

**Comprehensive Everglades Restoration Plan
Quality Assurance Oversight Team (QAOT)
Standard Operating Procedures (SOPs)**

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(Last Updated: 2-09-2018)

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COMPREHENSIVE EVERGLADES RESTORATION PLAN



QUALITY ASSURANCE OVERSIGHT TEAM

QAOT Standard Operating Procedure (SOP) and Document Control Requirements

QAOT SOP-001

Version: Revision 2.0

Version Date: March 1, 2012

QAOT Co-Chair Approval:

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Effective Date: March 28, 2012

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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

SOP and Document Control Requirements

- **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** with6.1.1. 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.

SOP and Document Control Requirements

- 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 Date
 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 (irresolvable at the project-level) 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: Quality Assurance Management - CERP Monitoring Project Quality Assurance Activities and Responsibilities	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

COMPREHENSIVE EVERGLADES RESTORATION PLAN



COMPREHENSIVE EVERGLADES RESTORATION PLAN

QUALITY ASSURANCE OVERSIGHT TEAM

Preparation of the Quality Assessment Report (QAR)

QAOT-SOP-003

Version: Revision 2.0
Version Date: December 31, 2012

QAOT Co-Chair Approval

April Anne Patterson - 1/11/13
April Patterson Date
USACE, Jacksonville District

Ming Chen, 5/15/13
Ming Chen Date
South Florida Water Management District

Effective Date: May 15, 2013

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

Variations 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
5.3 Biological/Ecological Monitoring Activities		
6.0 Laboratory Audits 6.1 QAOT Laboratory Assessments: Organics 6.2 QAOT Laboratory Assessments: Inorganics 6.3 Aqueous Inorganic Performance Evaluation Samples	<p>Summarizes the results of laboratory quality systems and procedures vs. the requirements of the QASR and methods.</p> <p>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
7.0 Quality of Data 7.1 Water Quality Data 7.2 Biological Data 7.3 Hydrology Data	<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
8.0 Alternative Procedures Approved	<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
9.0 Summary of Deviations from QASR and Corrective Actions	<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
10.0 Additional QAOT Activities 10.1 Communication and	<p>Summarizes QAOT activities not discussed in Sections 4-7,</p>	<ul style="list-style-type: none"> • Descriptions of presentations, workshops,

Preparation of Annual Quality Assessment Report

Quality Assessment Report Element	Description	Input Sources/Types
<p align="center">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>	

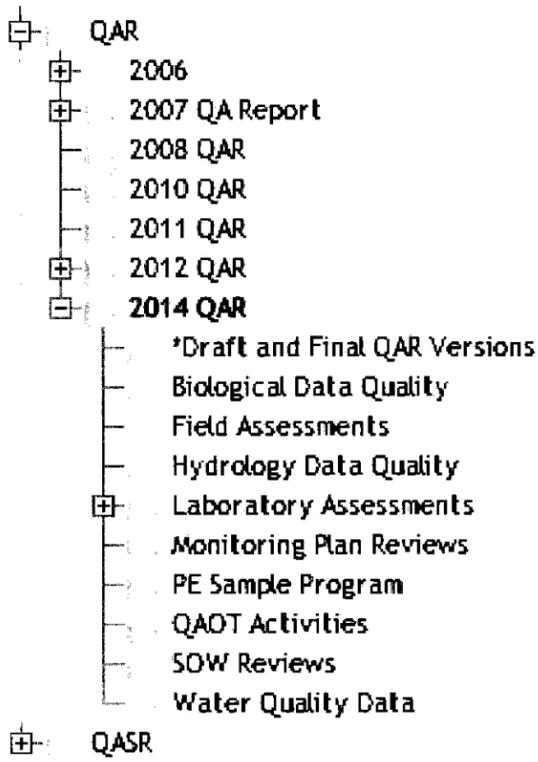
Preparation of Annual Quality Assessment Report

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



QUALITY ASSURANCE OVERSIGHT TEAM

Standard Operating Procedure

for

Review of Project-level Monitoring Plans and Scopes of Work

QAOT SOP-004

Version: Revision 2.0

Version Date: October 09, 2015

QAOT Co-Chair Approval:

Natalie Garrett
Natalie Garrett
USACE, Jacksonville District

11/19/2015
Date

Ming Chen
Ming Chen
South Florida Water Management District
(SFWMD)

Date

Effective Date: 12/01/2015

Review of Project-level Monitoring Plans and Scopes of Work

1.0 Purpose and Applicability

The purpose of this standard operating procedure (SOP) is to establish a procedure for Quality Assurance Oversight Team (QAOT) members in reviewing Project-level Monitoring Plans (PLMP) and/or Scopes of Work (SOW) for Comprehensive Everglades Restoration Plan (CERP) or CERP-related monitoring. This revision supersedes a previous version (Revision 1.0) of the SOP titled “Review of Project Monitoring Plans and Scopes of Work”.

2.0 Summary

The QAOT reviews the quality assurance and quality control (QA/QC) elements of PLMP/SOW specified in the CERP Guidance Memorandum (CGM) 40.02 for compliance with the CERP Quality Assurance System Requirements (QASR) Manual. 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/SOW to ensure that it meets the applicable CGM requirements.

