Washington State Department of Ecology

Environmental Assessment Program

Standard Operating Procedure for On-Site Audits of Environmental Laboratories

Version 1.0

Author – Stewart Lombard, Lab Accreditation Unit Supervisor
Date - June 15, 2007

Reviewer - Will Kendra, Statewide Coordination Section Manager
Date - October 29, 2007

QA Approval – William R. Kammin, Ecology Quality Assurance Officer
Date - November 2, 2007

LAU002

Please note that the Washington State Department of Ecology's Standard Operating Procedures (SOPs) are adapted from published methods, or developed by in-house technical experts. Their primary purpose is for internal Ecology use, although SOPs may have a wider utility. Our SOPs do not supplant official published methods. Distribution of these SOPs does not constitute an endorsement of a particular procedure or method.

Any reference to specific equipment, manufacturer, or supplies is for descriptive purposes only and does not constitute an endorsement of a particular product or service by the author or by the Department of Ecology.

Although Ecology follows the SOP in most instances, there may be instances in which Ecology uses an alternative methodology, procedure, or process.

SOP Revision History

Revision Date	Rev number	Summary of changes	Sections	Reviser(s)

1. Purpose and Scope

1.1 This document is the Environmental Assessment Program (EAP) Lab Accreditation Unit (LAU) Standard Operating Procedure (SOP) for on-site audits of environmental laboratories, including those certified for drinking water analyses.

1.2 An on-site audit (systems audit) is conducted every three years at all environmental laboratories accredited directly by Ecology as required by WAC 173-50-080. The LAU is responsible for implementing this requirement and this document lists the actions taken by unit staff in conducting on-site audits.

2. Applicability

2.1 These procedures are followed by LAU staff whenever an on-site audit of an environmental laboratory is conducted.

2.2 The emphasis in the audit is on evidence that the lab is producing accurate and defensible data. The lab's capability to carry out the written method is the basis for accreditation.

3. Definitions

3.1 **Analytical Method** - Written instructions describing the procedures to be followed by the analyst to obtain an analytical result.

3.2 **Certification Officer -** State personnel responsible for certifying (accrediting) laboratories under the federal Safe Drinking Water Act.

3.3 **Environmental laboratory** - A facility owned and managed by a single entity, situated in a single geographical locale, in which scientific data are collected on samples taken from the environment, including drinking water samples.

3.4 **Environmental Laboratory Accreditation Program (ELAP)** - The activities described in References 10.1 - 10.4 as implemented by the LAU.

3.5 **Lab Accreditation Unit (LAU)** - a unit of the Environmental Assessment Program of the Washington State Department of Ecology charged with implementing the ELAP.

3.6 **On-site audit** - an on-site inspection of laboratory capabilities, records and QA practices.

3.7 **Parameter** - Analytes or characteristics of a sample measured using a specific analytical method. Examples of parameters are "Residual Chlorine by SM 4500-Cl G," "Aluminum by EPA 200.7," or "Volatile Organic Compounds by EPA 8260".

3.8 **Proficiency Testing (PT)** - Analysis by an environmental laboratory of samples with concentrations unknown to laboratory staff obtained from approved providers. The results are used to evaluate ongoing capability of the laboratory to achieve accurate results for a specific parameter and matrix. Accredited labs must successfully analyze a PT samples for microbiological parameters in drinking water annually and for all other designated parameters and matrices semi-annually.

3.9 **Scope of Accreditation** - Document accompanying the Certificate of Accreditation that indicates the parameters for which the laboratory is accredited in each matrix category, and any applicable qualifications, such as interim or provisional accreditation.

4. Personnel Qualifications/Responsibilities

4.1 Auditors in the LAU have education and professional experience related to analytical chemistry, microbiology and/or toxicology.

4.2 Auditors evaluate information submitted by environmental laboratories in support of accreditation; assess laboratory capabilities through on-site evaluations of staff, facilities, equipment and procedures; and prepare documentation of findings and accreditation actions.

