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Comprehensive Everglades Restoration Plan
Quality Assurance Oversight Team
Standard Operating Procedure (SOP)

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COMPREHENSIVE EVERGLADES RESTORATION PLAN



COMPREHENSIVE EVERGLADES RESTORATION PLAN

QUALITY ASSURANCE OVERSIGHT TEAM

QAOT Standard Operating Procedure (SOP) and Document Control Requirements

QAOT SOP-001

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QAOT Co-Chair Approval:



April Patterson
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Date



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3/28/12
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SOP and Document Control Requirements

1.0 Purpose and Applicability

This Standard Operating Procedure (SOP) outlines the requirements for preparing SOPs used by the Comprehensive Everglades Restoration Plan (CERP) Quality Assurance Oversight Team (QAOT) to conduct their activities and requirements for control of all documents. The requirements apply to all documents prepared by the QAOT.

2.0 Background

The principle responsibility of the QAOT lies in coordinating and overseeing quality activities for all CERP environmental monitoring activities. In addition to developing a consistent approach to their duties and responsibilities, the QAOT must provide guidance and procedures to those individuals that are responsible for the environmental monitoring activities. These documents must be publicly available through the QAOT website.

To ensure that the most current document is being used, to have a documented history of drafts and revisions, and to ensure a standard format for all documents, the QAOT developed a document control procedure, and standardized format.

3.0 Summary

This SOP details the format of the SOPs used by the QAOT. It is itself a model that can be used for drafting other SOPs since the format of this SOP mirrors the format described in the document and contains most of the discussed elements.

4.0 Duties and Responsibilities

- 4.1. **Assigning Document Control IDs** – the QAOT Co-Chairs shall be responsible for ensuring that all documents have been assigned an appropriate document ID.
 - 4.1.1. When the first draft is circulated for QAOT review, the co-chairs shall assign a document control ID (see 21.0).
 - 4.1.2. The Co-Chairs must maintain a master list of all SOPs that identifies the ID, title and current revision date.
- 4.2. **History – the QAOT Co-Chairs will be responsible for ensuring that copies of all dated revisions of a given document are retained and archived.**
 - 4.2.1. Unauthorized access to final documents (and subsequent revisions) must be controlled by either publishing the documents as “read only” or as properly secured PDF files.
 - 4.2.2. Archival storage must ensure that the documents remain intact and are protected from all environmental and electronic influences.
 - 4.2.3. If documents are electronically archived, the QAOT must ensure that older documents can be retrieved and accessed.
- 4.3. **Document Retention** – All dated revisions shall be archived according to State or Federal policy, whichever provides the longest retention time.

5.0 Definitions

- **CERP**: acronym for Comprehensive Everglades Restoration Plan. A 30-year project whose objective is to restore the Florida Everglades
- **Document Control**: information uniquely identifying an SOP in a page header of standard format.
- **Essential SOP Elements**: elements that all SOPs must contain.
- **QAOT**: acronym for Quality Assurance Oversight Team for the CERP Program

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- **Shall:** denotes activities, procedures, or elements from which no deviation is allowed and is synonymous with “must”.
- **Should:** indicates that an associated element is recommended but not mandatory.
- **SOP:** acronym for Standard Operating Procedure. A written document of standard format that details in step-by-step fashion how to accomplish an activity or perform a procedure.
- **Supplementary SOP Elements:** SOP elements that must be included in some SOPs, but may be included in others.

6.0 SOP Elements - All SOPs shall have the following essential elements:**6.1. A Title Page with**6.1.1. A **title**6.1.2. **An identifying number** (see 21.0)6.1.3. A **revision number**. (The first approved version of an SOP is always revision “0”.)

6.1.3.1. Each document will go through several iterations:

6.1.3.1.1. All initial drafts shall be identified as “draft” with a different revision date if the document is significantly modified.

6.1.3.1.2. When a document is ready for final comment, the status shall be changed to “final draft” and published for comment. The “final draft” may also go through several iterations that should be identified with a different revision date if the document is significantly modified.

6.1.3.1.3. Once the document has been approved by the QAOT, the status will change to “final” and the revision date shall reflect the effective date (date of implementation).

6.1.3.1.4. When revisions are made to a final document, the document status will be identified as “revised draft”, “revised final draft” or “revised final” depending on the status.

6.1.3.2. Substantive revisions to an SOP increase the revision number by an integer. For example, Revision 3 would indicate that an SOP has been revised substantially three times after its original version.

6.1.3.3. For revisions to an SOP made only for editorial reasons or minor clarifications add a decimal number to an existing revision number. For example, Revision 2.4 would indicate that the second substantive revision of an SOP has undergone four editorial revisions.

6.1.3.4. A substantive revision to an SOP with a decimal number increases the SOP’s revision number to the next integer. For example, if SOP Revision 2.4 is revised substantially, it would become Revision 3.0 on approval.

6.1.3.5. Editorial changes made in conjunction to substantive revisions increase the SOP’s revision number to the next integer. For example, if SOP 7.5 is substantially revised and undergoes several editorial changes at the same time, it becomes Revision 8.0 on approval.

6.2. A **header** with control documentation for each page other than the cover page (see 8.1).6.3. A **footer** with page numbers for each page other than the cover page (see 8.2).6.4. A section specifying the SOP’s **purpose and applicability**6.5. A **summary** of the procedure or activity detailed.6.6. **Procedural sections**

- 6.7. **Supplementary SOP Sections** - Some SOPs may also contain all or some of the following:
- A table of contents.
 - A background section
 - A section listing related documents.
 - A “definitions” section.
 - A section discussing responsibilities of any individual having responsibility for the described activity
 - A section listing references made in the SOP or used in crafting it.
 - A “history” section summarizing approved changes made to a previously approved SOP.
 - Tables, figures, diagrams, charts, examples, checklists, or appendices.
- 6.8. All SOPs shall be formatted following a template provided by the QAOT. The template specifies paper size, margins, font choice and sizes, and text justification.
- 6.9. All sections and items are numbered using legal style numbering, as done here.
- 6.10. All final SOPs will reference an effective date, which is usually the date that the QAOT chairs have signed the document.
- 7.0 **Title Page Format** - The cover page of an SOP shall include in this order:
- A descriptive title.
 - An identifying number that follows the indexing system described in section 21.0 of this SOP.
 - The revision number of the SOP.
 - The date on which the QAOT Chairs signed the SOP.
 - The effective date of the SOP.
- 8.0 **Page Header and Footer Format** - All pages have a header with a standard format.
- 8.1. The header contains the following information in the format shown on this SOP:
- Document ID (left corner)
 - Current Revision date (right aligned) and status (see 6.1.3)
 - Document Title (centered on the next line)
- 8.2. All pages have a footer with a standard format. The footer contains the following information in the format shown on this SOP:
- “CERP QAOT Guidance/Procedure/Internal Operating Policy/etc.” at the left margin
 - “Page __ of __” (right aligned)
- 9.0 **Purpose and Applicability Section Content**
The first section of the SOP shall briefly explain the purpose of the document and its applicability. Applicability can be conveyed by listing the parties or activities covered or excluded by the SOP.
- 10.0 **Summary Section Content**
This section should describe briefly the content of the SOP. If desired, special features of a procedure can be highlighted in this section.
- 11.0 **Procedural Sections**
- 11.1. The text can be divided into as many sections as is necessary to completely describe a procedure.

SOP and Document Control Requirements

- 11.2. Procedural sections constitute the core of the SOP, describing in text and in detail the procedure or activity that is the object of the SOP.
 - 11.3. Although procedural sections can contain diagrams, graphs, charts, or tables if including them in the body of the SOP is essential for clearly understanding a step in a process, non-textual information is usually placed at the end of SOPs, after the reference section.
 - 11.4. These sections should be written in sufficient detail to allow someone with basic knowledge to complete or reproduce the referenced activity.
 - 11.5. SOPs shall be written in English, using grammar and style suitable for formal business documents.
- 12.0 Using Supplementary Elements in SOPs**
- 12.1. Some SOPs will require additional sections to completely describe a procedure or to make the procedure clear to those that are not completely familiar with the process described. The writer and the person approving the SOP should discuss the need for including supplementary elements.
 - 12.2. Sections 12 - 22 describe supplementary elements and indicate when it is appropriate to include them in an SOP.
- 13.0 Table of Contents Section**
- The table of contents should indicate the page number of the principal sections of an SOP (those with a zero decimal).
- 14.0 Background Section**
- In some SOPs, it may be useful to provide background information concerning the development of or the need for the SOP.
- 15.0 Duties and Responsibilities Section**
- This section is required when specific duties or responsibilities (such as oversight, assigning SOP numbers, etc.) are required for the implementation of the SOP.
- 16.0 Referenced Documents Section**
- 16.1. Some SOPs are intimately linked to others. When information contained in more than one document is necessary to complete a task, it is useful to include a cross-reference section in each document.
 - 16.2. When necessary, this section should be placed between the “Summary” and “Definitions” sections, or when the latter section is not necessary, between the “Summary” and the first procedural section.
- 17.0 Definitions Section**
- 17.1. This section defines any terms that are not universally understood or establishes the sense in which a term that can be defined in more than one way is used in an SOP.
 - 17.2. When terms that are not universally understood by the QAOT or that have more than one sense are used in an SOP and these terms can be found in a glossary, it is not necessary to include definitions of those terms in an SOP.
 - 17.3. Since SOPs should strive for clarity, it is sometimes appropriate to include definitions in an SOP even when the same definitions can be found in a common glossary.
 - 17.4. Uncommon acronyms should be fully spelled in the “Definitions” section. They do not need to be defined if the terms comprising the acronym are well-

understood.