3.0 Procedure

- 3.1. The CERP project delivery team (PDT) and/or project managers shall submit the PLMP/SOW to the QAOT co-chairs for QAOT review and approval before the document is finalized and distributed. It is strongly suggested that the PDTs consider QA and data management requirements at the early stage of project planning and prepare the PLMP/SOW using the CGM 40.02 templates.
- 3.2. The QAOT co-chairs will assign at least two QAOT members to conduct the review using a checklist (Attachment 1) to determine if the PLMP/SOW is in compliance with the CGM 40.02. The PLMP/SOW will be reviewed by the QAOT members within two weeks of receipt.
- 3.3. A letter will be sent to the PLMP/SOW author documenting the acceptability of the PLMP/SOW (Attachment 2) or itemizing deficiencies (Attachment 3) by the QAOT co-chairs.
- 3.4. The PDT and/or project managers should incorporate the QAOT review comments within two weeks or 5 to 10 business days after receiving the letter. A formal response letter or email needs to be submitted to the QAOT to notify the implementation of the review comments or clarification on why a specific review comment is not incorporated. If necessary, the revised PLMP/SOW needs to be resubmitted for additional QAOT review (Section 3.1).
- 3.5. The date and contents of the QAOT review comments and PDT responses shall be part of the monitoring plan review documentation, which shall be posted in CERP Documentum under the QAOT’s PLMP/SOW review folder.

4.0 Responsibility

It is the responsibility of the PLMP/SOW author to submit those and other associating documents to the QAOT for review, and to incorporate, clarify, and/or elaborate in writing why each of the QAOT’s review comments is not incorporated. It is the responsibility of the QAOT co-chairs to coordinate the QAOT review effort and to follow-up with the PDT and/or project managers to see if there is a contract, permit or other supporting document associating with the project for additional QAOT or technical review. This process includes assigning review tasks, sending letters to the PLMP/SOW author detailing the reviewer comments, and following up on QAOT review recommendations.

5.0 Deliverables

 Review of Project-level Monitoring Plans and Scopes of Work

- 1.1. Results of the QAOT review will be documented on the Quality Assurance Oversight Team PLMP/SOW checklist (Attachment 1).
- 1.2. The checklist will be accompanied by a cover letter that describes the review and response process and indicates whether or not the PLMP/SOW meets QASR requirements. Attachments 2 and 3 provide letter templates that accompany the checklists for acceptable monitoring plans and monitoring plans requiring revision, respectively.

6.0 References

QAOT. 2010. Agency Responsibility and Coordination for Quality Assurance, Quality Control and Data Validation for CERP Environmental Monitoring. CERP Guidance Memorandum 040.01. Quality Assurance Oversight Team, South Florida Water Management District, West Palm Beach, FL, and U.S. Army Corps of Engineers, Jacksonville, FL. Effective 21 July 2010.

QAOT. 2012. Project-level Monitoring and Assessment. CERP Guidance Memorandum 040.02. Quality Assurance Oversight Team, South Florida Water Management District, West Palm Beach, FL, and U.S. Army Corps of Engineers, Jacksonville, FL. Effective 01 April 2012.

QAOT. 2012. QAOT Standard Operating Procedure and Document Control Requirements. QAOT SOP-001, Revision 2.0. Quality Assurance Oversight Team, South Florida Water Management District, West Palm Beach, FL, and U.S. Army Corps of Engineers, Jacksonville, FL. Effective 03/28/2012.

QAOT. 2013. Quality Assurance System Requirements Manual. Quality Assurance Oversight Team, South Florida Water Management District, West Palm Beach, FL, and U.S. Army Corps of Engineers, Jacksonville, FL.

SOP 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
Revision 1.0	December 23, 2008	Review of Project Monitoring Plans and Scope of Works – final approval.	R. Buhl
Revision 2.0	October 09, 2015	Review of Project-level Monitoring Plans and Scope of Works – Revision of the review checklist according to CGM 40.02.	M. Chen

 Review of Project-level Monitoring Plans and Scopes of Work

Attachment 1**Quality Assurance Oversight Team *Monitoring Plan / Scope of Work* Review Checklist**

(revised October 2015)

Project Title:**Date:****Review Codes:**

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

U=unacceptable, required elements are not incorporated in text or by specific reference

NA=not applicable, not required for this Project Plan

Element	Review Code	Page	Comments
Introduction and General Requirements			
Project Description			
Project Objectives			
Active Mandates and Permits			
Project Reporting: Frequency, Content and Format			
Project Reporting: report recipients			
Organization Structure and Responsibilities			
Monitoring Plan Components*			
Hydrology			
Water Quality			
Ecology			

**Note if monitoring plan components are not applicable or provide review comments on next pages.*

General comments:

Reviewer:**Review Date:**

Review of Project-level Monitoring Plans and Scopes of Work

Attachment 1

Quality Assurance Oversight Team [Monitoring Plan / Scope of Work](#) Review Checklist

(revised October 2015)

Project Title:

Date:

Review Codes:

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

U=unacceptable, required elements are not incorporated in text or by specific reference

NA=not applicable, not required for this Project Plan

Hydrology Requirements	Review Code	Page	Comments
Data Quality Objectives: required reporting limits, precision, accuracy, comparability and acceptance criteria			
Data Collection and Field documentation			
Sampling Duration			
Sampling Locations, Frequency, and Naming Conventions			
QC Procedures: system for accessing data quality attributes			
QC Procedures: data quality qualifiers			
Field and Laboratory Audits: are specified in the contract / scope of work			
Data Analysis: data processing as per QASR			
Data Records Management and Storage (DBHYDRO and/or CID)			

General comments:

Reviewer:

Review Date:

Review of Project-level Monitoring Plans and Scopes of Work

Attachment 1

Quality Assurance Oversight Team [Monitoring Plan / Scope of Work](#) Review Checklist

(revised October 2015)

