Lab Director Approval: Mark Tolbert / 08/19/2021

QA Manager Approval: Jeffrey Moore / 08/19/2021

Georgia EPD Laboratory Standard Operating Procedure (SOP): Continuing Demonstration of Capability

Access to this SOP shall be available within the laboratory for reference purposes; the official copy of this SOP resides on the official Georgia EPD website at https://epd.georgia.gov/about-us/epd-laboratory-operations. Printed copies of this SOP will contain a watermark indicating the copy is an uncontrolled copy.

1 Purpose:

1.1 This SOP describes the Georgia Environmental Protection Division Laboratory continuing certification program and documentation, and the requirements for renewing certification.

1.2 This SOP also provides guidance for completing the appropriate forms for documentation of continuing certification.

2 Scope and Application:

2.1 This procedure details the requirements for analyst qualification, and continuing demonstration of method proficiency. The system is based on NELAC requirements for analyst certifications with modifications.

2.2 This procedure requires the development, presentation and documentation of the analyst's knowledge of an analytical measurement system and of the standard operating procedure(s) and method(s) upon which it is based.

2.3 All supervisors, scientists and technicians must meet the requirements of this Standard Operating Procedure in order to maintain laboratory certification and therefore the ability to perform analyses independently. Documentation will be maintained in the analyst's training file and available for review by authorized inspectors.

3 Summary:

3.1 Analysts are provided with Standard Operating Procedures (SOPs) and access to the methods and program requirements upon which those SOPs are based. The analysts are expected to be familiar with all aspects of the SOPs for which they are to be obtaining continuing certification.

3.2 Periodically, analysts perform specific analyses in order to demonstrate continued proficiency in those analyses.

3.3 If the proficiency testing results are within acceptable limits, the analyst may fill out the required forms. Upon approval by the analyst's supervisor and manager, the analyst is re-certified to perform the analyses under normal supervision.

4 Definitions:

4.1 Applicant – The supervisor, scientist or technician applying for re-certification in a particular procedure.

4.2 Continuing Demonstration of Capability (CDC) – Performance of a specific procedure within acceptable limits published in the associated SOP.

4.3 Continuing Demonstration of Capability Form (CDF) – Documentation verifying that the applicant has successfully completed the requirements of the procedure and that the applicant's supervisor and manager have reviewed and approved the application.

4.4 Initial Demonstration of Capability (IDC) – Performance of a specific procedure within acceptable limits published in the associated SOP.

4.5 Initial Demonstration of Capability Form – Documentation verifying that the applicant has successfully completed the requirements of the procedure and that the applicant's supervisor and manager have reviewed and approved the application.

4.6 Initial Demonstration of Capability Certification Statement – Certificate indicating that the applicant has successfully completed all of the requirements necessary to perform the procedure of interest.

5 Personnel Qualifications and Responsibility:

5.1 Applicants:

5.1.1 Each supervisor, scientist and technician have the responsibility for performing continuing demonstrations of capability in a timely manner and to see to it that their own certifications do not lapse.

5.1.2 Scientist and technicians must renew certifications within six months of initial certification, and every six months thereafter.

5.1.3 Supervisors must renew certifications within twelve months of initial certification, and every twelve months thereafter.

5.1.4 Managers are exempt from maintaining CDFs for reviewing, validating and reporting data however managers must maintain CDFs for any analysis that they actually perform to produce data.

5.1.5 Managers must renew certifications within twelve months of initial certification, and every twelve months thereafter if generating data.

5.1.6 The applicant is required to review the relevant method(s), laboratory SOP(s), MSDS(s) and waste streams for the analysis or activity of interest. Verification of these reviews is documented on the Continuing Demonstration of Capability Form (CDF).

5.1.7 The applicant is required to fill out the CDF template for chemistry or microbiology as is appropriate for the analysis, completing the form as described below. Analytical data supporting the application and the printed forms are submitted to the applicant's supervisor.

5.2 Supervisors and Managers:

5.2.1 The applicant's supervisor will complete the printed form after review and approval of all relevant data.

5.2.2 The supervisor will submit the data and forms to the laboratory manager for review and approval.

5.2.3 Supervisors must be certified in the analysis of interest in order to review and approve certification applications.