18.0 Reference Section Format

- 18.1. This section shall list any sources quoted, cited, or used in preparing an SOP.
- 18.2. References should be listed alphabetically by source title or author's last name, as appropriate.

19.0 History - Approved Changes Made to the SOP

- 19.1. This section details in chronological order substantive changes made and approved to a previously approved SOP. The first approved and effective version of an SOP does not require this section.
- 19.2. This section is included as the last one before any tables, figures, diagrams, charts, examples, checklists, or appendices.
- 19.3. The entries in this section shall reference the specific section of the SOP where the change occurred and include:
 - Revision Number
 - Revision Date
 - Description of Change
 - Author(s)
- 19.4. Editorial changes need not be itemized, but may be referenced in general terms in this section (see 6.1.3.2). For example a statement such as "several sections of the SOP were rewritten to correct grammar and punctuation errors, and to improve its clarity" may be included in this section.

20.0 Tables, Figures, Diagrams, Charts, Examples, Checklists, and Appendices Format

- 20.1. Some SOPs will need tables, figures, diagrams, charts, examples, or checklists to completely describe a procedure or to make it more understandable.
- 20.2. Generally, non-textual information is added at the end of an SOP after the "References" section, but this information can be part of a procedural section if this improves the SOP's clarity or is more convenient.
- 20.3. Some SOPs will make reference to other documents and at times, these should be included as Appendices if the referenced documents referenced are not readily available and reading them is essential to performing a procedure, such documents must be included with the SOP as appendices.
- 20.4. Appendices are identified by capital letters in ascending order. The pages of appendices composed as parts of SOPs are numbered in the "Page X of Y" format where the "X" is preceded by the letter identifying the appendix and the last number is the total number of pages in the specific appendix (e.g.: Page D3 of 7).
- 20.5. Documents conceived independently of an SOP can be included as appendices in their original format.

21.0 SOP Indexing System

- 21.1. All SOPs are assigned a unique ID based on the intended use:
- 21.2. Internal QAOT Operating Policies shall be identified as "**QAOT SOP-XXX**"

22.0 References

- 22.1. Format Guidelines for Standard Operating Procedures (SOPs) of The NELAC Institute (TNI). SOP 1-100, Revision 0, TNI Policy Committee.

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- 22.2. Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents. EPA QA/G-6. EPA/600/R-96/027; US EPA, Office of Research and Development.
- 22.3. Standard Operating Procedure for Document Control. SFWMD-QS-SOP-001-02. Effective 6/1/2010. Restoration Sciences Department, South Florida Water Management District, West Palm Beach, FL.

History

Revision Status/Number	Revision Date	Description	Author
0.0	January 2005	New Document	S. Labie
1.0	March 2008	Final for Signature	S. Labie
2.0 Revised Draft	March 2012	Simplified text and SOP Indexing System	M. Chen / D. Splichal

COMPREHENSIVE EVERGLADES RESTORATION PLAN



QUALITY ASSURANCE OVERSIGHT TEAM

Quality Assurance Activities and Responsibilities

QAOT SOP-002

Version: Revision 2.0

Version Date: May 30, 2013

QAOT Co-Chair Approval:

April Meadows Patterson

 April Patterson
 USACE, Jacksonville District

June 5, 2013

 Date

Ming Chen, *6/5/13*

 Ming Chen
 South Florida Water Management District

Effective Date: *June 5, 2013*

1.0 Purpose and Applicability

This document outlines the Quality Assurance (QA) Management activities that must be integrated into all Comprehensive Everglades Restoration Plan (CERP) monitoring projects. It assigns active responsibility, assistance, oversight, and guidance functions to the QA groups (or individuals) who are responsible for data quality decisions, implementation of QA and Quality Control (QC) procedures for CERP projects, and/or oversight of the QA process.

2.0 Summary

This document describes the QA responsibilities that the Quality Assurance Oversight Team (QAOT) and the Project Managers (PM) have during CERP project implementation.

3.0 Roles

The Project Delivery Team (PDT) is responsible and accountable for delivering a quality project to the customer and for ensuring effective, coordinated actions to deliver the completed project according to the PMP. Team members are responsible and accountable to the PDT for the timeliness and quality of their work and for keeping commitments for completion of their portion of the project, as well as coordination with and keeping all other team members informed. The PDT should consider the expectations of the stakeholders and beneficiaries in achieving the quality objectives.

The Project Manager (PM) manages the scope, schedule, quality and budget while leading the PDT to successful project execution. The PM is ultimately responsible for the quality of the project data. He/she is responsible for coordinating all work and activities that are a part of the stated study or project. The PM is authorized to make decisions concerning QA issues and data acceptability and may designate or delegate these functions to a PDT member with the appropriate technical expertise. Ultimately, the PM must ensure that sufficient QC measures are incorporated into the project and that the QA procedures are sufficient to monitor the quality of the data as it relates to the stated project objectives. (Adapted from USACE Guidance ER 5-1-11)

Principle Investigators (PIs) are contractors or Federal agency partners who are both stakeholders in the project and PDT members.

The Quality Assurance Oversight Team oversees the CERP monitoring and sampling QA and helps to assure the accuracy, precision, and reliability of CERP monitoring and sampling data in accordance with the QAOT Program Management Plan (PrMP).

4.0 Quality Assurance Activities and Responsibilities

4.1. Quality Assurance Responsibilities During the Planning Stage

To ensure that the appropriate QA/QC criteria are incorporated, the QAOT should be involved as early as possible (when applicable and appropriate) in the planning phase of environmental monitoring projects. Table 4-1 defines responsibilities for planning activities.

Table 4-1. QA Responsibilities during Planning

QA-Related Planning Activities	PDT	QAOT
1. Develops data quality objectives (DQOs), data quality indicators (DQIs) and measurement quality objectives (MQOs) for the project.	A	G
2. Develops the required planning documents.	A	G
3. Verifies that the project planning documents include the QASR required data review procedures.	A	G
4. Identifies and reports alternative procedures to the QAOT for approval.	A	G
5. Verifies that data deliverables and data formatting requirements conform to the standardized protocols established by the QAOT.	A	G
6. Specifies the appropriate data review and assessment procedures for the project	A	O
7. Verifies that proposed analytical laboratories are National Environmental Laboratory Accreditation Conference (NELAC)-certified (for chemical analysis).	A	O
8. Reviews field and laboratory statements of work (SOW) for QA/QC language and ensures that the Quality Assurance Systems Requirements (QASR) are incorporated.	A	A
9. Ensures completeness of required planning documents (monitoring plan, QA project plan [QAPP] or sampling and analysis plan [SAP]) and ensures that QASR requirements are incorporated.	A	G
10. Communicates gaps or deviations from the QASR, identified during QAOT reviews, to the PM.	-	A
11. Documents, prepares, and approves proposed alternative procedures.	A	O

A – Active Responsibility – These individuals must take an active role in performing the activity.

G – Guidance – Provides training and/or guidance to perform the activity.

O – Oversight – Oversees the activity as performed and implemented. These individuals or groups are responsible for assuring that the specified activity is performed as outlined.

-: Responsibility by the Team not required.

4.2. Quality Assurance Responsibilities During Audits of Field and Laboratory Activities

Field and laboratory audits are performed to identify potential process errors that could impact data quality and usability. Table 4-2 defines responsibilities during field and laboratory audits.

Table 4-2. QA Responsibilities during Field and Laboratory Audits

QA-Related Field and Laboratory Audit Activities	PDT	QAOT
1. Conducts audits of CERP field activities to assure that appropriate procedures are being used. Reports results to the QAOT.	-	A
2. Implements a formal inter-agency auditing program and conducts audits of laboratories analyzing samples for CERP to assure proper oversight and implementation of QASR protocols, standard operating procedures (SOPs), data handling, etc., over the lifetime of monitoring activities. Verifies that the laboratory has conducted an internal systems audit within one year of the previous internal systems audit and whenever corrective actions necessitate such an audit.	-	A
3. Provides the results of all audits to the PM with recommendations for follow-up and corrective actions.	-	A
4. Develops and implements a corrective action plan based on the recommendations.	O	G

A – Active Responsibility – These individuals must take an active role in performing the activity.

G – Guidance – Provides training and/or guidance to perform the activity.

O – Oversight – Oversees the activity as performed and implemented. These individuals or groups are responsible for assuring that the specified activity is performed as outlined.

