Region 4 U.S. Environmental Protection Agency Laboratory Services & Applied Science Division Athens, Georgia	
Operating Procedure	
Title: Training and Demonstration of Competency	**ID: LSASDPROC-1003-R2**
Issuing Authority: Deputy Director, LSASD	
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Purpose

This Operating Procedure is specific to the Region 4 Laboratory Services & Applied Science Division (LSASD) to maintain conformance to technical and quality system requirements. The purpose of this procedure is to ensure that all field investigators and laboratory analysts are properly trained and competent in the procedures required to properly collect, analyze and report data for decision making purposes.

Scope/Application

The requirements of this procedure apply to all personnel who perform work under the LSASD Quality Management System (QMS). Demonstrations of Competency (DOCs) must be established prior to utilizing LSASD procedures independently. Continued proficiency will be assessed and documented through the proficiency testing program. Some laboratory methods require specific procedures for establishing and maintaining competency, in those instances the method requirements will be observed. Variations between field and laboratory procedures for establishing and maintaining competency will be noted in this procedure, as applicable. While this SOP may be informative, it is not intended for and may not be directly applicable to operations in other organizations. Mention of trade names or commercial products in this operating procedure does not constitute endorsement or recommendation for use.

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1.0 Procedure

1.1 General Procedures

LSASD staff will be provided training needed for full participation in the operation of the LSASD Quality Management Systems (QMS). Training may be in the form of on the job training, formal LSASD training classes or training classes presented by outside entities such as contractors, instrument manufacturers or universities and may include technical conferences. Training will be provided initially and on a continual basis as required by each LSASD Branch. Technical training records will be maintained by the Quality Assurance Coordinator (QAC).

All new employees are required to complete the training courses identified by EPA's Office of Administration and Resource Management (OARM) prior to performing work activities. Training requirements can be found on OARM's website. The appropriate training classes will be identified by LSASD's management and assigned by the Section Supervisor to the trainee.

Additionally, new employees are required to complete all training identified by management as appropriate based on the assigned job duties. See Form LSASDFORM-1020 Quality Assurance New Employee Training-Setup Checklist, for required training. The checklist includes training for staff that influence the results of laboratory activities to include general knowledge of forensic science, criminal law, civil law, and testimony. The QAC will identify resources and provide this training on an annual basis for all new staff that have onboarded during the prior calendar year. An annual review of EPA's Scientific Integrity Policy must be completed by all management and staff annually and will be recorded by the QAC. All new employees will be required to complete Quality System Training, regardless of the duty assignment. Each LSASD Branch utilizes training checklists to document the required initial training. These checklists are retained by the employee's Section Supervisor until all training has been completed. Upon completion of the training, the checklist is forwarded to the QAC for inclusion in the employees training file. Health and safety training requirements are discussed in the SHEMP Procedures and Policy Manual.

Initial training for specific LSASD field or laboratory procedures will culminate in the successful completion of a demonstration of competency (DOC). The content of the competency demonstration for field and laboratory studies will differ due to method requirements; however, performance, evaluation and documentation of the studies for all procedures will be addressed as follows:

1.1.1 Staff will be paired with a Subject Matter Expert (SME) or Competent Staff, as deemed appropriate, by the Section or Branch Manager for initial training on the assigned procedure(s), which will be documented utilizing the appropriate format. Successful completion of the training will be determined by the Section Supervisor after consultation with the trainer. This determination is required prior to initiation of a DOC.

1.1.2 Training will address, as applicable, safety, operating procedures, equipment use, equipment maintenance and repairs, proper documentation procedures, data review and reporting.

1.1.3 Upon completion, as determined by the Section Supervisor, the QAC will schedule a Demonstration of Competency Study. DOC studies will be assigned a project number that will be used to track and document the project status and completion.

1.1.4 Competency demonstrations will be completed including submission of the final results and Demonstration of Competency Certification Statement (LSASD FORM-1021) to the QAC within 35 days of the project initiation date.