5.3 Manager:

5.3.1 The Laboratory Manager reviews and approved each CDC form for his/her lab.

5.4 Qualifications:

5.4.1 Individual laboratory job descriptions are maintained as part of the training record. The job description states the level of academic training and experience required for the position. A candidate must meet the minimum qualifications of the job description before being considered for a position before they can be considered for that position.

5.4.2 Regardless of the level of previous academic training and experience, all analysts must complete training requirements of this SOP for each method in order to continue analyzing samples.

6 Procedure:

6.1 Literature Review

6.1.1 The laboratory manager provides the applicant with controlled copies of all relevant SOPs. The applicant is also provided access to the methods and program documents upon which the procedure and SOPs are based. The applicant is shown where to find appropriate material safety data sheets (MSDSs) and is given ongoing training in the EPD Laboratory Quality Assurance Plan (QAP).

6.1.2 The applicant shall study the provided SOP and reference materials to refresh understanding of the procedure, safety information and method/program requirements, and to determine if the SOP properly documents the procedure as performed.

6.1.3 Following and/or parallel to the literature review proficiency testing may be performed.

6.2 Method Proficiency

6.2.1 Within six months of the effective date of the previous certification or re-certification, the applicant must begin performing the test needed to satisfy method proficiency requirements.

6.2.2 Chemistry Requirements

6.2.2.1 The applicant may perform one of the following to meet the proficiency testing requirements:

6.2.2.2 Four Replicate LCSs: The applicant may prepare/extract, document and analyze four reference samples, Laboratory Control Samples (LCSs). The replicates must be prepared and analyzed with proper quality assurance criteria met (Method Blank, valid initial and continuing calibrations, etc.).

6.2.2.3 The applicant may prepare/extract four and only four LCSs (identified as LCS1 to LCS4) to meet these requirements. Preparing five or more LCSs and "picking and choosing" the best four is not permitted.

6.2.2.4 For analyses that have more than one set of spiking compounds (for example Mixes A and B, Chlordane, Toxaphene, etc. for SW846-8081A) only one set of spiking compounds is necessary. It is recommended, but not required, that a set with a significant number of analytes be selected.

6.2.2.5 Each LCS must meet method recovery limits in force at the time of analysis. Refer to individual method SOPs or Labworks for these limits. If no method limits are stated, the SOP for the procedure should establish limits for the Initial and Continuing Demonstrations of Capability.

6.2.2.6 The Percent Relative Standard Deviation (%RSD) for the four replicates must be less than 20% unless otherwise specified by the method or program documentation.

6.2.2.7 These replicates must be prepared and analyzed within thirty days of the date on which the documentation and data for the recertification are turned in for review/approval.

6.2.2.8 Two LCS/LCSD Pairs: The applicant may perform two LCS/LCSD (Laboratory Control Sample Duplicate) pairs.

6.2.2.9 The LCS/LCSD pairs may be from two consecutive sample batches that the applicant processed in the current certification period (i.e. the certification period about to expire).

6.2.2.10 The LCS/LCSD pairs must have been part of valid batches and analyzed in valid sample queues (acceptable calibrations, Method Blanks, etc.).

6.2.2.11 Each LCS/LCSD must pass LCS recovery limits in force at the time of analysis.

6.2.2.12 Each LCS/LCSD pair must pass precision limits in force at the time of analysis.

6.2.2.13 The %RSD for the four LCSs and LCSDs must be less than 20% unless otherwise specified by the method or program documentation for IDCs.

6.2.2.14 The earlier of the LCS/LCSD pairs must have been analyzed within 60 days and the later pair within 30 days of the date on which the documentation and data for recertification are turned in for review/approval.

6.2.2.15 Blind: The applicant may prepare/extract, document and analyze an LCS of unknown concentration (Blind).

6.2.2.16 The Blind LCS must be prepared/extracted and analyzed with appropriate QC (valid calibrations, acceptable continuing calibrations, Method Blanks, valid sample queues, etc.).

6.2.2.17 The Blind is to be spiked by a supervisor or manager and recorded in a log to which the applicant is not allowed access.

6.2.2.18 The applicant will not to be informed what the expected concentration of the Blind is until the analysis has been completed and all data for the blind turned in to the primary supervisor. The applicant assesses the Blind in the same manner as a sample, surrogate recovery and internal standard response where applicable.