-: Responsibility by the Team not required.

4.3. Quality Assurance Responsibilities During Data Verification and Validation

QA of Data Verification and Validation is a critical step to ensuring data quality. Table 4-3 defines responsibilities for data verification and validation.

Table 4-3. QA Responsibilities for Data Verification and Validation

QA-Related Data Verification and Validation Activities	PDT	QAOT
1. Conducts data quality investigations to assess data quality and usability.	A	G
2. Verifies that data are provided through Automated Data Processing Tools (ADaPT or ADR).	A	G
3. Verifies that field data have been reviewed and/or validated according to the requirements of the QASR as defined by the SOW and the planning documents.	A	G
4. Verifies that laboratory data have been reviewed and/or validated according to the requirements of the QASR as defined by the SOW and the planning documents.	A	G
5. Ensures that the laboratory case narratives are reviewed to screen data for non-conformances identified by the laboratory.	A	G
6. Ensures that only final, reviewed data are used for reporting purposes.	A	G
7. Reports to the QAOT systemic QA/QC issues and problematic data (<i>irresolvable at the project-level</i>) for resolution. Determines if the disputed data meet the DQOs of CERP and the specific project.	A	O

A – Active Responsibility – These individuals must take an active role in performing the activity.

G – Guidance – Provides training and/or guidance to perform the activity.

O – Oversight – Oversees the activity as performed and implemented. These individuals or groups are responsible for assuring that the specified activity is performed as outlined.

4.4. **Quality Assurance Responsibilities For Corrective Action and Continuous Improvement**

Corrective action procedures are implemented to avoid repeating errors and to continually improve the efficiency and defensibility of data collected for CERP. Table 4-4 defines these responsibilities.

Table 4-4. QA Responsibilities for Corrective Action and Continuous Improvement

QA-Related Corrective Action & Continuous Improvement Activities	PDT	QAOT
1. Assesses compliance with the QASR and planning documents to identify issues that could impact data quality and reports the results in the QAOT biennial Quality Assessment Report (QAR). Communicates these issues to project management.	O	A
2. Recommends corrective actions.	A	A
3. Develops and implements a corrective action plan based on the recommendations and follow-ups	A	O
4. Tracks specific corrective and preventative actions to ensure that they are implemented effectively.	A	A

A – Active Responsibility – These individuals must take an active role in performing the activity.

G – Guidance – Provides training and/or guidance to perform the activity.

O – Oversight – Oversees the activity as performed and implemented. These individuals or groups are responsible for assuring that the specified activity is performed as outlined.

4.5. Quality Assurance Oversight Team Responsibilities

The QAOT is responsible for:

- Preparing and updating SOPs that define CERP-wide activities and procedures, and effectively communicating requirements and procedures to the CERP community.
- Performing field and laboratory audits according to QAOT audit SOPs.
- Coordinating CERP-related QA activities with the applicable agencies
- Communicating QA/QC problems to the PDTs
- Conducting outreach that informs PMs, and other CERP stakeholders of QASR requirements, QA/QC procedures and responsibilities, data verification and validation requirements, and the corrective action process.

The QAOT is accountable to the Design Coordination Team (DCT) for assuring that data quality assessments are performed, that the results are communicated, and

that data quality issues are addressed to avoid re-occurrence and minimize impact on CERP data quality.

SOP History

Revision Status/Number	Revision Date	Description	Author
Draft	June 2006	White Paper: <i>Quality Assurance Management - CERP Monitoring Project Quality Assurance Activities and Responsibilities</i>	S. Labie / R. Buhl
Revision 1.0 Final	December 2008	Final	L. Gued
Revision 2.0 Final	May 2013	Add definition section and update the Roles for QA/QC Responsibilities	D. Splichal / A. Patterson

Preparation of Annual Quality Assessment Report

1.0 PURPOSE AND APPLICABILITY

- 1.1 The Quality Assurance Oversight Team (QAOT) was established by Comprehensive Everglades Restoration Plan (CERP) Guidance Memorandum (CGM) 41, which specifies that the lead QAOT agencies will, *“Produce a QA report on CERP monitoring activities on a biennial basis, evaluating whether the QASR is being implemented by CERP projects and programs and/or their contractors.”* The frequency of the QAR is also established in the QAOT Program Management Plan.
- 1.2 This standard operating procedure (SOP) provides guidance for the preparation of the Quality Assessment Report (QAR).
- 1.3 The purpose of the QAR is to provide to CERP management an assessment of the state of data quality for monitoring activities being conducted for CERP.
- 1.4 The goals of the QAR are to assess the quality of data being generated for CERP, to identify practices that are contributing to quality data, to report on the activities of the QAOT, and to recommend improvements to the quality system.
- 1.5 This SOP applies to the QAOT and contributors to the QAR (defined as the Content Contribution Team, CCT).

2.0 SUMMARY OF PROCEDURE

- 2.1 The biennial QAR will be prepared using quantitative and qualitative input from CERP QAOT members and other CERP monitoring and assessment participants, including CERP project managers, RECOVER principle investigators, CERP information and data management (IDM) coordinators, project deliverable teams (PDTs), consultants, laboratories, and sampling groups.
- 2.2 Input to the QAR is gathered throughout the two-year report period either as part of the routine activities of the participating organizations (e.g., audits and data validation) or as specific activities of the QAOT (e.g., monitoring plan reviews and quality system interviews).
- 2.3 At the end of the biennial report period, the results are compiled, tabulated, analyzed, and summarized in the QAR.
- 2.4 The Draft QAR is reviewed by the QAOT and the QAR CCT, RECOVER. The Revised QAR receives a CERP-wide review, and the Final QAR is delivered to the CERP Design Coordination Team (DCT).

3.0 DEFINITIONS

- 3.1 **Alternative procedure:** Variances may involve the use of alternate laboratory or field procedures, QA/QC elements, and data validation or data management procedures.

Preparation of Annual Quality Assessment Report

Variances may be driven by project limitations, a need for enhancements or improvements such as better technology, or for experimental or research purposes. The ultimate goal of the variance process is to ensure that the proposed alternative procedure or method will produce comparable or better results and maintain consistency within CERP data gathering activities (QASR, 2009, Section 2.3).

- 3.2 **CERP:** acronym for Comprehensive Everglades Restoration Plan; a 30-year project whose objective is to restore the Florida Everglades. The term CERP is an umbrella term for many different activities. These include REstoration COordination and VERification (RECOVER) system-wide monitoring efforts (i.e., Monitoring and Assessment Plan [MAP]), project monitoring, and permit- driven regulatory monitoring.
- 3.3 **Data qualifiers or flags:** symbols or letters applied to the data to alert the end user to potential quality concerns/issues that may impact the usability of the data (e.g., QC acceptance limits that were not met).
- 3.4 **Finding:** an assessment conclusion, referenced to a documented Standard and supported by objective evidence that identifies a deviation from the Standard requirement (adapted from NELAC Standards, 2003).
- 3.5 **QAOT:** acronym for Quality Assurance Oversight Team for the CERP Program.
- 3.6 **Quality system:** a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC (NELAC, 2003).

4.0 PROCEDURE

- 4.1 Preparation of the QAR is a collaborative effort that is directed and coordinated by members of the QAOT.
 - 4.1.1 Collection of Data Input
 - 4.1.1.1 To the extent possible, data input for the QAR should be collected systematically so that it is representative (i.e. not biased or censored). It is not possible for the QAOT to collect all the QA/QC input for the QAR. In order for the QAR to be representative and accurate, input on QA practices and QC results will be solicited from CERP Project and CERP Systems stakeholders as input to the QAR.
 - 4.1.1.2 Folders will be established in Documentum prior to May 1 of the first year of the reporting period so that QAR input can be collected in real time as it is identified (see Section 4.1.5.1).

Preparation of Annual Quality Assessment Report

4.1.1.3 In April of the second year of the reporting period, a QAR outline will be produced and a kickoff meeting should be held to discuss the input available for the report. The QAR outline and contents of the Documentum folders will be distributed to the QAOT for review.

4.1.2 Schedule and Milestones

4.1.2.1 The QAR reporting period is based on water years (WYs), which are defined as from May 1st of the first year to April 30th of the second year (e.g., May 1, 2012 through April 30, 2014). The biennial QAR will cover two WYs.

4.1.2.2 An example of the report schedule and milestones is provided in Table 1.

4.1.3 Contents: The QAR should contain, at a minimum, the elements defined in Table 2.

4.1.4 Report Review Process

4.1.4.1 Four versions of the QAR are prepared for each report cycle: draft, revised draft, final draft and final. Table 1 provides examples of the review schedule for each version.

4.1.4.2 The draft and revised draft report versions are for internal QAOT and RECOVER review only, and should not be distributed beyond the QAR Contents Contribution Team.

4.1.4.3 The draft final report is distributed for CERP-wide review and thus provided to a wider distribution list composed of QAOT interested parties and selected CERP System reviewers.