1.1.5 If the study results do not meet the requirements detailed in this procedure, additional training will be scheduled by the Section/Branch Supervisor or QAC. Personnel may not perform work under the quality system independently until competency has been successfully established.

1.1.6 QAC will maintain a Table of Authorizations on the LAN to document and track the status of competency evaluations.

1.2 Field Demonstrations of Competency

Initial competency evaluations for field sampling and measurement procedures will be conducted by the designated SME. All field investigators should establish and maintain competency for the following procedures, at a minimum:

1.2.1 pH
1.2.2 Specific Conductance
1.2.3 Turbidity
1.2.4 Dissolved Oxygen
1.2.5 Sediment Sampling
1.2.6 Surface Water/Groundwater Sampling
1.2.7 Soil Sampling
1.2.8 Potable Water Sampling
1.2.9 GPS
1.2.10 Field chemistry methods i.e., ferrous iron, sulfide, etc.

Field competency evaluations will include a written exam with a required score of 80% or higher and a field practicum. Both components must be successfully completed to establish competency. The field practicum will be performed on site during a mock field sampling event prior to routine field investigation or sampling events. If a field practicum is performed, the project leader or other competent team member will serve as the SME as approved by the Section Supervisor and will perform the evaluation. Staff should consult with the project lead and Section Supervisor to coordinate this additional activity prior to field deployment. Evaluations of field competency for all procedures should assess the following:

1.2.11 Knowledge and awareness of pertinent literature and appropriate published methods/procedures.
1.2.12 Determination and selection of the appropriate tools and equipment to perform the activity.
1.2.13 Utilization of the appropriate tools and equipment in the required manner.
1.2.14 Performance of the required calibrations or verifications and ensuring that the instrument/equipment is operating correctly and knowledge of software.
1.2.15 Performance of equipment repairs or adjustments, as required.

1.2.16 Obtaining a measurement using a sample of known value, where feasible, and successfully obtaining acceptable results, as defined by the SME.

1.2.17 Completion of the required sampling, calibration and measurement documentation.

After successful completion of the competency evaluation, the candidate will submit a Demonstration of Competency Certification Statement (LSASD FORM-1021) through the SME, Section Supervisor and then to the QAC along with the results of the written exam and any SME notes on the competency evaluation. For competency evaluations performed in conjunction with field investigations or sampling projects, copies of the field logs or notes should be included with the Competency Statement and the Demonstration of Competency tracked with the project identifier.

Documentation of the competency evaluation shall be completed by the staff member being evaluated and routed through the SME for review and concurrence of findings prior to routing to the Section Supervisor and QAC for final approval. Documentation of the evaluation must be completed within 45 days of the evaluation to be deemed valid.

For field employees issued credentials, management will ensure the training requirements of EPA Order 3500.1 are satisfied. Management can select other topics as needed. The training is provided by the organizational unit that has functional responsibility for the topic.

1.3 Laboratory Demonstration of Competency Study

For laboratory procedures, to demonstrate competency an analyst must successfully take a Blind Test Sample through preparation and analysis, and prepare and analyze a Demonstration of Competency (DOC). The culmination of the two components is known as a Demonstration of Competency Study. These two components can be completed in any order but are required prior to analysis of routine samples. Analyst DOC Studies are specific to the method only, demonstrating the analyst's ability to successfully perform the method. As such, they are not matrix or analyte specific except for methods that include critical matrix specific sample preparation. Analyst DOCs for drinking water methods are evaluated for each method and analyte.

Demonstration of Competency

A DOC consists of four replicates of a Laboratory Control Sample. A DOC demonstrates an analyst's ability to produce acceptable precision and bias using a test method. Analyst DOCs for drinking water methods are evaluated for each method and analyte. Some methods are not amenable to spiking, or other standard recovery (bias) procedures (e.g., pH), therefore, are not applicable for a formal DOC. In those instances, where no method specific criteria are available, the analyst, in consultation with the Section Supervisor or QAC will establish a DOC scheme for the method that will be documented in the SOP. DOC requirements include:

1.3.1 Preparation and analysis of a minimum of 4 replicates of a Laboratory Control Sample (LCS) taken through the entire analytical process, including both preparation and analysis.