Project Title:

Date:

Review Codes:

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

U=unacceptable, required elements are not incorporated in text or by specific reference

NA=not applicable, not required for this Project Plan

Water Quality Requirements	Review Code	Page	Comments
Data Quality Objectives: required reporting limits, precision, accuracy, comparability and acceptance criteria			
Data Collection and Field documentation			
Sampling Duration			
Sampling Locations, Frequency, and Naming Conventions			
QC Procedures: system for accessing data quality attributes			
QC Procedures: data quality qualifiers			
Field and Laboratory Audits: are specified in the contract / scope of work			
Data Analysis: data processing as per QASR			
Data Records Management and Storage (DBHYDRO and/or CID)			

General comments:

Reviewer:

Review Date:

Review of Project-level Monitoring Plans and Scopes of Work

Attachment 1

Quality Assurance Oversight Team [Monitoring Plan / Scope of Work](#) Review Checklist

(revised October 2015)

Project Title:

Date:

Review Codes:

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

U=unacceptable, required elements are not incorporated in text or by specific reference

NA=not applicable, not required for this Project Plan

Ecological Requirements	Review Code	Page	Comments
Data Quality Objectives: required reporting limits, precision, accuracy, comparability and acceptance criteria			
Data Collection and Field documentation			
Sampling Duration			
Sampling Locations, Frequency, and Naming Conventions			
QC Procedures: system for accessing data quality attributes			
QC Procedures: data quality qualifiers			
Field and Laboratory Audits: are specified in the contract / scope of work			
Data Analysis: data processing as per QASR			
Data Records Management and Storage (DBHYDRO and/or CID)			

General comments:

Reviewer:

Review Date:

Review of Project-level Monitoring Plans and Scopes of Work

Attachment 2

Example Letter for Acceptable Monitoring Plans / Scopes of Work

LOGOS/LETTERHEAD

Date (month dd, yyyy)

Project Manager Name
Project Manager Address

Subject: Monitoring Plan / Scope of Work Review (Date)
Title of Monitoring Plan / Scope of Work

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 / scope of work](#) for [\(Title of Monitoring Plan / Scope of Work\)](#). The purpose of the QAOT review was to determine if the [monitoring plan / scope of work](#) adequately addressed the quality assurance and quality control requirements for CERP projects defined in the Quality Assurance Systems Requirements (QASR) manual and specified further at the CERP Guidance Memorandum (CGM) 40.02.

The results of the [monitoring plan / scope of work](#) review are summarized on the attached checklist. Our review found that the [monitoring plan / scope of work](#) 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-level Monitoring Plans and Scopes of Work

Attachment 3

Example Letter for Monitoring Plans / [Scopes of Work](#) Requiring Revision

[LOGOS/LETTERHEAD](#)

[Date \(month dd, yyyy\)](#)

[Project Manager Name](#)
[Project Manager Address](#)

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

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 / scope of work](#) for ([Title of Monitoring Plan / Scope of Work](#)). The purpose of the QAOT review was to determine if the [monitoring plan / scope of work](#) adequately addressed the quality assurance and quality control requirements for CERP projects defined in the Quality Assurance Systems Requirements (QASR) manual and specified further at the CERP Guidance Memorandum (CGM) 40.02.

The results of the [monitoring plan / scope of work](#) review are summarized on the attached checklist. As noted in the checklist, [insert number of "U" codes](#) QA/QC elements were not adequately described (U code) in the draft [monitoring plan / scope of work](#). It is important that this [monitoring plan / scope of work](#) be revised to address these missing elements to ensure that the data quality is adequate. Please revise the [monitoring plan / scope of work](#) 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

COMPREHENSIVE EVERGLADES RESTORATION PLAN



QUALITY ASSURANCE OVERSIGHT TEAM

Standard Operating Procedure for Administering and Reporting Analytical Performance Evaluation Studies of Inorganic Analytes

QAOT-SOP-005

Revision 3.0

March 2017

QAOT Co-Chair Approval

RAMOS-
GINES.ORLANDO.12
58618382

Digitally signed by RAMOS-
GINES.ORLANDO.1258618382
DN: c=US, o=U.S. Government,
ou=DoD, ou=PKI, ou=USA, cn=RAMOS-
GINES.ORLANDO.1258618382
Date: 2017.04.17 16:18:43 -04'00'

Orlando Ramos-Gines
U.S. Army Corps of Engineers

Date

Ming Chen
South Florida Water Management District

Date

Effective Date: April 07, 2017

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ATTACHMENTS

- A. PE Study Schedule
- B. Analyte Classes and Parameters Typically 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
- F. SOP History

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 who provide, or may provide, analytical data for inorganic analytes for CERP projects or CERP-related monitoring. The purpose of these studies is to allow an objective assessment the ability of participating laboratories to accurately quantify concentrations of inorganic 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. A separate SOP is utilized by the QAOT for assessing the performance of laboratories in producing data for organic analytes for CERP projects (QAOT SOP-006, Revision 0.0, March 2017).

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 (CERP Guidance Memorandum CGM 041.01; July 21, 2010). A PE study involving two or more laboratories analyzing samples provided by a qualified vendor for a defined set of analytes provides an objective means of evaluating individual laboratory performance and assessing the extent of comparability of analytical data between and among participating 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 or USACE contractors. In some instances, laboratories being considered for contracts may be recommended by SFWMD or USACE project managers for inclusion in the study for a given year. The QAOT also encourages certain laboratories who are interested in CERP or CERP-related studies to voluntarily participate in the PE study at their own cost. The results of the PE studies help project managers and the QAOT ensure 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 the QAOT 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 routinely used to analyze samples for CERP or 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 of interest to the QAOT are interpreted 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.