6.2.2.19 The supervisor will calculate the actual recoveries based on the Blind spiking log entry and compare these results to the method recovery limits in force at the time of analysis.

6.2.2.20 The blind must have been prepared and analyzed within 30 days of the date on which the documentation and data for recertification are turned in for review/approval.

6.2.2.21 PT: The applicant may use passing results from performance evaluation samples (PTs) to meet requirements, providing the applicant was the primary analyst of record for the PT. The official results must be received from the PT supplier before the PT results can be used for recertification.

6.2.2.22 The PT sample must have been analyzed within 90 days of the date on which the documentation and data for recertification are turned in for review/approval.

6.2.2.23 MDL Study: The applicant may use an approved MDL Study to meet requirements, providing that the applicant was the primary analyst of record for the study.

6.2.2.24 The replicate sample analyses for the MDL Study must have been completed within 30 days of the date on which the documentation and data for recertification are turned in for review/approval.

6.2.2.25 If the applicant fails to achieve satisfactory results for the four LCSs, the Blind QC Blind or PT, he/she may repeat the four LCSs, Blind, QC Blind or PT, for the failed analytes.

6.2.2.26 If, after two attempts, the applicant has not passed recertification criteria, the applicant must undergo additional training before attempting a full set of IDC samples (calibration, LCSs, blank and Blind) again. A third attempt at continuing recertification is not permitted.

6.2.2.27 If an applicant fails two attempts, the Laboratory Director and the QA Manager must be notified.

6.2.3 Microbiology Requirements

6.2.3.1 The applicant may examine a Blind sample. Blind sample may be used if passing results are achieved.

6.2.3.2 The applicant must achieve 100% Accuracy (PA) and/or recoveries of both Blinds must be within control limits (MF/MPN).

6.2.3.3 The applicant may use passing results from performance evaluation samples (PTs) to meet requirements, providing the applicant was the primary analyst of record for the PT. The official results must be received from the PT supplier before the PT results can be used for recertification.

6.3 Documentation

6.3.1 The Continuing Demonstration of Capability Forms (CDFs) for chemistry and microbiology are located on the shared data drive (the "S:" drive for most users) as:

6.3.1.1 S:\Approved Forms\Form 12.4 Continuing Demonstration Form – Chemistry – Office2010jsm.docx. See Appendix 11.1.

6.3.1.2 S:\Approved Forms\Form 12.5 Continuing Demonstration Form – Protozoan – Office2010jsm.docx. See Appendix 11.2.

6.3.1.3 S:\Approved Forms\Form 12.6 Continuing Demonstration Form – Bacti – Office 2010jsm.docx. See Appendix 11.3.

6.3.2 The appropriate form is filled out online after all documentation review and method proficiency requirements have been met by the applicant and approved by the supervisor.

6.3.3 All available electronic fields are to be competed before the form is printed.

6.3.4 Saving a partially or completely filled out form for later reuse is not permitted.

6.3.5 The forms contain usage tips that will "pop up" when the mouse pointer hovers above one of the highlighted areas of the documents. These comments are intended as brief reminders of the following requirements for filling out the forms:

6.3.5.1 Date (Page 1) – Automatically filled as the current date by the software.

6.3.5.2 Effective Date (Page 1) – Date of Lab Manager approval. To be completed by the Lab Manager.

6.3.5.3 The effective date must be within 30 days of the expiration of previous certification unless otherwise approved by the QA Manager.

6.3.5.4 Analyst (Page 1) – Applicant's name.

6.3.5.5 Position Number (Page 1) – The applicants state position ID number. This number is unique to each individual.

6.3.5.6 Class of Analytes (Page 1) – A simple description of the type of analytes of concern to the procedure (for example, "E. coli " or "Chlorinated Herbs").

6.3.5.7 Matrix (Page 1) – Dropdown selection box. Select the appropriate matrix.

6.3.5.8 Method Reference(s) (Page 1) – The parent method and a description of the analyte, compound class, or physical parameters being measured. Include any associated methods (additional sample prep or cleanup methods) or document references.

6.3.5.9 Examples:

6.3.5.10 For SW846-8081A, the parent method, additional reference to SW846-8000 would be required.

6.3.5.11 For EPA 524.2 (Drinking Water) the parent method, the Drinking Water Certification Manual (this abbreviated name would be acceptable) would be referenced.