1.3.2 The DOC aliquots should be spiked at a level within the calibration range, above the MRL, typically at the mid-range of the calibration.

1.3.3 The preparation and analysis of the DOC may be performed over a period of time such as would occur if four consecutive LCSs were used from actual analytical batches.

1.3.4 Acceptable bias of the DOC is demonstrated if the average of the % recovery of the replicates is within the established acceptance criteria for the LCS.

1.3.5 Acceptable precision of the DOC is demonstrated if the relative standard deviation of the replicates is within the predetermined acceptance criteria.

1.3.6 In a DOC for an analyst with multi-component test methods, it is only necessary to spike as many analytes as is practical and makes sense to ensure the veracity of the demonstration.

1.3.7 If an acceptable number of target analytes (see §1.3.13) that have been spiked into a DOC sample do not meet both bias and precision criteria, capability has not been demonstrated and the DOC must be repeated.

Blind Test Sample

A Blind Test Sample demonstrates an analyst's ability to cover the spectrum of anticipated tasks, including analysis of unknown results. The Section Supervisor will designate a trainer who is responsible for preparing a blind test sample upon completion of method specific training. If a Proficiency Test (PT) sample is scheduled and available for the analyst to perform, the PT sample can serve as the Blind Test Sample, provided the final results are unknown to the analyst. When preparing the Blind Test Sample, the trainer must initiate LSBFORM-1207, current version, and submit a copy to the QAC. A Blind Test Sample requirements include:

1.3.8 Preparation and analysis of Blind Test Sample taken through the entire analytical process, including both preparation and analysis.

1.3.9 The Blind Test Sample should be prepared at the PS Level, or a point suitable to be evaluated within the working range of the method and must remain unknown to the analyst.

1.3.10 Acceptable recovery of the Blind Test Sample shall default to ±50%, or routine QC limits if a PS level is prepared.

1.3.11 In a Blind Test Sample for an analyst with multi-component test methods, it is only necessary to prepare as many analytes as is practical and makes sense to ensure the veracity of the demonstration.

1.3.12 If an acceptable number of target analytes do not meet acceptance criteria, capability has not been demonstrated, corrective action may be necessary, and the Blind Test Sample must be repeated.

Successful completion of the Demonstration of Competency Study (DOC and Blind Test Sample) is determined based on the following requirements:

1.3.13 Use the chart below to determine the number of analytes that may be allowed to exceed specification, yet still have an acceptable DOC study.

1.3.1.1.1 Greater than 90 analytes spiked, 5 analytes are allowed to fail

1.3.1.1.2 From 71-90 analytes spiked, 4 analytes are allowed to fail
1.3.1.1.3 From 51-70 analytes spiked, 3 analytes are allowed to fail
1.3.1.1.4 From 31-50 analytes spiked, 2 analytes are allowed to fail
1.3.1.1.5 From 11-30 analytes spiked, 1 analyte are allowed to fail
1.3.1.1.6 Less than 11 analytes spiked, no analytes are allowed to fail

DOC results are tabulated and assessed against the precision and bias criteria specified in the method or using in-house limits. DOC results may be reported through Element®. In some cases, it may not be possible to use the report (e.g. method specified recovery limits for DOC studies), in those cases, a spreadsheet is used to calculate the DOC results. The results are submitted, with a Demonstration of Competency Certification Statement (LSASD FORM-1021, current version) through the Section Supervisor to the QAC. If results of the DOC are not within the acceptance criteria, additional training will be scheduled by the Section Supervisor and the analyst will not be allowed to analyze samples independently until a successful DOC is completed.

