the full report will include a full copy of the paginated report scanned and stored in portable document format (PDF) for potential future submission to the client, supporting final reports, and for long term storage in the project files.

15.0 ASSESSMENT/OVERSIGHT

The QA program under which this project will be performed could include audits, with independent checks of the data obtained from sampling, analysis, and data-gathering activities. The essential corrective action steps in the QA program for addressing any problems that could occur during the project are as follows:

- Identify and define the problem.
- Assign responsibility for investigating the problem.

- Investigate and determine the cause of the problem.
- Identify the corrective action.
- Assign and accept responsibility for implementing appropriate corrective action.
- Establish the effectiveness of and implement the corrective action.
- Verify that the corrective action has eliminated the problem.

Many of the technical problems that might occur can be solved on the spot by the staff members involved; for example, by modifying the technical approach, repairing instrumentation that is not working properly, or correcting errors or deficiencies in documentation. Immediate corrective actions form part of normal operating procedures and are noted in records for the project. Problems not solved this way require more formalized, long-term corrective action.

If quality problems that require attention are identified, the laboratory Project Manager and [Municipal Agency] Project Managers will determine whether attaining acceptable quality requires short- or long-term actions. If a failure in an analytical system occurs (e.g., performance requirements are not met), the appropriate laboratory QA Officer and section supervisor will be responsible for corrective action and will immediately inform the laboratory Project Manager and [Municipal Agency] Project Managers.

Corrective actions could include resampling, reanalysis, etc. [consider what corrective actions might be performed]. The [Municipal Agency] Project Managers and QA Officers, and laboratory Project Manager and QA Officer have primary responsibility for monitoring the activities of this project and identifying and verifying that any quality problems are sufficiently investigated, that appropriate solutions are evaluated, and that corrective actions are implemented, verified to be adequate to address the problem(s), and documented in project reports.

Failure to meet any QC requirements requires that appropriate corrective actions be taken. All major QC failures and associated corrective actions (and their effectiveness) will be documented on a corrective action form [consider developing a form that documents this information]. Laboratories routinely use similar, “Nonconformance Memos” which are more specialized toward their core business. Data associated with QC problems will be clearly identified in such reports, along with an assessment as to the potential effects(s) of the QC failure on data quality. The laboratory Project Manager or QA Officer will notify the [Municipal Agency] Project Managers of such problems/corrective actions as soon as possible after the actual occurrence.

16.0 DATA REVIEW, VERIFICATION, VALIDATION AND USABILITY

Data review, validation, and verification provide methods for determining the usability and limitations of data and provide a standardized data quality assessment.

Data assessment is the process of using results from verification and validation steps in conjunction with any other information known about the data collection event to determine overall data usability. Results of the data assessment are compiled into a Data Usability

Assessment Report (DUAR) which helps inform data users' on whether the collected environmental information meets their project objectives.

The laboratory QA Officer will be responsible for reviewing and approving data deliverables before releasing results to the [Municipal Agency] Project Managers. The [Municipal Agency] Quality Assurance Officer will be responsible for verifying and reviewing at least 10 percent of the entries received in laboratory deliverables, for verifying the quality of the data, and ensuring that laboratory QA and QC procedures are effectively managed throughout the data collections. In addition, the [Municipal Agency] Quality Assurance Officer will perform reviews of field and meta data.

16.1 Data Review, Verification, and Validation

Data quality will be assessed by comparing entered data to original data or by comparing analytical results with the performance criteria summarized in Section 8.2 to determine whether to accept, reject, or qualify the data. No data will be rejected outright without consultation with the Peconic PM. As laboratory data will be transferred electronically, the 10% review sufficiently represents verification of the data transfer process in the laboratory.

All data which require transfer to an electronic database will be reviewed initially by someone other than the person who prepared the electronic file, and all discrepancies (100%) will be resolved. Such data will also be evaluated for (1) data representativeness, (2) data comparability, and (3) data completeness during these reviews. The laboratory will provide a hardcopy data package including, but not limited to: a summary report of the parameters analyzed, concentrations detected, units of measure, QC measures (data qualifiers), and associated QC sample results (including all laboratory QC [negative controls: field and laboratory blanks, as appropriate; and positive controls: control samples, spiked blanks or commercially prepared and procured standard reference materials] and other sample QC and associated QC summaries of surrogate and internal standard recoveries, blank association, and any additional supporting observations from laboratory staff. The data package should also include an analytical narrative describing any analyses that did not meet established internal acceptance criteria, project measurement criteria and DQOs, and a professional assessment of their impact on data usability. The [Municipal Agency] Quality Assurance Officer will examine the data package for compliance with chain-of-custody procedures, holding time limits, and for reporting of method calibration, initial/ongoing QC results, blank results, and QC charts and limits, if appropriate.