4.1.4.4 The final report is presented to the DCT and once approved, is posted to the QAOT Web page on www.evergladesplan.org.

4.1.5 Records Management

4.1.5.1 The final QAR will be saved to the QAOT Documentum/QAOT Documents/QAR cabinet/20xx (report year) (Documentum is the archival record for CERP). The cabinet structure is illustrated in Figure 1. Subfolders represent anticipated data input and can be modified as needed.

4.1.5.2 QARs will be available for five years on EvergladesPlan.org.

Preparation of Annual Quality Assessment Report

5.0 QUALITY ASSURANCE AND QUALITY CONTROL

- 5.1** It is critical that the QAR be accurate, complete, and unbiased.
- 5.1.1** The QAR will include data input from a variety of sources. Accurate handling, interpretation, and representation of these data in tables and figures must be verified to ensure that the report is accurate and complete. Table 3 summarizes the QA/QC procedures appropriate during the QAR development. The following report quality control procedures must be implemented:
- Hand-entered data must be verified 100% for transcription errors.
 - Changes to data to achieve data uniformity must be verified 100%.
 - Tables and figures that depict numeric data must be audited vs. the data input provided to the author.
- 5.1.2** The draft QAR must receive an internal technical, editorial, and quality assurance review prior to submission to the QAOT. In particular, the report text must be verified against the tables and figures to ensure that data are discussed accurately.
- 5.1.3** It is assumed that input from SFWMD, USACE, QAOT members, RECOVER, IDM, PDTs and other stakeholders is accurate for use, as received (e.g., the accuracy of audit reports or monitoring plan review forms will be used without further investigation during QAR development).
- 5.1.4** Completed sections of the draft QAR and potential tables and figures may be distributed to the QAOT for review and input during the QAR development for feedback.
- 5.1.5** Any text, tables, or figures pertaining to RECOVER will either be inserted as provided by RECOVER or distributed to RECOVER for review and input during the QAR development for feedback.
- 5.2** QAOT Review
- 5.2.1** The QAOT and RECOVER will review the draft QAR to ensure that the presentation is clear, accurate, and professional. Section 4.1.4 describes the review process.
- 5.3** Corrective Action and Continuous Improvement
- 5.3.1** A lessons-learned session will be incorporated into the QAR kick-off meeting to identify problems in the preparation of the previous QAR and to identify procedures that will minimize re-occurrence of problems.
- 5.3.2** Comments and lists of proposed changes to this SOP will be compiled by the QAR primary authors from USACE and SFWMD for future QAR in the coming reporting period.

Preparation of Annual Quality Assessment Report

6.0 REFERENCES

- 6.1** EPA (U.S. Environmental Protection Agency), 2007. Guidance for Preparing Standard Operating Procedures (SOPs). EPA QA/G-6. EPA/600/B-07/001, Office of Environmental Information. April 2007.
- 6.2** NELAC (National Environmental Laboratory Accreditation Conference), 2003. 2003 NELAC Standards, Effective July 2005.
- 6.3** QAOT (Quality Assurance Oversight Team). Comprehensive Everglades Restoration Plan (CERP) Quality Assurance Systems Requirements (QASR) Manual.
- 6.4** QAOT (Quality Assurance Oversight Team). Comprehensive Everglades Restoration Plan (CERP) Quality Assurance Program Management Plan.

Preparation of Annual Quality Assessment Report

Table 1. Example Schedule of QAR Milestones and Deliverables

Activity	Initiate By Date	Duration	End Date
Establish QAR Folder in Documentum	April 30, 1 st year	1 day	April 30, 1 st year
Produce QAR Outline and conduct QAR Kickoff	April 25, 2 nd year	1 week	May 2, 2 nd year
Deadline for input	April 30, 1 st year	2 years	May 15, 2 nd year
Develop Draft QAR 8/5: All writing complete 8/6-7: Pull all text into report format 8/8-10: QAR author(s) read-through 8/13: Format report	May 15, 2 nd year	14 weeks	Aug 15, 2 nd year
Submit Draft QAR to QAOT and RECOVER for review	Aug 17, 2 nd year	1 day	Aug 17, 2 nd year
QAOT and RECOVER review Draft QAR	Aug 17, 2 nd year	3 weeks	Sept 10, 2 nd year
Comments due on Draft QAR	Sept 10, 2 nd year	1 day	Sept 10, 2 nd year
Respond to QAOT and RECOVER comments on Draft QAR	Sept 10, 2 nd year	2 weeks	Sept 24, 2 nd year
Submit Revised Draft QAR to QAOT and RECOVER for review	Sept 24, 2 nd year	1 day	Sept 24, 2 nd year
QAOT and RECOVER review Revised Draft QAR	Sept 24, 2 nd year	3 weeks	Oct 15, 2 nd year
QAR comments due on Revised Draft QAR	Oct 15, 2 nd year	1 day	Oct 15, 2 nd year
Respond to QAOT and RECOVER comments on Revised Draft QAR	Oct 15, 2 nd year	2 weeks	Oct 29, 2 nd year
Submit Draft Final QAR for CERP-Wide review	Oct 29, 2 nd year	1 day	Oct 29, 2 nd year
CERP-Wide review of Draft Final QAR	Oct 29, 2 nd year	3 weeks	Nov 19, 2 nd year

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QAR comments due on Final Draft QAR	Nov 19, 2 nd year	1 day	Nov 19, 2 nd year
Respond to CERP-Wide comments on Draft Final QAR	Nov 19, 2 nd year	3 weeks	Dec 10, 2 nd year
Submit Final QAR to QAOT	Dec 10, 2 nd year	1 day	Dec 10, 2 nd year
Develop PowerPoint presentation for DCT	Dec 10, 2 nd year	2 weeks	Dec 24, 2 nd year

Preparation of Annual Quality Assessment Report

Table 2. Quality Assessment Report Outline

Quality Assessment Report Element	Description	Input Sources/Types
Title Page		
Acronyms and Abbreviations		
Executive Summary	Discusses the purpose and presentation of the report; summarizes the major report findings, conclusions, and recommendations.	
Table of Contents		
1.0 Introduction	Background and purpose of the QAR.	
2.0 Scope and Application	Defines the report period, input sources, applicability, and limitations.	
3.0 List of Key Participants and Organization	Acknowledges the QAR contributors. Names of specific participants are included at the discretion of the QAOT.	
4.0 Current QA/QC Processes 4.1 QAOT Document Updates 4.2 Monitoring Plan Reviews 4.3 Quality Assessment Report (for previous reporting period) 4.4 QAOT Initiatives	Summarizes the status and results of routine QAOT activities and initiatives taken by the QAOT during the report period.	<ul style="list-style-type: none"> • QAOT documents created or updated • Monitoring plan reviews • Summary of the previous report period QAR. • Summary of QAOT initiatives • Input will be provided by the CERP, RECOVER, and QAOT stakeholders
5.0 Evaluation of CERP Project Field Data 5.1 Water Quality Monitoring Activities 5.2 Hydrology Monitoring Activities	Summarizes the results of field data quality assessments.	<ul style="list-style-type: none"> • Results of field audits for water quality, hydrology, and biological/ecological monitoring. • Input will be provided by SFWMD and USACE

Preparation of Annual Quality Assessment Report

Quality Assessment Report Element	Description	Input Sources/Types
<p>5.3 Biological/Ecological Monitoring Activities</p>		
<p>6.0 Laboratory Audits 6.1 QAOT Laboratory Assessments: Organics 6.2 QAOT Laboratory Assessments: Inorganics 6.3 Aqueous Inorganic Performance Evaluation Samples</p>	<p>Summarizes the results of laboratory quality systems and procedures vs. the requirements of the QASR and methods. Summarizes the results of QAOT-sponsored performance evaluation samples</p>	<ul style="list-style-type: none"> • Results of laboratory audits • Results of performance evaluation samples and round robins • Input will be provided by SFWMD and USACE
<p>7.0 Quality of Data 7.1 Water Quality Data 7.2 Biological Data 7.3 Hydrology Data</p>	<p>Summarizes the results of data quality assessments based on data qualifiers.</p>	<ul style="list-style-type: none"> • DBHYDRO output for CERP projects • Database output from other sources for CERP projects • Input will be provided by SFWMD, USACE, and other data sources
<p>8.0 Alternative Procedures Approved</p>	<p>Identifies any alternative procedures approved during the previous year.</p>	<ul style="list-style-type: none"> • Descriptions of alternative procedures • Input will be provided by the CERP, RECOVER, and QAOT stakeholders
<p>9.0 Summary of Deviations from QASR and Corrective Actions</p>	<p>Summarizes any deviations from the QASR or CGMs during the reporting period, and any corrective action taken to address the immediate deviation and to avoid re-occurrence of the deviation. The discussion may include major corrective actions for recurring problems such as suspension or termination of a service provider, etc.</p>	<ul style="list-style-type: none"> • Reports • Results of inspections and audits • Input will be provided by the CERP, RECOVER, and QAOT stakeholders
<p>10.0 Additional QAOT Activities 10.1 Communication and</p>	<p>Summarizes QAOT activities not discussed in Sections 4-7,</p>	<ul style="list-style-type: none"> • Descriptions of presentations, workshops,