The Blind Test Sample results are tabulated and assessed against ±50% recovery, or routine QC limits if a PS level is prepared. A spreadsheet is used to calculate the Blind Test Sample results, LSBFORM-1208, current version. The results are submitted with a Blind Test Sample Competency Statement, (LSBFORM-1207, current version) through the Section Supervisor to the QAC. If results of the Blind Test Sample are not within the acceptance criteria, additional training will be scheduled by the Section Supervisor and the analyst will not be allowed to analyze samples independently until a successful Blind Test Sample is completed. If a PT sample is used in lieu of the Blind Test Sample, the Blind Test Sample Competency Statement will still need to be submitted to complete the DOC Study.

1.4 Continuing Demonstrations of Proficiency (Proficiency Testing)

All field investigators and laboratory analysts who have established competency for a specific procedure must successfully complete a proficiency evaluation at least every four years. During this four-year cycle, the field investigator or laboratory analyst must complete at least one proficiency evaluation per year in each discipline, which the individual conducts work, as outlined on the LSASD scope of accreditation. Laboratory procedures for drinking water parameters require annual evaluations and will be performed as directed by the applicable method. If an analyst or field investigator's proficiency with a given method has not been evaluated within the four-year cycle, a new Demonstration of Competency (See Section1.2 and 1.3) must be completed prior to completing any independent work with that method.

The proficiency testing (PT) program is used to re-qualify LSASD staff to independently perform environmental data collection and/or analytical work. Field investigators must complete a proficiency evaluation similar to the field practicum portion of the competency evaluation detailed in Section 1.2. This proficiency evaluation, for field personnel, can be administered by any field personnel deemed competent in the subject being evaluated. Field staff are encouraged to perform proficiency evaluations each year to prevent a lapse in competency. Staff competency should be evaluated as part of the project planning and should be incorporated into field projects annually.

Laboratory staff are deemed proficient upon successful completion of an external proficiency testing sample. In the absence of an applicable external PT sample, a DOC study as detailed in Section 1.3 will be required to demonstrate continuing proficiency.

1.5 External Proficiency Testing Samples

Each calendar year, at a minimum, unknown proficiency testing samples will be obtained from an ISO 17034 accredited proficiency testing materials provider. The samples will be utilized to establish continued proficiency with analytical procedures. External PT samples not only establish continued proficiency but are also a required element in support of LSASD's ISO 17025 accreditation and the Laboratory Services Branch's drinking water certification. A 4-year PT schedule will be maintained by the QAC and available for review on the LSASD LAN. PT samples for field investigations will be analyzed for pH, specific conductivity, and turbidity annually. All external PT samples will be evaluated as follows:

1.5.1 The QAC, or designee will be responsible for purchasing and scheduling the PT samples.

1.5.2 The PT samples will be logged into the LSASD Project Log tracking system by the QAC or designee as a unique project, and will be tracked, analyzed and reported similar to a project containing field samples.

1.5.3 The QAC will notify the appropriate staff of the assigned PT.
sample as well as the expected due date of the project based upon the PT study requirements.

1.5.4 Samples will be prepared and analyzed as routine samples, following the instructions provided. PT samples will be reported to three significant figures as required by the PT provider.

1.5.5 Results will be generated, and peer reviewed prior to submittal to the QAC for final reporting to the external PT provider.

1.5.6 Final results of the PT samples will be provided to all staff upon completion of the study. Upon receipt of the study results, a Demonstration of Competency Certification Statement (LSASD FORM-1021) should be completed with the acceptable study results attached and routed to the QAC through the Section Supervisor. Upon receipt of the Certification Statement, the System Manager will update the Table of Authorizations.

1.5.7 A formal corrective action will be initiated and documented in accordance with LSASD Operating Procedure for Corrective and Preventive Actions (LSASD PROC-1005) for any PT sample analyte that exceeds the study acceptance criteria.

1.6 LSB Drinking Water Team

In addition to requirements in Section 1.1 of this document, LSASD scientists assigned to the Laboratory Services Branch Drinking Water Team must also attend and pass the EPA Office of Water's laboratory certification course for inorganic chemistry, organic chemistry, and/or microbiology. With the proper certification training and continuing education, the members of the LSB Drinking Water Team are known as Safe Drinking Water Act (SDWA) Certification Officers (CO). The Drinking Water Certification Manual defines the CO as the regional and state

personnel who have the responsibility of certifying laboratories under their purview. In order to maintain certification status, the SDWA certification team members must be nominated to attend an EPA Office of Water Laboratory Certification refresher course, for each specialty in which they are certified, every five years.