CERP Project Managers

CERP project managers are responsible for communicating with the QAOT to make sure the laboratories they are using or plan to use are aware of the QAOT's expectation that they will participate in the QAOT-sponsored PE studies or other quality assessment activities mandated under CGM 041.01. CERP project managers also are responsible for providing feedback to the QAOT on laboratory performance issues.

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). As part of this responsibility, the QAOT selects the matrices to be analyzed by each laboratory and identifies the specific analytes to be reported.

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, obtains feedback from laboratories earning unsatisfactory performance scores, 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.

The PE Administrator is also responsible for coordinating with the PE Provider to provide the samples for the PE study. This includes preparing, splitting, shipping, and distributing the PE samples to the laboratories, as well as 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 must 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.

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 PROCEDURES

6.1 Selection of a PE Provider

The PE Provider must 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;

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.

- 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, and total mercury (Attachment B). Although the PE samples typically 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), or as specified by the QAOT and communicated to the laboratories by the PE Administrator at the initiation of the study. Restricting the list of reported analytes to only those of interest to the QAOT will allow easier inter-laboratory comparisons and maximize the study's relevancy to CERP-related projects.

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 for which each laboratory is responsible for analyzing. The PE samples are purchased by the QAOT (except for laboratories participating voluntarily) and provided to the QAOT-sponsored laboratories at no charge. Laboratories voluntarily participating in this PE study must contact the PE Administrator at least one month in advance to confirm their participation, with PE samples purchased on the laboratories' own cost.

Prior to receiving samples, the laboratories will provide (as applicable) the following information to the PE Administrator.

1. The names of all USACE and/or SFWMD Project Managers who coordinate with the laboratory for CERP-related projects
2. The known CERP projects for which the laboratory provides data or for which the laboratory intends to provide data.
3. All USACE and/or SFWMD contract numbers for which the laboratory provides CERP data or for which the laboratory intends to provide CERP data.
4. The specific parameters for which the laboratory provides CERP data or for which the laboratory intends to provide CERP data.

This information is used by the QAOT and PE Administrator to improve future studies and to provide documentation to the QAOT for inclusion in CERP QAOT Quality Assurance Reports.

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 email to establish and 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, including the voluntary participants, their shipping addresses, laboratory contact names, telephone numbers, and e-mail addresses, 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 voluntary participants will pay the PE Provider separately. The PE Administrator will instruct the PE Provider to copy the PE Administrator on all e-mail communications with QAOT-sponsored participants, including the voluntary 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 will be made aware of the possibility 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). The PE Administrator will confirm each participating laboratory received the samples in good condition and logged the samples into their laboratory system for the required analyses. Before the final date for submitting results, the PE Administrator will contact each laboratory to confirm the laboratory has or will be submitting results on time. 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.

6.4.3 PE Sample Procurement

The PE Administrator is responsible for procuring the PE samples from the PE Provider for the QAOT-sponsored laboratories (i.e., excluding any voluntary participants). PE sample procurement costs are paid by the PE Sponsor (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 the 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.

6.4.4 Establishment of PE Codes

The PE Administrator will communicate with the PE Provider to 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.

6.4.5 PE Sample Receipt, Log-in, and Analysis

PE samples must be received, logged in, handled, prepared, and analyzed by the participating laboratories in the same manner as 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. The PE Administrator will contact the QAOT-sponsored laboratories, including the voluntary participants, shortly after the projected receipt dates, to confirm the samples were received in good condition and logged in for the required analyses.

6.4.6 Reporting of Results

The PE Administrator will communicate with the PE Provider to 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 will facilitate this process by sending an e-mail to participants about impending due dates and reporting requirements or by contacting the laboratories to confirm the samples were analyzed as requested and data will be reported.

6.4.7 Data Compilation

The PE Administrator will communicate with the PE Provider to analyze the analytical results, assemble the data submitted by the participating laboratories, and generate both a draft and final data report to include all participating laboratories. The PE Administrator will review the draft report to confirm participation by all QAOT-sponsored laboratories, including the voluntary participants, as planned and determine whether there is evidence of reporting errors. The PE Administrator will forward a copy of this preliminary report to the QAOT and notify any non-participation or results that appear anomalous or suggestive of reporting errors.

Each QAOT-sponsored laboratory, including the voluntary participants, must carefully review their results in the preliminary report to confirm the results correctly reflect those intended by the laboratory. If the laboratory identifies reporting errors or has any questions associated with the reported results, the laboratory must submit responses or questions to the PE Provider and the PE Administrator for review and resolution by a specified date. The PE Administrator will inform all QAOT-sponsored laboratories, including the voluntary participants, that corrections made during this time period properly include corrections for gross reporting error; e.g., corrections to ensure the results incorporated the proper sample preparation factors, were adjusted for any dilution factors, and were reported in the required reporting units, as the quality and usefulness of the statistical evaluations made by the PE Provider for each parameter and analyte class depend on the data having been correctly reported by each participating laboratory. The PE Administrator will communicate with the PE Provider to have the data entry or reporting errors made by the laboratory during this review and resolution time period corrected for the final report before it is released by the PE Provider. The PE Administrator will request the PE Provider supply the data in electronic format, in addition to the formal report, so the PE Administrator can compile, query, evaluate, and summarize the data electronically and minimize manual data entry for the summary report to the QAOT.

6.4.8 Preparation of PE Study Report

The PE Administrator will prepare a report for the QAOT that summarizes the results of the PE study (Attachment D). The source documents for the most recently completed report will be used as templates for the current report. A separated category to include results for the voluntary participants can be created in the report if needed. The report will 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 or were otherwise recommended to the QAOT for sponsorship 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 or as otherwise instructed by the QAOT via the PE Administrator. Should a laboratory have chosen to report analytes not requested by the QAOT, the laboratory must have obtained a separate laboratory PE code from the PE Provider so the results do not affect the PE Provider's scoring for the QAOT-requested analytes. Data for any analytes reported by a laboratory that were not requested may be excluded from the PE study report.

The PE Administrator will submit a draft report in Microsoft Word to the QAOT within four weeks of the release of final data by the PE Provider or in advance by at least one week of the next scheduled QAOT meeting. 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.

6.4.9 Review of PE Study 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, generally in advance by at least one week of the next scheduled QAOT meeting. If necessary, unresolved comments can be discussed during the QAOT meeting or 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 and to the participating laboratories.

6.4.10 Review of PE Study Report

The PE Administrator is responsible for following up with any laboratories for which a performance score of "Poor" was assigned by the PE Provider for one or more analyte classes. Each laboratory will be asked for information regarding any investigations undertaken to determine the cause of the poor performance and any corrective actions implemented or planned. Laboratory follow-up may not have been completed when the draft PE Study Report is generated, but enough information should be available by the time the final PE Study Report is generated such that it can be summarized in the report.

6.4.11 Release the PE Study Reports to CERP Project Managers

The QAOT will send a copy of the final PE study report to CERP project managers to help assist the project managers with laboratory selection and decision-making. Laboratories who were recommended by the project managers for participation in the study but who chose not to participate may be excluded from

CERP work at the discretion of the QAOT; in which case, a full QAOT quality assessment of the laboratory quality system may be appropriate.

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 the report is accurate and complete. The verification process is conducted first by the individual who initially worked with the data (e.g., the PE Administrator) and then by a qualified individual within the PE Administrator's organization. The following procedures must be performed by both of these individuals 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 peer review by a senior-level technical staff member within the PE Administrator's organization, prior to submission of the draft report to the QAOT. In particular, the report text must be verified versus the tables and figures to ensure study findings are presented and discussed accurately.

7.1 Participant Survey

After the PE study results have been received, a survey will be sent by the PE Administrator to each participating laboratory to obtain feedback and suggestions for improvement of the PE study process (Attachment E). The PE Administrator will summarize the results of the survey in a short memorandum to the QAOT within one month of completion of the final PE study report. Suggestions will be incorporated into the next PE study when 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.

International Standard. 2010. ISO/IEC 17043:2010. Conformity Assessment – General Requirements for Proficiency Testing. ISO 2010. First Edition. February 1, 2010.

International Standard. 2005. ISO 13528:2005(E). Statistical Methods for the Use in Proficiency Testing by Interlaboratory Comparisons. ISO 2005. First Edition. September 1, 2005.

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

Quality Assurance Oversight Team, 2017. Standard Operating Procedure for Conducting Laboratory Assessments. QAOT SOP-006. Revision 0.0. March 2017.

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	Mid-April	2 weeks
2.	Initial planning stage for PE study (identification of QAOT-sponsored laboratories and scope of testing)	Early April	Early May	1 month
3.	PE Administrator contacts laboratories to provide notice of upcoming study.	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; PE Administrator confirms acceptable receipt and log-in.	Early June		72 hours
6.	Laboratories analyze PE samples.	Early June	Late July	2 months
7.	Laboratories submit PE results; PE Administrator confirms laboratory participation and submittal of results.	Early June	Late July	2 months
8.	PE Provider submits preliminary data to participating laboratories and PE Administrator; PE Administrator reviews data to confirm laboratory participation and for evidence of obvious reporting errors.	Mid-August		
9.	Laboratories provide corrections to preliminary data to PE Provider. PE Administrator contacts laboratories for which there is evidence of possible reporting errors to encourage review and correction, if needed, by the laboratories.	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 final laboratory responses regarding performance and corrective actions into report and generates final PE Study Report.	Mid-November	Late November	2 weeks
14.	PE Administrator provides email to SFWMD's QAOT member summarizing feedback from participating laboratories.	November	December	
15.	PE Administrator provides input to biennial Quality Assessment Report.	December	January	

* Schedule is based on the study conducted each summer by Environment and Climate Change Canada (ECCC) of Burlington, Ontario.

Attachment B

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

Compound Class*	Parameter Name
Low-Level Mercury	Mercury
Major Ions and Nutrients in Water	Ammonia as N
	Calcium, Ca
	Chloride
	Conductivity
	Dissolved Organic Carbon
	Magnesium, Mg
	NO ₂ /NO ₃ as N
	Sulfate
	Total alkalinity as CaCO ₃
	Total Hardness
	Total Kjeldahl as N
	Total Nitrogen
Trace Elements (Metals) in Water or Sediment	Silver, Ag
	Aluminum, Al
	Arsenic, As
	Barium, Ba
	Beryllium, Be
	Cadmium, Cd
	Calcium, Ca
	Chromium, Cr
	Copper, Cu
	Magnesium, Mg
	Nickel, Ni
	Lead, Pb
	Antimony, Sb
	Selenium, Se
	Thallium, Tl
Zinc, Zn	
Total Phosphorus in Water	Total Phosphorus as P

* Compound Class is based on the study conducted each summer by Environment and Climate Change Canada (ECCC) of Burlington, Ontario.