6.3.5.12 The parent method should be correctly identified including any appropriate prefix.

6.3.5.13 SW846 methods should be identified as SW846-<method number>, EPA methods should be identified as EPA-<method number>, and Standard Methods should be identified as SM<method ID>.

6.3.5.14 Other method groups should be identified as appropriate for the source of the methods.

6.3.5.15 Standard Operating Procedure ID: SOP Rev. 0 (Page 1) – Identify the SOP number and revision, for example, this SOP would be SOP "6-1" Rev. "3" or the current revision number.

6.3.5.16 The applicant's initials and date are written here verifying that he/she has reviewed the referenced documents as part of the training process and is familiar with the requirements therein.

6.3.5.17 SOP(s), etc. (Page 1) – SOP from page 1 plus any additional sample preparation, etc. SOPs that would be appropriate to list.

6.3.5.18 The applicant's initials and date are written here verifying that he/she has studied the referred SOPs as part of the training process and is familiar with the requirements therein.

6.3.5.19 Quality Assurance Plan (Page 1) – Current QAP.

6.3.5.20 The applicant's initials and date are written here verifying that he/she has received training in the QAP of the EPD Lab as part of the training process.

6.3.5.21 MSDS Review(s) (Page 1) – The applicant's initials and date are written here verifying that he/she has reviewed all of the MSDSs for all chemicals associated with the procedure as part of the training process.

6.3.5.22 Waste Management (Page 2) – Waste streams and the final disposition of the waste associated with the procedure are listed in the table.

6.3.5.23 Specific waste streams for the procedure must be identified.

6.3.5.24 The final disposition of each waste stream may be determined from the laboratory SOP for Waste Management, SOP 6-015, Revision 0 or most current revision, Table 6.3.

6.3.5.25 Method Proficiency (Page 2) – This section is filled out as is appropriate for the method proficiency testing performed by the applicant.

6.3.5.26 Comments (Page 2) – Information that later reviewers should be aware of that is not otherwise indicated on the form.

6.3.5.27 Supporting Documentation (Page 2) – Indicate whether or not supporting data (chromatograms, sequence printouts, etc.) are attached and if not, why.

6.4 Approvals

6.4.1 The supervisor reviews the documentation for completeness and accuracy determining if the applicant has met all requirements. If approved, the supervisor initials and dates page 1 as is appropriate and passes the package to the Laboratory Manager.

6.4.2 The Lab Manager reviews the documentation, and if approved, initials or signs where appropriate on page 1. The CDC package is filed within the respective labs.

7 Criteria:

7.1 Most methods contain or reference quality assurance criteria required for Initial Demonstrations of Capability. EPD Lab SOPs contain or reference quality assurance criteria required for LCS/LCSD pairs in batches. In the event these criteria conflict with the requirements of this document, the specific SOP for the procedure should indicate appropriate criteria and procedures for obtaining CDC recertification.

8 Records Management:

8.1 CDFs and supporting documentation are filed as part of the applicant's permanent training records and will retained as long as the applicant is employed at the GA EPD Lab and will be disposed of only after termination of the applicant's employment or after the appropriate program required archiving period has expired, whichever is longer.

8.2 Routine Drinking Water – 10 Years

8.3 Lead and Copper – 12 Years

8.4 Air Monitoring – 7 Years

8.5 Hazardous Waste Projects – 5 Years

8.6 Water Quality Projects – 10 Years

9 Quality Control/Quality Assurance:

9.1 Certifications must be renewed periodically. Scientists and technicians must recertify within six months of the QA Manager approving an IDF and every six months thereafter of the Lab Manager approvals of CDFs. Supervisors must recertify within 12 months of the QA Manager approving an IDF and every 12 months after the Lab Manager approving CDFs. Laboratory Managers are not required to receive certifications to perform analyses within the scope of their lab and overall experience.