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Quality Assessment Report Element	Description	Input Sources/Types
<p>Outreach</p> <p>10.2 QAOT Collaboration with other CERP Entities</p> <p>10.3 Status of QAOT Action Items</p>	<p>including presentations, workshops, outreach activities and collaboration of the QAOT with other CERP entities during the reporting period.</p>	<p>outreach, and collaboration activities.</p> <ul style="list-style-type: none"> • Input will be provided by the QAOT stakeholders
<p>11.0 Recommendations for QA/QC Program Improvements</p>	<p>Summarizes action items and needs to improve CERP QA/QC processes and procedures.</p>	<ul style="list-style-type: none"> • Recommendations identified during the reporting period • Action items identified in Sections 4-10 of the QAR. • Input will be provided by the CERP, RECOVER, and QAOT stakeholders
<p>12.0 Resource and Input Needs</p> <p>12.1 Management Support from CERP and Participating Agencies</p> <p>12.2 Financial Support for QA/QC Activities</p>	<p>Summarizes QAOT resources needed to achieve the mandate defined in CGM 041, including project, personnel, and material.</p>	<p>Input will be provided by the QAOT co-chairs.</p>
<p>13.0 References</p>	<p>Lists any documents referenced in the QAR.</p>	

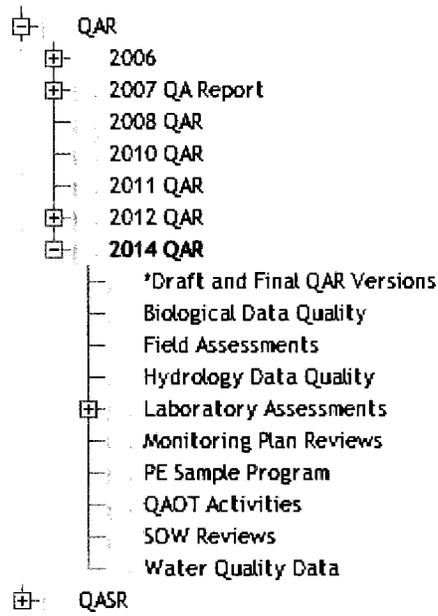
Preparation of Annual Quality Assessment Report

Table 3. Quality Control Procedures for QAR Data Input

Data Input Type	Quality Control Procedures
Field and laboratory audits	<p>Only the results of final audit reports are included in the QAR. Final audit reports include the assessment of audit responses to eliminate “non-issues” from the analysis.</p> <p>Categories of deficiencies must be assigned uniformly.</p>
Quality control data Results of data validation	<p>Parameter names, field and laboratory organizations, and qualifiers must be synchronized prior to analysis. Non-synchronized data will not be used in assessments although at the discretion of the QAOT it may be provided as QAR attachments.</p> <p>All changes and update queries must be documented within the database to ensure traceability.</p>
Performance evaluation samples	Only chemical analytes being analyzed by the laboratory for CERP will be included.

Preparation of Annual Quality Assessment Report

Figure 1. Folder Structure for the QAR in Documentum



Preparation of Annual Quality Assessment Report

SOP HISTORY

Version Status/Number	Revision Date	Description	Author
Draft	5/6/04	Not applicable. Original draft	D. Ivanoff
Revision 0.0/ Final	6/27/08	QAR review process and contents updated based on feedback for the 2007 QAR. Schedule update based on RECOVER and QAOT comments. Signature block standardized.	R. Buhl
Revision 1.0	9/21/2009	Table 2 was updated to reflect changes made to the QAR outline during the QAR kickoff meeting on 6/24/2009.	S. Smith- Tembe
Revision 2.0 Draft	12/31/12	QAR scope changed from annual to biennial. The Documentum folder organization was modified. The outline, contents, and schedule tables were modified.	R. Buhl D. Splichal

COMPREHENSIVE EVERGLADES RESTORATION PLAN



COMPREHENSIVE EVERGLADES RESTORATION PLAN

QUALITY ASSURANCE OVERSIGHT TEAM

Review of Project Monitoring Plans and Scopes of Work

QAOT SOP-004

Version: Revision 1.0

Version Date: September 15, 2008

QAOT Co-Chair Approval:


John Hess
USACE, Jacksonville District

Date

12-09-08


Ming Chen
South Florida Water Management District
(SFWMD)

Date

12-23-2008

Effective Date: _____

Review of Project Monitoring Plans for CERP Projects

1.0 Purpose and Applicability

The purpose of this standard operating procedure (SOP) is to establish the procedures for Quality Assurance Oversight Team (QAOT) reviews of Comprehensive Everglades Restoration Plan (CERP) Project Level Monitoring Plans (PLMP) and all Scopes of Work (SOW) arising from the PLMP.

2.0 Summary

The QAOT reviews the quality assurance and quality control (QA/QC) elements of PLMPs/SOW for compliance with the Quality Assurance Systems Requirements (QASR). Results of the review are summarized on a checklist and provided to the author of the PLMP/SOW. The PLMP/SOW author responds to the issues identified and revises the PLMP to ensure that it meets the QASR requirements.

3.0 Procedure

The CERP project delivery teams (PDTs) shall submit the PLMP/SOW to the QAOT monitoring plan review subteam for review when it is submitted for review by the PDT. Two weeks should be allowed for PLMP/SOW review by the QAOT. The subteam will assign at least two QAOT members to conduct the QAOT review using a checklist to determine if the PLMP is in compliance with the QASR. A letter will be sent to the PLMP/SOW author documenting the acceptability of the PLMP/SOW (Attachment 2) or itemizing deficiencies; if necessary the PLMP/SOW will be resubmitted. The date and contents of the QAOT review comments and PDT responses shall be part of the monitoring plan review track sheet, which shall be posted on CERP Documentum.

4.0 Responsibility

It is the responsibility of the person who authors PLMP/SOWs to submit those plans to the QAOT for review. It is the responsibility of the QAOT monitoring plan review subteam to establish coordinators from the SFWMD and USACE.

5.0 Deliverables

- 5.1. Results of the QAOT review will be documented on the Quality Assurance Oversight Team Monitoring Plan/Quality Assurance Project Plan Checklist (Attachment 1).
- 5.2. The checklist will be accompanied by a cover letter that describes the review and response process and indicates whether or not the PLMP meets QASR requirements. Attachments 2 and 3 provide letter templates that accompany the checklists for acceptable monitoring plans and monitoring plans requiring revision, respectively. The review letter should be addressed to the person who is the author.

References

CERP (Comprehensive Everglades Restoration Plan). 2007. Quality Assurance System Requirements (QASR) Manual. CERP Quality Assurance Oversight Team. 12/10, 2007. http://www.evergladesplan.org/pm/program_docs/qasr.aspx.

CERP (Comprehensive Everglades Restoration Plan). 2008. Project-level Water Quality and Hydrometeorologic Monitoring and Assessment. CERP Guidance Memorandum (CGM) 040.01. CERP, Effective 20 May 2008. http://www.cerpzone.org/documents/cgm/CGM_040-01_Final_5-20-08.pdf.

CERP (Comprehensive Everglades Restoration Plan). 2003. Agency Responsibility and Coordination for Quality Assurance, Quality Control and Data Validation for CERP Environmental Monitoring. (CGM) 040.00. CERP, Effective 19 November 2003. http://www.cerpzone.org/documents/cgm/cgm_041.00.pdf.

QAOT (CERP Quality Assurance Oversight Team), 2008. SOP-001 Format for QAOT Standard Operating Procedures (SOPS) and Document Control Procedures. QAOT, Effective 05/30/2008.