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 serves as the PE Administrator for 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 **(Laboratory Name)** participate in **(number)** programs: **(list of analyte classes)**.

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 or two-day delivery, to the address given at the top of this letter. The samples may not be temperature- or 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)**. It is your responsibility to carefully review these data for accurate reporting on or before the date indicated by the PE Provider. Please note the PE Provider expects to make corrections to data that were inadvertently misreported by the laboratory (e.g., with incorrect dilution factors or incorrect units), and **(Laboratory Name)** is expected to take advantage of this opportunity to make any such corrections before the end of the preliminary data review period, after which, no corrections can be made. 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. Note that the PE Administrator is responsible for conducting follow-up with laboratories earning a score of "Poor" for one or more analyte classes. It is expected **(Laboratory Name)** will respond to requests by the PE Administrator for information regarding any investigations and corrective actions so this information can be reported to the QAOT and included in the final PE Study report produced by the PE Administrator. A non-response will be interpreted as no action take.

Upon receipt of this letter, please confirm the accuracy of the shipping information, as well as your willingness to participate in this study and provide any needed follow-up information to the PE Administrator and QAOT, 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)
 - 2.5.5 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 Recommendations
- 7.0 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.
Revision 3.0	3/2017	Specifications to parameters, participating laboratories, and project managers' responsibilities added to text. SOP title revised to indicate that this SOP addresses PE studies of inorganic analytes.	Cindy Lee Westergard, HSW Engineering, Inc.

COMPREHENSIVE EVERGLADES RESTORATION PLAN



QUALITY ASSURANCE OVERSIGHT TEAM

Standard Operating Procedure
for
Conducting Laboratory Assessments

QAOT SOP-006

Version: Revision 0.0

Version Date: August 18, 2017

QAOT Co-Chair Approval

Orlando Ramos-Gines
U.S. Army Corps of Engineers

Date

Ming Chen

Ming Chen
South Florida Water Management District

8/18/17

Date

Effective Date: _____

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1.0 PURPOSE AND APPLICABILITY

The goal of the Comprehensive Everglades Restoration Plan (CERP) laboratory assessment program is to assess, at the bench level, the laboratory's proficiency to perform chemical analysis and to ensure the analytical chemistry laboratories meet the Quality Assurance/Quality Control (QA/QC) requirements defined in the methods which are required for the project, CERP Quality Assurance Systems Requirements (QASR) manual chapter 4, and Chapter 62-160, Florida Administrative Code, Quality Assurance (Florida Department of Environmental Protection). This program is designed to help laboratories improve their performance. The program is one of the assessment tools, along with laboratory certification, the yearly Quality Assurance Oversight Team (QAOT) sponsored inorganic Performance Evaluation (PE) study, and historical performance that should be used by project managers (PM) in the selection of laboratories for monitoring activities. The desired outcome of these assessments is to enhance assurance that laboratories are producing reliable and accurate data for CERP samples by following the QASR manual.

This Standard Operating Procedure (SOP) documents the process followed by the QAOT in performing laboratory assessments for facilities that conduct or may conduct analysis of samples for CERP projects. This SOP supersedes any organizational SOPs previously used by the QAOT for conducting laboratory assessments for CERP monitoring. These documents include the South Florida Water Management District (FWMD) Quality System SOP for Conducting Laboratory Audits (SFWMD 2011) and the U.S. Army Corps of Engineers (USACE) SOP for Laboratory Assessment Support for the Quality Assurance Oversight Team of the Comprehensive Everglades Restoration Plan for Remote and On-Site Assessments (USACE 2012), and/or their previous versions.

The performance evaluation (PE) study process described in Section 6.4 of this SOP only applies to organic parameters. The inter-laboratory PE study for inorganic parameters is following a separate QAOT SOP for Administering and Reporting Analytical Performance Evaluation Studies (QAOT SOP-005, QAOT 2017).

2.0 BACKGROUND

The QAOT is responsible for administering a QA/QC program for CERP monitoring activities (CGM 041.01; July 21, 2010). Furthermore, the Information and Data Program Management Plan (PMP) directs the QAOT to implement a QA/QC audit program for CERP monitoring activities including laboratory, field, and project assessments (Information and Data Management Program Management Plan, May 2011).

It is not practical to assess a laboratory when CERP samples are received, prepared and analyzed, therefore an assessment of laboratory operations is one way of verifying laboratory performance. The process described in this SOP complements the FDOH Environmental Laboratory Certification Program audit process, and does not replace it; rather, the focus is on laboratory performance on only those methods used (or that may be used) for CERP sample analysis. The QAOT has used this process to conduct 30 assessments since its inception in 2006 to help ensure the efficient use of funding.

3.0 SUMMARY

The laboratory assessment process includes the following:

- Remote desk assessment of the laboratory's documentation. This first step includes review of SOPs for the methods being assessed, method performance criteria and supporting QA/QC practices as detailed in the laboratory's Quality Manual.
- When applicable, analysis of appropriate commercial organic PE samples is provided at no charge to the laboratory. These single-blind samples are to be analyzed by the laboratory as routine samples, and results are evaluated by the assessor based on acceptance limits provided by the PE sample supplier.
- On-site visit to verify documented processes are being followed by the laboratory. This includes entrance and exit briefings, discussion of the desk assessment report, and a thorough walk-through and discussion with the analysts performing the sample preparation and analysis.

4.0 DUTIES AND RESPONSIBILITIES

4.1 Project Managers

It is the responsibility of CERP Project Managers or their point-of-contact (POC) to provide QAOT, and the assessor, necessary information and assistance to ensure laboratories used in their projects are participating in the inorganic PE studies and are submitting the request to the QAOT for a laboratory quality assessment.