9.2 Calculations:

9.2.1 LCS Percent Recovery (%):

9.2.1.1 $$\% = \frac{LCS_{Calculated\ Conc.}}{LCS_{Expected\ Conc.}} * 100$$

9.2.1.2 Where:

9.2.1.3 $LCS_{Calculated\ Conc.}$ = Calculated concentration of an individual LCS replicate

9.2.1.4 $LCS_{Expected\ Conc.}$ = Expected concentration of the LCS(s)

9.2.1.5 See specific SOPs for LCS calculated and expected concentration calculations.

9.2.2 Percent Relative Standard Deviation (%RSD):

9.2.2.1 $$\%RSD = \frac{\sigma_{n-1}}{\overline{LCS}} * 100$$

9.2.2.2 Where:

9.2.2.3 $\overline{LCS}$ = Average of four LCSs

9.2.2.4 σ_{n-1} = Sample Standard Deviation (n – 1)

10 References:

10.1 Georgia EPD Laboratory Quality Assurance Plan, online revision.

10.2 Georgia EPD Laboratory SOP "Technical Analyst Training; Initial Demonstration of Capability", SOP 6-001, online revision.

10.3 Georgia EPD Laboratory Safety/Chemical Hygiene Plan & Fire Safety Plan, online revision.

10.4 Georgia EPD Laboratory SOP – EPD Laboratory Waste Management SOP, SOP 6-015, online revision.

10.5 Manual for the Certification of Laboratories Analyzing Drinking Water, EPA/815-R-05-004, January 2005 or most current revision.

11 Appendices:

11.1 Chemistry CDF

11.2 Protozoan CDF

11.3 Bacteriological CDF

12 Updates:

Online revision statement added.
Section 6.3: File names updated
Section 8: CDF retention description updated.

11.1 Appendix: Chemistry CDF Form 12.4

Continuing Demonstration of Capability Form (CDF)
Chemical Analysis

Date: 08/18/2021 | Supervisor Approval (☐ NA) – Initials: _____ Date: _____

Manager Approval – Initials: _____ Date: _____

Effective Date: _____

Analyst Name: _____ Position Number: _____

Class of Analytes: _____ Matrix: Drinking Water

Documentation Review

Method Reference(s): _____

"I have reviewed the method(s). I am familiar with terminology, acronyms, and requirements of the method(s)."

Analyst Initials: _____ Date: _____

SOP(s) – Title(s) & Revision(s): _____

SOP Rev.

"I have reviewed the SOP(s). I am familiar with and understand the terminology, acronyms, and requirements of the SOP(s). I am aware of, and understand the reasons for any discrepancies or contradictions between the method(s) and the SOP(s)."

Analyst Initials: _____ Date: _____

Quality Assurance Plan (QAP) – Date and Revision: September 2020 Revision 12

"I have participated in ongoing training on the QAP within the last six months."

Analyst Initials: _____ Date: _____

MSDS Review(s):

"I have reviewed the MSDSs for all chemicals associated with this procedure. I understand the health and safety risks associated with each chemical, including steps that should be taken in the event of a spill or accident involving these chemicals.

Analyst Initials: _____ Date: _____

Waste Management

Waste Stream(s) – EPD Lab Waste Mgmt SOP, 6-015 Rev. 2, Appendix A Rev. 2 Tables A.1 – A.5:

Waste streams and final disposition of the wastes associated with this procedure:

Waste Stream Source	Primary Waste Stream Hazardous Components	Final Laboratory Disposition

Method Proficiency

The analyst has analyzed and met continuing demonstration criteria by one of the following:

☐ 1.) Reference Sample Recovery:

Analyst has successfully performed the procedure on four reference samples achieving required accuracy and precision:

Accuracy: Individual - ☐ Yes ☐ NA Average - ☐ Yes ☐ NA

Precision (20% RSD unless otherwise specified -): - ☐ Yes ☐ NA

☐ 2.) Unknown (Blind) Sample Analysis within Control Limits (Blind ID #:)

☐ 3.) Passing results for the analysis of a Performance Evaluation Sample (Study ID:)

☐ 4.) Passing MDL Study

Procedure Requirements Met: ☐ Yes ☐ No If no explain:

Comments:

Supporting Documentation

Copies of all raw data necessary to reconstruct and validate these analyses are attached: ☐ Yes ☐ No If no explain:

11.2 Appendix: Protozoan CDF Form 12.5

Continuing Demonstration of Capability Form (CDF)
Protozoan Analysis

Date: 08/18/2021 | Supervisor Approval (☐ NA) – Initials: _____ Date: _____

Manager Approval – Initials: _____ Date: _____

Effective Date: _____

Analyst Name: Position Number:

Class of Analytes: Matrix: Drinking Water

Documentation Review

Method Reference(s):

"I have reviewed the method(s). I am familiar with terminology, acronyms, and requirements of the method(s)."