History

Revision Status/Number	Revision Date	Description	Author
Draft	December 2007	SOP for QAOT Review of Project Monitoring Plans for CERP Projects initiated.	R Terry
Draft	January 2008	SOP updated to include monitoring plan checklist.	R Terry
Draft Rev 0	August 2008	SOP reformatted to QAOT SOP-001 standards.	R Buhl
Draft Rev 1	August 15, 2008	Addressed M Wright and M Chen (SFWMD) comments.	R Buhl
Final Rev 1.0	August 26, 2008	Addressed L Gued (USACE) comments.	R Buhl

Attachment 1

Quality Assurance Oversight Team Monitoring Plan Checklist

Project Title:

Date:

Reviewer:

Review Date:

Review Codes

A = acceptable, required elements are incorporated in text or by specific reference

U = unacceptable, required elements are not incorporated in text nor by specific reference

NA = not applicable, not required for this Project Plan

Element	Review Code	Page	Comments
Title Page			
Contains project title, revision and date			
Contains QA Manager signature			
Project Organization and Responsibilities			
Data Assessment Organizations and Responsibilities			
Data Quality Objectives			
Data use background: defines project specific data needs; describes media and analyses required to meet the data needs			
Measurements of quality objectives: required reporting limits, precision, accuracy, comparability and acceptance criteria			
Sample Receipt, Custody and Holding Time Requirements			
Analytical Procedures			
Preventative maintenance			
Calibration procedures and frequency			
Laboratory QC procedures: type and frequency of internal QC measures			
Performance and system audits			
Nonconformance / corrective actions for field and laboratory			
Data reduction / calculation of data quality indicators: describes bias, accuracy, limits of detection, and precision calculations			
Report Documentation: Defines Report format and Data Archival Requirements			
Data Assessment Procedures			
Data verification			
Data validation			

Attachment 2
Example Letter for Acceptable Monitoring Plans

LOGOS/LETTERHEAD

Date (month dd, yyyy)

Project Manager Name
Project Manager Address

Subject: [Monitoring Plan Review \(Date\)](#)
[Title of Monitoring Plan](#)

Dear [Project Manager Name](#),

On behalf of the Comprehensive Everglades Restoration Plan (CERP) Quality Assurance Oversight Team (QAOT), I wish to thank you for the opportunity to review the monitoring plan for [\(Title of Monitoring Plan\)](#). The purpose of the QAOT review was to determine if the monitoring plan adequately addressed the quality assurance and quality control requirements for CERP projects defined in the Quality Assurance Systems Requirements (QASR).

The results of the monitoring plan review are summarized on the attached checklist. Our review found that the monitoring plan meets the QASR requirements. If you have questions or would like to discuss the results of our review, please feel free to contact me at [telephone number](#) and/or [email address](#).

Sincerely,

[Organization](#)

Attachment

Review of Project Monitoring Plans for CERP Projects

Attachment 3
Example Letter for Monitoring Plans Requiring Revision

LOGOS/LETTERHEAD

Date (month dd, yyyy)

Project Manager Name
Project Manager Address

Subject: Monitoring Plan Review (Date)
Title of Monitoring Plan

Dear Project Manager Name,

On behalf of the Comprehensive Everglades Restoration Plan (CERP) Quality Assurance Oversight Team (QAOT), I wish to thank you for the opportunity to review the monitoring plan for (Title of Monitoring Plan). The purpose of the QAOT review was to determine if the monitoring plan adequately addressed the quality assurance and quality control requirements for CERP projects defined in the Quality Assurance Systems Requirements (QASR).

The results of the monitoring plan review are summarized on the attached checklist. In general, the project monitoring plan met the QASR requirements. As noted in the checklist, insert number of "U" codes QA/QC elements were not adequately described (U code) in the draft monitoring plan. It is important that this monitoring plan be revised to address these missing elements to ensure that the data quality is adequate. Please revise the monitoring plan to provide the information requested and return the final document to me. If you have questions or would like to discuss the results of our review, please feel free to contact me at telephone number and/or email address.

Sincerely,

Organization

Attachment

TABLE OF CONTENTS

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ATTACHMENTS

- A. PE Study Schedule
- B. Typical Analyte Classes and Parameters Included in Inorganic QAOT-Sponsored PE Studies
- C. Example Letter to QAOT-Sponsored Participating Laboratories
- D. PE Study Report Outline
- E. Example Survey for QAOT-Sponsored Participating Laboratories

1.0 PURPOSE AND APPLICABILITY

This Standard Operating Procedure (SOP) describes the process to be followed by the Comprehensive Everglades Restoration Plan (CERP) Quality Assurance Oversight Team (QAOT) in conducting performance evaluation (PE) studies of environmental laboratories that provide, or may provide, analytical data for CERP projects or CERP-related monitoring. The purpose of these studies is to assess the ability of participating laboratories to accurately quantify concentrations of analytes of interest in naturally-occurring environmental samples. The PE study is one of several assessment tools that may be used by project managers to assist with the selection of laboratories for monitoring activities and may form part of the laboratory audit process. The results of the study provide useful information to project managers and other stakeholders and help laboratories improve their analytical performance.

2.0 BACKGROUND

The QAOT is responsible for administering a Quality Assurance/Quality Control (QA/QC) program for CERP, part of which includes overseeing field and laboratory comparison studies (CGM 041.01; July 21, 2010). A PE study involving two or more laboratories provides an objective means of evaluating individual laboratory performance and determining the extent of comparability of data between and among laboratories. The laboratories selected to participate in the CERP QAOT PE study program each year are those with current South Florida Water Management District (SFWMD) or U.S. Army Corps of Engineers (USACE) laboratory support contracts or who hold contracts with SFWMD contractors. The results of the PE studies help project managers and the QAOT ensure that data and work products produced for CERP projects are of known and documented quality.

3.0 PROCESS OVERVIEW

The PE program is administered by the QAOT directly or by a contractor acting on behalf of the QAOT. Laboratories selected by USACE and SFWMD for participation in the study are registered with the PE Provider and receive single-blind samples (i.e., samples known by the laboratories as PE samples but with unknown concentrations of analytes of interest). The participating laboratories analyze the samples utilizing the same methodologies that routinely would be used to analyze samples for CERP-related projects. Upon receipt of laboratory results, the PE Provider generates a final report with the results of the PE study. These results are then reviewed by the QAOT or contracted PE Administrator and used to prepare a report in which the results and performance of the participating laboratories are evaluated and summarized. Adherence to key dates by all parties is essential for each year's study to be a success (Attachment A).

4.0 DUTIES AND RESPONSIBILITIES

Participants in the PE study have important roles to play in making each study a success. These roles and responsibilities are described as follows.

Quality Assurance Oversight Team

The QAOT is responsible for administering a QA/QC program for the CERP, including overseeing field and laboratory comparison studies to assess consistency and comparability among agencies involved in CERP monitoring activities (CGM 041.01; July 21, 2010).

PE Administrator

The PE Administrator is responsible for coordinating the PE study and communicating with the PE Provider and participating laboratories. It is the duty of the PE Administrator to register the participating laboratories with the PE Provider and arrange for the purchase of the PE Provider services. The PE Administrator receives the final results of the study from the PE Provider, tabulates and analyzes the data, and presents a summary of the findings, with recommendations, in a formal report to the QAOT. The report is submitted first as a draft and, after reviewer comments are incorporated, as a final report. The PE Administrator also is responsible for reviewing the status of the current PE study program, providing the initial summary of the PE study (included in the biennial QAOT Quality Assessment Report, QAOT-SOP-003, Section 6.3), and updating this PE Study SOP, as necessary.

PE Provider

The PE Provider is responsible for providing the samples for the PE study. This includes preparing, splitting, shipping, and distributing the PE samples to the laboratories. The PE Provider also is responsible for conducting a thorough analysis of the laboratory results.

Participating Laboratories

The participating laboratories are responsible for analyzing the PE samples, utilizing the same methods, and in the same manner, afforded routine samples. Unless warranted by standard quality control (QC) and data acceptance criteria, replicate analyses, analyses at multiple dilutions or other special handling processes for PE samples are unacceptable.

All analytical QC samples required by the method must be incorporated into the analysis sequence (e.g., initial and continuing calibration verifications, method QC samples, etc.). PE samples should be analyzed in the same analytical run as routine environmental samples. No special handling is allowed.

5.0 DEFINITIONS

Accuracy: The extent of agreement between an observed value and an accepted reference value (known or assigned). Accuracy includes a combination of random error (precision) and systematic error (bias) components. The *z-score* is a measure of accuracy.

Analytical bias: The difference between the laboratory's test result and the assigned value, calculated as $D = x - X$, where D is the deviation, x is the laboratory's test result, and X is the *assigned value*¹. This deviation, normalized with the robust standard deviation, is evaluated with the *z-score* calculation².

Systemic bias is indicated when the laboratory's test results (ranked by the *Youden non-parametric analysis*³ for an individual parameter) are consistently higher or lower than the assigned value. Systemic bias may be indicated by the Youden rankings even when the test results have not been flagged for deviation from the assigned value.

¹ ISO 13528:2005(E), Statistical Methods for the use in Proficiency Testing by Interlaboratory Comparisons, Calculation of Performance Statistics, Section 7.1.1 and 7.1.2, p18-19.

² ISO 13528:2005(E), Statistical Methods for the use in Proficiency Testing by Interlaboratory Comparisons, z-scores, Section 7.4.1 and 7.4.2, p25-26.

³ Ranking Laboratories by Round-Robin Tests, W.J. Youden, Precision Measurement and Calibration, H.H. Ku, Editor, NBS Special Publication 300-Volume 1, U.S. Government Printing Office, Washington, D.C., 1969.

Assigned Value: The value attributed to a particular property of a proficiency test item (ISO 17043:2010 Section 3). ISO 13528:2005 allows different procedures for determining the assigned value, including calculation of the robust mean from participant results, utilized by EC.

Performance evaluation (PE) sample: A sample, the composition of which is unknown to the analyst, provided to test whether the analyst / laboratory can produce analytical results within specified acceptance criteria. (USEPA QAMS).

Proficiency testing (PT): A systematic program in which one or more standardized samples is analyzed by one or more laboratories to determine the capability of each participant. (USEPA QAMS).