[Describe who will review the following data and how it will be performed; some example text is provided following these lists]

Field

- Monitoring performed per SOPs (placeholder – include field SOPs in Attachment 1) or QAPP
- Samples properly preserved in the field
- Field QC samples collected
- Chain of custody maintained

- Deviations from QAPP/SOPs documented

Lab

- Data entry and transcription errors
- Calculation/reduction errors
- Holding time limits met
- Lab QC samples analyzed
- Deviations from QAPP/SOPs (placeholder – include lab SOPs in Attachment 2) documented
- Proper sample storage
- Missing samples documented

The laboratory QA Officers or designee will be responsible for reviewing data entries and transmittals for completeness and correctness based on the original data sheets and will verify calculation of appropriate dilution reporting. These verifications generally occur within the operational groups collecting measurement data and are reviewed further by supervisory or QA staff. Data quality will be assessed by comparing entered data with original data or by comparing results with the measurement performance criteria (accuracy and precision) summarized in Section 8.2 of this QAPP to determine whether to accept or qualify the data based on those requirements. Recommendations for any rejected data, if appropriate, will also be documented in the laboratory final reports including the reason for the recommendation. Final decision on data acceptance, qualification, or rejection are the responsibility of the [Municipal Agency] Project Managers in subsequent review and usability assessment.

Data that do not meet the requirements described in this QAPP and its attachments will be identified. The [Municipal Agency] Project Managers will make the final determination to reject data. If fewer than 90 percent of the data are judged valid (completeness requirement), statistical procedures and best professional judgment will be applied to verify whether the remaining data will make it possible to draw the correct conclusions. Limitations in the data set will be described in the final reports (DUARs) prepared for the project.

The laboratory Project Manager and laboratory QA Officer will review all field data sheets and chain-of-custody records accompanying samples to the laboratory. Any discrepancies in the records will be reconciled with the [Municipal Agency] Project Managers who will communicate with the appropriate field or laboratory personnel. Fully reconciled field data sheets and custody records will be transmitted to the [Municipal Agency] Project Managers. The [Municipal Agency] QA Officer, or designee, will check records to ensure that they are complete and accurate, that samples are being appropriately identified in the laboratory and inspected on receipt, and that holding times for the samples have not been exceeded.

The laboratory Project Manager or QA Officer will report violations of holding times to the [Municipal Agency] Project Managers immediately upon discovery. The [Municipal Agency] Project Managers and QA Officers will collaborate on available corrective action options before issuing a technical directive to the laboratory Project Manager. Calculations of precision, accuracy, and completeness will be performed as soon as possible following completion of the sample collection and analyses. The validation and verification of the laboratory measurement

parameters will primarily be the responsibility of the laboratory Project Manager with verification by the laboratory QA Officer.

The [Municipal Agency] Project Managers will inspect forms to see that all appropriate data fields have values entered and that entries are legible and reasonable, they will also ensure that all planned samples have been collected, and that all planned surveys have been performed. The [Municipal Agency] Project Managers are ultimately responsible for seeing that all forms are present and that they are delivered to the laboratory.

Transmission of deliverables is the de facto indicator that the data were completely reviewed and believed to be accurate. Tetra Tech personnel responsible for reviewing the data will never be the person who originally keyed in the data. Raw data received in hard copy format will be entered into the standard database. All entries will be compared to the original hard copy data sheets by the team personnel. Screening methods will be used to scan through the database and flag data that are outside typical ranges for a given parameter. Data will also be manipulated, if necessary for development of validation reporting and results summaries, using specialized programs and Microsoft Excel 2007 or more recent.

Data verification and assessment will include addition or inclusion of data qualification to aid users in interpreting the data collected. Data qualification (qualifiers) applied during evaluation and assessment of results will follow the basic guidelines of EPA's "Pumpkin Book" formally titled Solutions to Analytical Chemistry Problems with Clean Water Act Methods (EPA 2007). These guidelines are well established and ensure that data collected and submitted under the current study retain their usefulness for future data investigations where similar DQOs and project goals are specified.

16.2 Reconciliation with User Requirements

The [Municipal Agency] Project Managers will evaluate the parameters measured and results of calculations performed for this project qualitatively and quantitatively to determine whether the data are of the type, quality, and quantity to support the decisions to be made.

The [Municipal Agency] Project Managers will assess precision, accuracy, and completeness measures and compare them with the criteria discussed in Section 8.2. This will represent the final determination of whether the data collected are of the correct type, quantity, and quality to support their intended use for this project. Any problems encountered in meeting the performance criteria (or uncertainties and limitations in the use of the data) will be discussed with the Peconic Program QA Officer and will be reconciled with the laboratory PM, if possible. Reconciliation might involve reanalyzing a sample, if holding times or other analytical limitations have not been exceeded, or reviewing the performance criteria to determine whether different criteria (for example, percent recoveries for positive controls, or 90 percent completeness) are capable of meeting project objectives. Noncompliant data that cannot be reconciled will be rejected, and a collaborative decision will be made whether to revisit a site and recollect samples and field data or to exclude those data from further analysis. No data will be rejected outright on the basis of their review and assessment; rather, the laboratory Project Manager and QA Officer will work closely with the [Municipal Agency] Project Managers as to

the overall usability of the results and their potential limitations within the framework of the current data collection effort objectives.

17.0 REPORTING, DOCUMENTS AND RECORDS

Thorough documentation of all activities related to the analysis and reporting of water and sediment quality data is necessary for the proper interpretation of study results. Each type of survey measurement will be documented using a written field form for each site selected. All compiled electronic and hardcopy data and records will be subject to the contract-specific records management requirements.

The [Municipal Agency] Project Managers will maintain files, as appropriate, as repositories for information and data used in the preparation of any reports and documents during the project and will supervise the use of materials in the project files. The following information will be included:

- Any reports and documents prepared.
- Project QAPP.
- Sample collection and handling records.
- QC sample records.
- Written summaries of results of technical reviews, data quality assessments, and training exercises.
- Communications of significance (affecting roles/procedures, data analysis/interpretation, transmittal of data, meeting summaries, deviations from the QAPP, etc.). These communications may be memoranda, internal notes, telephone conversation records, letters, meeting minutes; and all written correspondence of significance among the project team personnel, subcontractors, suppliers, or others.
- Maps, photographs, and drawings.
- Studies, reports, documents, and newspaper articles pertaining to the project.
- Special data compilations.
- Electronic data files.
- Data reconciliation results and associated recommendations.

Original handwritten data sheets will be maintained by the originator and scanned copies will be provided to the [Municipal Agency] Project Managers.

If any changes to field protocols or methodologies are needed during the study, the [Municipal Agency] Project Managers will direct the appropriate staff to ensure that revised methods are distributed to all staff and that they become the standard for all subsequent survey analyses.

The [Municipal Agency] Project Managers will distribute copies of the approved QAPP to the personnel on the QAPP distribution list. The laboratory Project Manager will distribute the approved QAPP to the appropriate laboratory staff, as appropriate. If any changes to the QAPP

are required, a memo detailing the changes will be distributed to all participants, after obtaining proper approvals. Upon completion of the project, the [Municipal Agency] Project Managers and [Municipal Agency] Quality Assurance Officer will compile and make available a DUAR.

The [Municipal Agency] Project Managers will maintain a central project file in the Peconic Program's Riverhead, New York, office to contain all related documents, reports, communications, data compilations, checklists or other records, and deliverables (electronic files and hard copies). Draft and final reports will contain descriptions of the work performed and data sets used in analyses.

REFERENCES

- USEPA. 2001 (Reissued May 2006). *Requirements for Quality Assurance Project Plans, EPA QA/R-5*. EPA 240-B-01-003. U.S. Environmental Protection Agency, Office of Environmental Information, Washington, DC.
- USEPA. 2002. *Guidance for Quality Assurance Project Plans, EPA QA/G-5*. EPA 240-R-02-009. U.S. Environmental Protection Agency, Office of Environmental Information, Washington, DC.
- USEPA. 2004. *USEPA Region 2 Guidance for the Development of Quality Assurance Project Plans*. U.S. Environmental Protection Agency Region 2, Air and Water Quality Assurance Team, Edison, NJ.

Attachment 1. Field Standard Operating Procedures
[Placeholder – include field SOPs in this Attachment]

Attachment 2. Laboratory Standard Operating Procedures
[Placeholder – include lab SOPs in this Attachment]

Attachment 3. Field Forms and Labels
[Placeholder – include Field Forms and Labels in this Attachment]

Attachment 4. Chain-of-Custody Form
[Placeholder – include Chain-of-Custody Form in this Attachment]