1.7 Records Management

Proficiency evaluation and testing documents, to include a Demonstration of Competency Certification Statement (LSASD FORM-1021), PT sample results and records of any corrective action will be stored by the QAC for a minimum of five years. Additionally, A Table of Authorizations, listing the status of competency for all staff will be maintained by the QAC and posted on the LAN for all staff to review.

A current listing of all position descriptions and job duty assignments is maintained by the LSASD Security Manger and will be made available upon request.

During the annual Management Review of the LSASD QAC, the Regional QA Manager, and LSASD management will evaluate the effectiveness of the LSASD training program. The QAC maintains records of proficiency testing results, internal audits and external assessments as a means of measuring the effectiveness of the training that was provided to field and laboratory personnel.

Additional training needs may be identified as a result of the evaluation. Training records are kept in individual folders by the QAC, or designee. If the expected results are not attained during any monitoring activity, the accrediting body must be notified within 30 days. (See ANAB FM 2831, Client Notification – Technical Change Request)

2.0 Definitions

2.1 Demonstration of Competency (DOC)- Initial evaluation of a field investigator or analyst to determine if they have demonstrated the necessary skills and knowledge to independently perform data collection or analytical procedures. Upon demonstration of competency, staff are deemed proficient in that procedure for a period of four years.

2.2. Continuing Demonstration of Proficiency- a demonstration of a field investigator or analyst's continuing proficiency in the use of a procedure or technology. Depending on the program, a continuing demonstration of proficiency may be required annually. For programs that do not specify requirements for continuing proficiency demonstrations, evaluation should occur every four years. Acceptable results from a proficiency testing (PT) sample will serve as a demonstration of continuing proficiency in lieu of a formal study.

2.3 Proficiency Test Sample (PT)- a sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria.

2.4. Subject Matter Expert -An analyst or field investigator who, as determined by

management exhibits a high level of expertise with a sampling procedure.

3.0 References

Competency Evaluation and Proficiency Testing Review Form, LSASD FORM-1021, current version.

SOP Revision History

This table shows changes to this controlled document over time. The most recent version is presented in the top row of the table. Previous versions of the document are maintained by the LSASD Document Control Coordinator.

History	Effective Date
LSASDPROC-1003-R3, Training and Competency Update training requirements for new employees. Included required annual scientific integrity review. Revised field demonstration of competency to require a field practicum via a mock field sampling event prior to project sampling. Updated the Laboratory Demonstration of Competency to include a blind test sample or PT. Added the requirement to notify the accrediting body of unexpected results.	July 3rd, 2024
LSASDPROC-1003-R1, Training and Demonstration of Competency, replaces LSASDPROC-1003 Updated Division and Branch naming convention due to Agency re-alignment. Replaced SESD with LSASD throughout. Replaced system manager with quality assurance coordinator. Section 1.2 added The field practicum will be performed on site whenever possible. Field practicums can be performed during routine field investigation or sampling events. If a field practicum is performed, the project leader or other competent team member will serve as the SME and will perform the evaluation. Staff should consult with the project lead to coordinate this additional activity prior to field deployment. Documentation of the competency evaluation shall be completed by the staff member being evaluated and routed through the SME for review and concurrence of findings prior to routing to the Section Chief and QAC for final approval. Documentation of the evaluation must be completed within 45 days of the evaluation to be deemed valid. Section 1.4 added Field staff are encouraged to perform proficiency evaluations each year to prevent a lapse in competency. Staff competency should be evaluated as part of the project planning and should be incorporated into field projects annually	August 6,2020
SESDSD PROC-1003, Training and Demonstration of Competency, Original Issue	October 1, 2017