Robustness: The sensitivity of a statistical test method to departures from underlying assumptions. (USEPA QAMS).

*Youden non-parametric analysis*³: A method for determining if the measurement distribution of any one of a group of objects has a mean significantly different from the rest.

Z-score: The number of standard deviations a laboratory's test result differs from the assigned value, calculated by subtracting the assigned value from the laboratory's test result and dividing the difference by the robust standard deviation of all participants' test results from the assigned value. Warning limits and action limits typically are established at z-scores exceeding |2.0| and |3.0|, respectively.

6.0 PROCEDURE

6.1 Selection of a PE Provider

The PE Provider should be accredited by an accrediting body recognized by the National Environmental Laboratory Accreditation Conference (NELAC) and conform to NELAC and *ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories* Standards. The final selection of the PE Provider is made by the QAOT, based on the PE Provider's ability to

- prepare samples and evaluate data within the timeframe identified by the QAOT;
- supply PE samples with concentration ranges representative of the South Florida area;
- ensure participation by a sufficient number of laboratories to allow for a robust evaluation of the data; and
- be responsive to participant and PE Administrator questions or concerns.

6.2 Analytes of Interest

The analytes of primary interest and relevance to CERP projects include major ions and nutrients, trace metals, total phosphorus, turbidity, and total mercury (Attachment B). Although the PE samples contain a full suite of parameters, each laboratory is expected to analyze only the parameters listed in its District or USACE Statement of Work (SOW).

6.3 Selection of Participating Laboratories

The QAOT will supply the names of laboratories designated for participation in the QAOT PE Study to the PE Administrator. The list also will identify the matrices (water or sediment) and parameter groups or analyte classes that each laboratory is responsible for analyzing. The PE samples are provided to the selected laboratories at no charge.

6.4 PE Administration

6.4.1 Communication with PE Provider

To initiate the PE study, the PE Administrator will contact the PE Provider via telephone and / or email to establish or review important details of the PE study. The PE Administrator will provide the PE Provider, via e-mail, the names of the QAOT-sponsored laboratories, their shipping addresses, laboratory contact name, telephone number, and e-mail address, and the required matrices and analyte classes specific for each laboratory participant. The PE Provider is then required to submit a final price quote to the PE Administrator for all analytical services associated with the study, including shipping costs (an estimate of foreign transaction fees, if any, should be obtained by the PE Administrator from the bank or credit card company used to transact the purchase). The PE Administrator should instruct the PE Provider to copy the PE Administrator on all e-mail communications with QAOT-sponsored participants.

6.4.2 Communication with Laboratories

When the final PE study details are established with the PE Provider, the participating laboratories are contacted via telephone by the PE Administrator to communicate the pertinent details and provide each laboratory with a general understanding of the study scope and time frame. This initial communication is followed by a formal letter sent via e-mail to each of the participating laboratories (Attachment C). Participants should be made aware of the possibility that the samples may require a shipping time of 48 hours (e.g., if the PE Provider is not located within the continental United States) and may be shipped without temperature preservation (no ice). At the completion of the PE Study, the PE Administrator will send a survey to each participating laboratory with questions associated with the completed study. This survey is used by the QAOT and PE Administrator to improve future studies.

6.5 PE Procurement

The PE Administrator is responsible for procuring the PE samples from the PE Provider. PE sample procurement costs are paid by the PE Sponsor (i.e., the QAOT) and included in the PE Administrator's contract and work order. Costs include the cost of the PE samples, shipping and container costs, and any other incidental expenses incurred by the PE Provider, including any foreign transaction fees. The purchase order (PO) generated by the PE Administrator contains an order form supplied by PE Provider that includes participant contact information, the number of samples, and a list of analyses requested of each laboratory by the QAOT. If the PE Provider is located outside of the continental United States, it will be necessary for the PE Administrator to estimate costs based on current exchange rates; the actual costs will be based on exchange rates on the date the order is accepted by the PE Provider and foreign transaction fees charged by the bank or lending company.

6.6 Establishment of PE Codes

The PE Provider will supply a secure laboratory code to each participating laboratory in the PE study. The participating laboratories must supply the PE Administrator with their laboratory codes; the PE Provider will not do this. These unique codes will be used by the laboratories when reporting data to the PE Provider and by the PE Provider when reporting the PE results to the QAOT and PE Administrator. Once assigned by a particular PE Provider, the laboratory's code does not change, regardless of how frequently or infrequently the laboratory may participate in studies conducted by the PE Provider.

6.7 PE Sample Analysis

PE samples must be handled, prepared, and analyzed by the participating laboratories in the same manner as that used for routine samples. Unless warranted by standard QC and data acceptance criteria, replicate analyses, analyses at multiple dilutions, or special data handling processes for PE samples are unacceptable. All records associated with the analyses of PE samples may be reviewed during future on-site laboratory audits.

6.8 Reporting of Results

The PE Provider will supply specific reporting instructions with the PE samples. Upon completion of PE sample processing and analysis, the analytical laboratories will report the PE sample results by the date specified by the PE Provider using the reporting process defined by the PE Provider. The PE Administrator may facilitate this process by sending an e-mail to participants about impending due dates and reporting requirements.

6.9 PE Provider Data Compilation

The PE Provider will analyze the analytical results, assemble the data submitted by the participating laboratories, and generate both a draft and final data report. The PE Provider will submit a draft report to each participating laboratory and the PE Administrator for review and verification. If the laboratory identifies errors or has any questions associated with the reported results, the laboratory will submit responses or questions to the PE Provider for review and resolution by a specified date. In the event that errors are made by the PE Provider, the errors will be corrected; however, data entry errors made by the laboratory but not corrected during this review and resolution time period will not be corrected for the final report. The PE Provider will then release the final PE study report and individual laboratory results to the PE Administrator and participating laboratories. The PE Administrator should request that the PE Provider supply the data in electronic format, in addition to the formal report, so that the PE Administrator can compile, query, evaluate, and summarize the data electronically and not by manual means.

6.10 Preparation of PE Report

The PE Administrator will prepare a report for the QAOT that summarizes the results of the PE study (Attachment D). The report should contain the following disclaimer, as appropriate.

The laboratories were selected for participation in this PE study because they are contracted by either USACE or SFWMD and could thus be used for the analysis of samples that support CERP projects. Each laboratory was instructed to analyze PE analyte classes

based on their current CERP-related analyses. Some laboratories elected to analyze parameters within an analyte class that they are not currently analyzing for CERP-related projects at this time. Therefore, a low rating on a specific parameter does not necessarily indicate that data for CERP were generated by a poor-scoring laboratory.

The PE Administrator will submit a draft report in Microsoft Word format to the QAOT for review within four weeks after the release of final data by the PE Provider. A summary of participant scores may be provided via e-mail or telephone communication, prior to the draft report being issued, to give the QAOT a general sense of participant performance.

6.11 Review of PE Report

The PE report will be prepared as one draft and one final version, with one formal comment review cycle. Upon receipt of the draft PE report, the QAOT will review the report and submit traceable, electronic comments, usually within ten business days of submission of the draft report. The PE Administrator will address QAOT comments and provide the final report within ten business days of receipt of comments or otherwise agreed-upon due date. If necessary, unresolved comments can be discussed during the next QAOT meeting or during a separate conference call. When the report is final, it will be posted in Documentum in the QAOT QA Cabinet by a designated member of the QAOT. The QAOT is responsible for the distribution of the draft and final PE reports to the entire QAOT distribution list.

7.0 QUALITY ASSURANCE AND QUALITY CONTROL

Accurate handling, interpretation, and representation of PE results presented in report tables and figures must be verified to ensure that the report is accurate and complete. The following procedures must be performed before the draft report is submitted to the QAOT.

- Hand-entered data or data generated from database queries must be verified 100% for transcription or logic errors.
- Changes to data to achieve data uniformity (e.g., units of measurement) must be verified 100%.
- Tables and figures that depict numeric data must be compared with the results provided by the PE Provider and confirmed as being 100% accurate.
- The draft PE report must receive an internal technical, editorial, and quality assurance review by the PE Administrator's company, prior to submission to the QAOT. In particular, the report text must be verified versus the tables and figures to ensure that data are discussed accurately.

7.1 QAOT Review

The QAOT will review the draft and final PE reports to ensure that the presentation is clear, accurate, and professional. After the PE study results have been received, a survey will be sent to each participating laboratory to obtain feedback and suggestions for improvement of the PE study process (Attachment E). The results of the survey will be summarized in a short memorandum to the QAOT. Suggestions will be incorporated into the next PE study whenever possible.

7.2 Revisions to this SOP

This SOP will be updated as needed to reflect PE study improvements. Changes to the SOP will be documented (Attachment F).

8.0 REFERENCES

CERP, 2010. Agency Responsibility and Coordination for Quality Assurance, Quality Control and Data Validation for CERP Monitoring Activities. CGM 041.01; July 21, 2010.

ISO 17043:2010. Conformity Assessment – General Requirements for Proficiency Testing.