4.2 Quality Assurance Oversight Team

The QAOT is responsible for administering a QA/QC program for the CERP, including overseeing laboratory assessments (CGM 041.01; July 21, 2010). Team members are responsible for identifying laboratories in need of assessment.

QAOT Co-Chairs are responsible for coordinating with QAOT members in identifying laboratories in need of assessment and providing the assessor with the laboratory's POC. The Co-Chairs are also responsible for providing funding to the assessor to complete the assessment.

4.3 Assessor

The assessor is responsible for notifying the laboratory Quality Assurance Officer and Laboratory Manager to inform them of selection by the QAOT for an assessment for CERP. The assessor requests proper documentation, performs the reviews, performs the on-site visit, coordinates the laboratory specific organic PE samples when applicable, follows-up with the laboratory for responses to corrective actions, and writes draft and a final assessment reports.

Note: For the organic PE samples, don't be confused with the QAOT sponsored PE study for inorganic parameters, which is conducted separately by following QAOT SOP-005.

4.4 Laboratory

The laboratory is responsible for providing the assessor with all documentation requested, providing access to the facility and employees for the on-site visit, and analyzing PE samples when applicable (at no cost to the QAOT).

5.0 DEFINITIONS

- 5.1 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)
- 5.2 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).
- 5.3 NELAC/NELAP - National Environmental Laboratory Accreditation Conference / National Environmental Laboratory Accreditation Program.

6.0 PROCEDURE

6.1 Initiation Procedure

The QAOT member who identified the laboratory in need of assessment, with assistance of the CERP PMs or their POC, will provide the assessor with the methods to be assessed. It is recommended that no more than five methods be identified for assessment; this will keep the time required to be at the laboratory for the on-site visit to one day. The assessor will then contact the laboratory via a phone call informing the laboratory they have been selected for an assessment. The assessor will then email the laboratory with a detailed listing of documentation required requesting it be received within 10 working days. This listing includes current copies of the following:

- Quality Manual
- SOPs (SOP) for the methods/applicable parameters of interest
- Method Detection Limit (MDL) studies (current and for time of data deliverable assessed if MDL has changed)
- Control charts
- QAOT sponsored PE study results for applicable inorganic parameters
- NELAP PT sample results from the last three rounds
- FDOH certification (current certification and for time of data deliverable assessed if certification has changed)
- Complete data deliverable produced during the previous year from the CERP project, (if available) – including instrumental raw data, Electronic Data Deliverable (EDD), and the final report sent to the client
- Contract, scope of work, work order, purchase order, monitoring plan – as necessary

In addition, the laboratory will provide (as applicable):

- A list of all USACE and/or SFWMD PMs who coordinate with the laboratory for CERP related projects

- The known CERP projects for which the laboratory provides data or for which the laboratory intends to provide data.
- All USACE and/or SFWMD contract numbers for which the laboratory provides CERP data or for which the laboratory intends to provide CERP data.
- The specific parameters for which the laboratory provides CERP data or for which the laboratory intends to provide CERP data.

This information is used by the QAOT to allow for coordination with PMs on findings and to provide documentation to QAOT for inclusion in the CERP QAOT Quality Assurance Reports.

6.2 Remote Assessment Review Procedure

The review consists of reading the documentation provided and comparing against the contract, scope of work, etc. noting inconsistencies. If issues are found, the context of the findings are categorized at the discretion of the assessor as follows:

- Observation (O): No impact on data quality (e.g. typographical errors in SOPs) and general information required to make the report useful (e.g. statement that the method detection limit study was performed correctly).
- Recommendation (R): Deviations from method requirements which could impact data quality (e.g. not calibrating volumetric glassware).
- Deficiency (D): Deviations from method/project requirements which will impact data quality (e.g. analyte response factors not evaluated properly resulting in not reporting analytes at low levels (false negatives)).

The draft report is sent to the laboratory for their review and response. The assessor will review the laboratory's responses and if sufficient, will schedule an on-site visit. If a laboratory's response is not satisfactory, the assessor will contact the laboratory (either via a phone call or email) to resolve the issue. If agreement cannot be reached, the assessor will contact the QAOT co-chairs and a phone call to the PM to discuss the issue will ensue. The PM will decide whether or not to continue with the assessment. The draft desk assessment report will then be titled 'draft final' (and listed as 'Enclosure 1' in the Final Report). Note that timelines for the Remote Assessment process is dependent on many variables; the target deadline for completion of the 'draft final' report is 45-calendar days from when documentation was furnished to the assessor.

6.3 On-Site Assessment Procedure

The assessor will contact the laboratory to schedule an on-site visit once the draft final desk assessment report is completed. The assessor will provide a schedule for the on-site assessment. Depending on the complexity of the review needed at the laboratory, two assessors may be needed to adequately perform the on-site visit. The visit will include the following:

- Entrance briefing: Introduction of assessor(s) and laboratory personnel, purpose of the assessment, and review of the schedule.
- Draft final desk assessment report discussion: Any items not resolved through phone calls or emails are deliberated face-to-face to ensure the laboratory and the assessor are completely clear on any issue not resolved. This is not a confrontational discussion; rather it is fact finding driven.