4.3 Personnel assigned to assess the capability of drinking water laboratories participating in the ELAP must meet the education, training and experience requirements established in the EPA drinking water certification manual. [Reference 10.3]

5. Equipment and Supplies

5.1 LAU staff may use the following equipment during on-site audits:

5.1.1 NIST-traceable digital thermometer

5.1.2 Class I standard weights

5.1.3 Velometer

5.1.4 Lap-top or Notebook portable computers with specialized software installed.

5.2 LAU staff are provided the following protective items for on-site audits:

5.2.1 Lab coat

5.2.2 Protective eye-wear

5.2.3 Ear plugs

5.2.4 Surgical gloves

6. Procedures

6.1 PLAN AUDIT

6.1.1 Determine when laboratory is due for an on-site audit.

6.1.2 Assemble an audit team, if necessary.

6.1.2.1 The team may include specialists in procedures for general chemistry, metals, organics, microbiology, radiochemistry and/or aquatic toxicology.

6.1.2.2 For drinking water laboratories, the audit team must include at least one certification officer.

6.1.3 Schedule on-site audit when mutually convenient.

6.1.3.1 Request information needed from the laboratory.

6.1.3.2 Request that any necessary procedures be scheduled during the audit.

6.1.3.3 Request that key lab staff be present during the audit.

6.1.4 Assemble preliminary information, including:

6.1.4.1 PT sample results

6.1.4.2 Scope of Accreditation and denied parameters list

6.1.4.3 Recent correspondence with the laboratory

6.1.5 Review relevant information, including the previous audit report and PT sample results since the previous audit.

6.1.6 Prepare checklists.

6.1.6.1 Checklists are required for all DW parameters.

6.1.6.2 Send checklists to the laboratory in advance of the audit as appropriate.

6.1.7 Arrange for travel to the laboratory.

6.2 TRAVEL TO LABORATORY

Allow enough travel time to arrive on schedule.

6.3 CONDUCT ON-SITE AUDIT

6.3.1 Initial Interview

6.3.1.1 Convene initial interview with laboratory manager, QA officer and any others requested by laboratory management.

6.3.1.2 Introductions

6.3.1.3 Overview of audit procedure

6.3.1.4 Request documents needed:

6.3.1.4.1 Checklists completed by lab personnel

6.3.1.4.2 Data packages for recent PT samples

6.3.1.4.3 Analyst training records

6.3.1.4.4 SOPs

6.3.1.4.5 Control Charts

6.3.1.5 Tentative schedule for lunch break and exit briefing

6.3.2 Checklists

6.3.2.1 Note any discrepancies or missing information.

6.3.2.2 Verify lab is using methods for which it is accredited.

6.3.3 Analysts

6.3.3.1 Determine whether staff meet minimum requirements for education, training and experience.

6.3.3.2 Determine whether Initial Demonstrations of Capability are completed as required.

6.3.3.3 Determine whether current copies of methods are available to the analyst.

6.3.3.4 Observe analyst conducting analyses when necessary.

6.3.4 Equipment

6.3.4.1 Check condition of all equipment required for analyses.

6.3.4.2 Check temperatures of drying ovens, sample storage coolers, and incubators.

6.3.4.3 Check that balances are calibrated annually and calibration is verified daily.

6.3.4.4 Check that thermometers are calibrated against a NIST-traceable thermometer annually.

6.3.5 Supplies

6.3.5.1 Verify that all supplies needed for analyses are on hand in sufficient quantities and are stored properly.

6.3.5.2 Check that reagents are clearly labeled and that their expiration dates have not passed.

6.3.5.3 Check that glassware is clean and in good condition.

6.3.5.4 Check on availability of reagent water required for each type of analysis.

6.3.6 Facility

6.3.6.1 Verify that access to the laboratory is controlled.

6.3.6.2 Verify that there is effective separation between areas where activities are incompatible.

6.3.6.3 Determine whether work space and storage space are adequate for the tests conducted.

6.3.6.4 Verify that HVAC and lighting are adequate .

6.3.6.5 Determine whether work areas are safe and that adequate safety equipment is available.

6.3.6.6 Examine procedures for storage and disposal of chemical wastes.

6.3.6.7 Check that adequate fume hoods are available and working properly.

6.3.7 Sample Management

6.3.7.1 Identify the designated sample custodian.

6.3.7.2 Check that the integrity of samples has been maintained and documented.

6.3.7.2.1 Examine procedures for receipt, inspection, preservation and storage of samples.

6.3.7.2.2 Check that sample temperatures are recorded on arrival at the lab.

6.3.7.3 Check that holding times are routinely met and verify procedures for dealing with holding time exceedences.

6.3.8 Data Management

6.3.8.1 Check raw data, calculations, transcription and data entry procedures, and data reports.

Verify that final results can be calculated from the raw data for at least one analyte.

6.3.8.2 Check paginated logs are used in the laboratory.

6.3.8.2.1 Check that entries are in indelible ink and are dated and initialed.

6.3.8.2.2 Check that corrections are crossed out with a single line, dated and initialed.

6.3.8.3 Verify that records of standards preparation are maintained and can be traced to each sample batch for which they are used.

6.3.8.4 Review sample preparation records and bench sheets.

6.3.8.5 Review LIMS capabilities.

6.3.8.5.1 Identify the individual with primary responsibility for the LIMS.

6.3.8.5.2 Verify that a backup and recovery system is in place.

6.3.8.5.3 Verify that access to the LIMS is limited to essential personnel.

6.3.8.6 Verify that archival practices meet ELAP requirements.

Records should be maintained for at least five years.

6.3.8.7 Review equipment maintenance logs.

6.3.8.8 Verify that Method Detection Limits and Reporting Limits are documented and current.

6.3.9 Quality Control

6.3.9.1 Request and review selected records.

Verify that method blanks, check standards, analytical duplicates, matrix spikes/matrix spike duplicates, surrogates and internal standards are analyzed with each batch of samples as appropriate.

6.3.9.2 Ensure that PT samples are analyzed like routine samples and are not given special treatment.

6.3.10 Exit Briefing

6.3.10.1 Each assessor reviews findings and serious deficiencies.

6.3.10.2 Discuss time frame for corrective action.

6.3.10.3 Thank staff for hospitality and cooperation.

6.4 AUDIT REPORT

6.4.1 The audit report is completed within 30 days of the on-site visit.

6.4.2 Describe findings.

6.4.3 Discuss importance of each finding.

6.4.3 Recommend actions necessary to assure resolution of problems.

6.5 FOLLOW-UP

Verify implementation of recommendations in the audit report.

7. Records Management

7.1 Place copy of audit report in lab file along with revised scope, if necessary.

7.2 Retain copies of all checklists for DW procedures.

8. Quality Assurance

Audit reports are reviewed by LAU supervisor or delegate.

9. Safety

Follow all safety procedures required by the laboratory.

10. References

10.1 Chapter 173-50 WAC, "Accreditation of Environmental Laboratories,"

10.2 "Procedural Manual for the Environmental laboratory Accreditation Program," Ecology Publication No. 02-03-055, November 2002.

10.3 "Manual for the Certification of Laboratories Analyzing Drinking Water," 5th Ed., EPA Document 815-R-05-004, January 2005.

10.4 "MEMORANDUM OF UNDERSTANDING Between the Washington State Department of Health (WDOH) and the Washington State Department of Ecology (WDOE) Related to the MANAGEMENT AND IMPLEMENTATION OF THE WASHINGTON STATE LABORATORY CERTIFICATION PROGRAM FOR REGULATORY DRINKING WATER ANALYSES," DOH #N10804, 4/02.

Related SOPs

SOP for Accrediting Environmental Laboratories