ISO 13528:2005(E). Statistical Methods for the Use in Proficiency Testing by Interlaboratory Comparisons.

NELAC, 2011. Environmental Laboratory Sector. Volume 1. Management and Technical Requirements for Laboratories Performing Environmental Analysis.

United States Environmental Protection Agency, 2010. Quality Assurance Glossary of the U.S. EPA Quality Assurance Management Staff (QAMS). November 8, 2010.

Attachment A

PE Study Schedule*

Activity		Date		Duration
		Initiated	Completed	
1.	PE Administrator contacts PE Provider	Early April		
2.	Initial planning stage for PE study (identification of QAOT-sponsored laboratories and scope of testing)	Early April		
3.	PE Administrator contacts laboratories	Early May	Mid-May	2 weeks
4.	PE Administrator submits purchase order to PE Provider	Early May	Mid-May	2 weeks
5.	PE samples shipped to participating laboratories	Early June		48 hours
6.	Laboratories analyze PE samples	Early June	Late July	2 months
7.	Laboratories submit PE results	Early June	Late July	2 months
8.	PE Provider submits preliminary data to participating laboratories and PE Administrator	Mid-August		
9.	Laboratories provide corrections to preliminary data to PE Provider	Mid-August	Early September	2 weeks
10.	PE Provider submits final report	Early September	Late September	2 weeks
11.	PE Administrator submits draft PE Study Report to the QAOT	Early October	Early November	1 month
12.	QAOT reviews draft PE Study Report and conducts telecon as needed	Early November	Mid-November	2 weeks
13.	PE Administrator incorporates QAOT comments and generates final PE Study Report.	Mid-November	Late November	2 weeks
14.	PE Administrator provides memorandum to QAOT summarizing feedback from participating laboratories.	October	November	
15.	PE Administrator provides input to biennial Quality Assessment Report	December	January	

* Schedule is based on the study conducted each summer by Environment Canada of Burlington, Ontario.

Attachment B

Typical Analyte Classes and Parameters Included in QAOT-Sponsored PE Studies

Compound Class	Parameter Name	
Mercury	Mercury	
	Major Ions and Nutrients	Ammonia as N
		Boron, B
		Calcium, Ca
		Chloride
		Color
		Conductivity
		Dissolved Organic Carbon
		Dissolved Inorganic Carbon
		Fluoride, F
		Potassium, K
		Magnesium, Mg
		Sodium, Na
		NO ₂ /NO ₃ as N
		pH
		Silicates as SiO ₂
		Sulfate
Total alkalinity as CaCO ₃		
Total Hardness		
Total Kjeldahl as N		
Total Nitrogen		
Trace Metals	Silver, Ag	
	Aluminum, Al	
	Arsenic, As	
	Boron, B	
	Barium, Ba	
	Beryllium, Be	
	Bismuth, Bi	
	Cadmium, Cd	
	Cobalt, Co	
	Chromium, Cr	
	Copper, Cu	
	Iron, Fe	
	Lithium, Li	
	Manganese, Mn	
	Molybdenum, Mo	
	Nickel, Ni	
	Lead, Pb	
	Antimony, Sb	
	Selenium, Se	
	Tin, Sn	
	Strontium, Sr	
	Titanium, Ti	
	Thallium, Tl	
	Uranium, U	
	Vanadium, V	
	Tungsten, W	
	Zinc, Zn	
Total Phosphorus	Total Phosphorus as P	
Turbidity	Turbidity	

Attachment C

Example Letter to QAOT-Sponsored Participating Laboratories

Date

Laboratory Contact, Title

Laboratory

Street Address

City, State Zip code

(Area Code) Telephone number

Re: Performance Evaluation (PE) Study administered by the Comprehensive Everglades Restoration Plan (CERP) Quality Assurance Oversight Team (QAOT)

Dear Laboratory Contact:

Thank you for agreeing to participate in the **(Study Name or ID)** performance evaluation (PE) study being conducted by the CERP QAOT. **(Contractor Name)** is a contractor to the South Florida Water Management District (SFWMD or District) and is assisting the QAOT in administering this study for CERP monitoring led jointly by the District and the US Army Corps of Engineers (USACE). For this particular study, the QAOT has requested that **(Laboratory Name)** participate in five programs: (1) major ions and nutrients, (2) trace elements in water, (3) total phosphorus in water, (4) low-level mercury in water, and (5) trace elements in sediment.

The PE samples will be provided by **(Vendor Name)** as part of **(Study Name or ID)**. The samples will be shipped on **(Date)**, by priority overnight delivery, to the address given at the top of this letter. The samples may not be temperature-preserved during shipment and may not be chemically preserved but should be intact and in good condition upon receipt. The samples must be received and logged into the laboratory in accordance with your laboratory's standard operating procedures (SOPs). **(Laboratory Name)** must immediately notify the PE Provider and PE Administrator if **(Laboratory Name)** believes the PE samples were compromised during shipment. The samples must be analyzed in the same manner afforded routine samples. The methods used must be those that are or would be used for CERP or other District- or USACE-related work.

There is no cost to **(Laboratory Name)** for the purchase and shipment of these samples, and the laboratory is to conduct the analyses at no cost to the QAOT, the District, or USACE. The analytical results must be reported to **(Vendor Name)** by no later than **(Date)**. Preliminary data will be provided to **(Laboratory Name)** and other participants by **(Date)**. You will have until **(Date)**, to respond to the preliminary data. Final reports will be issued by **(Vendor Name)** on **(Date)**. **(Contractor Name)** will conduct a rigorous statistical analysis of the data and will provide a final report in electronic format to the QAOT, who will be responsible for distributing copies of **(Contractor Name)**'s report to the participants. The confidentiality of all laboratories will be protected by blind laboratory number coding.

Upon receipt of this letter, please confirm the accuracy of the shipping information by e-mail reply to **(Contractor Contact)** at the e-mail address given below. Please feel free to contact the undersigned via telephone or e-mail if you have any questions regarding this study.

Sincerely,

CONTRACTOR NAME

Name

Title

email address

Attachment D
PE Study Report Outline

- 1.0 Introduction
- 2.0 Materials and Methods
 - 2.1 Selection of Laboratories
 - 2.2 Selection of PE Provider
 - 2.3 Selection of Analyte Classes
 - 2.4 PE Study Scheduling and Communication
 - 2.5 Analyte Classes of the PE Study
 - 2.5.1 Major Ions and Nutrients in Water (MI)
 - 2.5.2 Trace Elements in Water (TE)
 - 2.5.3 Total Phosphorus in Water (TP)
 - 2.5.4 Turbidity in Water (TU)
 - 2.5.5 Total Mercury (low-level) in Water (HG)
 - 2.5.6 Trace Elements in Sediment (SED)
- 3.0 Analysis
 - 3.1 Assigned Values
 - 3.2 Z-Scores
 - 3.3 Analytical Bias
 - 3.4 Performance Rating System
- 4.0 Results
 - 4.1 Flagged Results
 - 4.2 Biased Parameters
 - 4.3 Laboratory Performance
 - 4.4 Laboratory Feedback and Corrective Actions
- 5.0 Summary
- 6.0 References

Attachment E

Example Survey for QAOT-Sponsored Participating Laboratories

PE Study Element		Goal	Improvements Needed?		Participant Comments
			No	Yes	
1.	Pre-study communication by PE Administrator	Clear and timely; responsive to questions or concerns.			
2.	PE sample shipment and arrival	Arrival date / time allow holding times to be met. Preservation acceptable; labeling clear.			
3.	Sample preparation and analysis instructions	Clear and complete.			
4.	Reporting instructions	Clear and complete.			
5.	On-line reporting process	Clear; user-friendly.			
6.	Review of draft results of PE sample analysis	Clear, easy access, accurate.			
7.	Responsiveness of PE Provider to questions regarding draft results of PE sample analysis	Prompt and satisfactory resolution of issues.			
8.	Review of final results of PE sample analysis	Clear, easy access, accurate.			
9.	PE Provider report	Clear, easy access, accurate.			
10.	Communication with PE Administrator	Timely and satisfactory responses provided by the PE Administrator.			
11.	Communication with PE Provider	Timely and satisfactory responses provided by the PE Provider.			
12.	Participant performance and scoring	Adequate feedback on participant's overall performance and identification of potential sources of analytical error or bias allowing successful corrective action.			
13.	Suggestions for improving the CERP QAOT PE study process	Implementation of suggestions that improve the quality and usefulness of the PE study.			

Attachment F
SOP HISTORY

Revision Status/Number	Revision Date	Description	Author
Revision 0.0 / Final	1/18/2012	Not applicable. Original draft	Rosanna Buhl, Battelle
Revision 1.0	12/16/2013	Additional details added to text. Attachments revised for improved clarity and flexibility.	Cindy Lee Westergard, HSW Engineering, Inc.
Revision 2.0	1/19/2015	Additional details or clarification added to text.	Cindy Lee Westergard, HSW Engineering, Inc.