- Walk through of the sample receipt area and discussion with sample log-in personnel to ensure this critical operation is being properly performed.
- Sample Preparation and Analysis discussion with the appropriate technicians and analysts occurs in the rooms where these functions are performed. This is an important aspect of the on-site visit because it involves an in-depth discussion of the procedures/processes used. Sample analysis is reviewed with the analyst at the instrument level.
- Exit briefing: The assessor will document the deficiencies noted. Afterwards, the appropriate lab personnel meet with the assessor to discuss the findings. A final resolution to these findings is not done at this time; rather, this gives the lab a notification on what was found during the on-site visit.

6.4 Organic PE Sample Evaluation Procedure

If applicable, the assessor will purchase, with QAOT funds, organic PE samples from a commercial PT provider for the parameters of interest. The laboratory receives the samples from the provider with instructions on how to prepare and analyze the samples only; the assessor receives both the instructions and the acceptance ranges. The laboratory is told to analyze the samples as they would field samples once the appropriate spiking has occurred. The results are provided to the assessor who will compare the labs results to the acceptance ranges.

If the results from the laboratory are acceptable, (based on acceptance limits provided by the PE samples supplier), the draft PE sample report is written. If any result is deemed unacceptable, the assessor contacts the laboratory for resolution. The laboratory has the option of reanalyzing the PE sample (if possible), or providing documentation as to what may have occurred during the process to produce an unacceptable result. Once resolved, the report becomes 'draft final' (and listed as 'Enclosure 3' in the Final Report). Note that timelines for the PE Sample Evaluation process is dependent on many variables; the target deadline for completion of the 'draft final' report is 45-calendar days.

For inorganic parameters, PE studies are conducted separately by following QAOT SOP-005 (QAOT 2017).

6.5 Draft Laboratory Assessment Report

The assessor may request additional information from the laboratory during the desk assessment (Section 6.2), the on-site visit (copies of log books, chromatograms, etc.) (Section 6.3) and/or the PE study (Section 6.4), which will be helpful for writing the draft assessment report using the categorization (O,R,D) as defined in Section 6.2. The draft report is sent to the laboratory for their review (check for accuracy) and response. The assessor will review the laboratory's responses, and if sufficient, will finalize the report. If a laboratory's response is not satisfactory, the assessor will contact the laboratory (either via a phone call or email) to resolve the issue. If agreement cannot be reached, the assessor will contact the QAOT co-chairs and a phone call to the project PM to discuss the issue will ensue. The project PM will decide if the unresolved issue needs further investigation. The draft assessment report then becomes 'draft final'. Note that timelines for the processes of the Desk Assessment, On-Site Assessment, and the PE Study are dependent on many variables; the target deadline for completion of the 'draft final' report is 45-calendar days.

6.6 Final Laboratory Assessment Report

The “draft final” report will be sent to the co-chairs, who will distribute it to the QAOT members and USACE/SFWMD POCs who are directly associated with the project, for their review. If needed, the appropriate parties will convene a conference call to discuss any outstanding issues. However, these calls should be infrequent because all parties would have already discussed unresolved issues during the draft-final stage for the individual reports. Note that timeline for the Final Laboratory Assessment Report is dependent on many variables; the target deadline for completion of the Final report is 30-calendar days.

Once finalized, a cover letter describing which methods were assessed is attached to the front of the report with the appropriate signature included. In the case of USACE, the Director of the Environmental and Munitions Center of Expertise.

6.7 Release of the Final Laboratory Assessment Report

The combined Final Laboratory Assessment Report consisting of a signed cover page, desk assessment, on-site assessment and PE sample evaluation enclosures is issued, via email, to the laboratory by one of the co-chairs. The assessor will place a copy in Documentum. The project managers who are using the laboratory, or their POC, should be included in the final report loop to make sure that the issues needed to be solved and/or also let them know how the laboratory performed for the data to be generated for the project in their decision making.

6.8 Timeline

The timeline for the entire laboratory assessment process (from Initiating Procedures to Releasing Final Laboratory Report) shouldn't be over 120 calendar days.

7.0 QUALITY ASSURANCE AND QUALITY CONTROL

- 7.1 Review of draft documents by the QAOT and project team members will provide the opportunity to resolve issues and interpretations internally. This will enhance the accuracy of the laboratory findings that may impact the project.
- 7.2 After the final report has been issued to the laboratory, a summary of laboratory activities will be presented by the assessor at the next QAOT meeting. This will give the team the opportunity to not only discuss technical issues, but will provide a forum to discuss the laboratory assessment process which suffices for corrective action and continuous improvement.
- 7.3 A summary of each assessment will be included in the biennial CERP Quality Assurance Report.

8.0 REFERENCES

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

QAOT, 2011. Program Management Plan – CERP Monitoring Programs Quality Assurance and Quality Control. Information and Data Management Project Management Plan Appendix F. May 2011.

QAOT, 2009. Quality Assurance Systems Requirements (QASR) Manual, 19 March 2009.

QAOT, 2017. Standard Operating Procedure for Administering and Reporting Analytical Performance Evaluation Studies. QAOT-SOP-005. Revision 3.0. Effective April 30, 2017.

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

USACE, 2012. Standard Operating Procedure for Laboratory Assessment Support for the Quality Assurance Oversight Team of the Comprehensive Everglades Restoration Plan for Remote and On-Site Assessments. U.S. Army Corps of Engineers Directorate of Environmental and Munitions, Center of Expertise. Omaha, NE. Effective February 3, 2012.

9.0 SOP HISTORY

The SOP history will be updated to summarize changes to each version of the SOP.

Revision Status/Number	Revision Date	Description	Author
Revision 0.0 / Final	8/18/2017	Not applicable. Original version.	David Splichal, USACE

Attachment 1.

Laboratory Assessment Flowchart