Analyst Initials: _____ Date: _____

SOP(s) – Title(s) & Revision(s):

SOP Rev.

"I have reviewed the SOP(s). I am familiar with and understand the terminology, acronyms, and requirements of the SOP(s). I am aware of, and understand the reasons for any discrepancies or contradictions between the method(s) and the SOP(s)."

Analyst Initials: _____ Date: _____

Quality Assurance Plan (QAP) – Date and Revision:

"I have participated in ongoing training on the QAP within the last six months."

Analyst Initials: _____ Date: _____

MSDS Review(s):

"I have reviewed the MSDSs for all chemicals associated with this procedure. I understand the health and safety risks associated with each chemical, including steps that should be taken in the event of a spill or accident involving these chemicals.

Analyst Initials: _____ Date: _____

Waste Management

Waste Stream(s) – EPD Lab Waste Mgmt SOP, 6-015 Rev. 2, Appendix A Rev. 2 Tables A.1 – A.5:

Waste streams and final disposition of the wastes associated with this procedure:

Waste Stream Source	Primary Waste Stream Hazardous Components	Final Laboratory Disposition

Method Proficiency

Cryposporidium/Giardia

The analyst has analyzed and met continuing demonstration criteria by one of the following:

☐ 1.) Unknown (Blind) Sample Analysis Meets Criteria/within Control Limits

☒ 2.) Passing results for the analysis of a Performance Evaluation Sample

☐ 3.) NA Explain: _____

Procedure Requirements Met: ☒ Yes ☐ No If no explain: _____

Training Session Title: _____

Comments:

Supporting Documentation

Copies of all raw data necessary to reconstruct and validate these analyses are attached: ☒ Yes
☐ No If no explain: _____

11.3 Appendix: Bacteriology CDF Form 2.6

Continuing Demonstration of Capability Form (CDF) Bacteriological Analysis

Date: 08/18/2021 | Supervisor Approval (☐ NA) – Initials: _____ Date: _____

Manager Approval – Initials: _____ Date: _____

Effective Date: _____

Analyst Name: Position Number:

Class of Analytes: Matrix: Drinking Water

Documentation Review

Method Reference(s):

"I have reviewed the method(s). I am familiar with terminology, acronyms, and requirements of the method(s)."

Analyst Initials: _____ Date: _____

SOP(s) – Title(s) & Revision(s):

SOP Rev.

"I have reviewed the SOP(s). I am familiar with and understand the terminology, acronyms, and requirements of the SOP(s). I am aware of, and understand the reasons for any discrepancies or contradictions between the method(s) and the SOP(s)."

Analyst Initials: _____ Date: _____

Quality Assurance Plan (QAP) – Date and Revision:

"I have participated in ongoing training on the QAP within the last six months."

Analyst Initials: _____ Date: _____

MSDS Review(s):

"I have reviewed the MSDSs for all chemicals associated with this procedure. I understand the health and safety risks associated with each chemical, including steps that should be taken in the event of a spill or accident involving these chemicals.

Analyst Initials: _____ Date: _____

Waste Management

Waste Stream(s) – EPD Lab Waste Mgmt SOP, 6-015 Rev. 2, Appendix A Rev. 2 Tables A.1 – A.5:

Waste streams and final disposition of the wastes associated with this procedure:

Waste Stream Source	Primary Waste Stream Hazardous Components	Final Laboratory Disposition

Method Proficiency

Media Prep

The analyst has analyzed and met continuing demonstration criteria by one of the following:

☐ 1.) Unknown (Blind) Sample Analysis Meets Criteria/within Control Limits

☐ 2.) Passing results for the analysis of a Performance Evaluation Sample

☒ 3.) NA Explain:

Procedure Requirements Met: ☒ Yes ☐ No If no explain: _____

Training Session Title: _____

Comments:

Supporting Documentation

Copies of all raw data necessary to reconstruct and validate these analyses are attached: ☐ Yes
☒ No If no explain: