GUIDANCE ON PREPARATION OF

LABORATORY QUALITY ASSURANCE PLANS

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U.S. ENVIRONMENTAL PROTECTION AGENCY

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This document is designed to provide guidance on the preparation of laboratory quality assurance plans. A laboratory QA plan needs to include some of the elements from both QAMS-004 Interim Guidance for the Preparation of QA Program Plans (1) and QAMS-005 Interim Guidance for the Preparation of QA Project Plans (2) plus some additional topics. It is expected that laboratories that prepare a QA plan following this guidance will produce a plan that will cover all their operations and therefore would not produce "project specific" laboratory QA plans unless required. It is assumed that most laboratories operate at some specified level, i.e., parameter specific quantitation limits for a majority of their work. The laboratory may do work on specific projects that may require lower quantitation limits or tighter precision or accuracy goals than the lab's normal operating basis; only in these cases would project specific QA plans be required for those parameters that are not covered by normal laboratory operations. The laboratory QA plan is designed to be written to cover a single lab operating at a single location.

This guidance document is designed to be generic in nature so that all types of labs may follow it. This would include analytical chemistry labs, geotechnical service labs and other lab facilities. It is designed to include a statement of QA policy, organizational structure, facility layout and equipment, personnel qualifications, and QA/QC.

The minimum elements of the lab QA plan would include:

1. Title Page
2. Table of Contents
3. Quality Assurance Policy Statement
4. Corporate Ethics Policy on Waste, Fraud, and Abuse
5. Quality Assurance Management
6. Administrative Organization
7. Personnel Qualifications
8. Facility Description and Capital Equipment
9. Preventive Maintenance
10. Corrective Action
11. Laboratory Evaluation and Audits
12. Quality Assurance Reports to Management
13. Lab Documentation and Forms
14. Sub-Contracting of Services
15. Standard Operating Procedures
16. Laboratory Personnel Training Record

The content expected in each section is briefly described below. The lab QA plan will be prepared in document control format. This will consist of revision, date and page number on each page of the document.

1. Title Page

The title page will include the name and address of the lab, and dated signature approval lines for the company's management, lab director, QA director and other chief officers. A separate dated signature page may be used if necessary. The lab QA plan will be signed by the chief officers to concur with the contents of the lab QA plan and to show their commitment to provide the resources necessary to ensure proper quality operation of the lab facility. A suggested title page format is shown in Figure 1.

Laboratory Quality Assurance Plan

For

Laboratory Name

Street Address

City, State ZIP Code

Phone Number

Revision

Date

Approvals:

Name:_____
Title:_____
Signature:_____ Date:_____

Name:_____
Title:_____
Signature:_____ Date:_____

Name:_____
Title:_____
Signature:_____ Date:_____

Figure 1 - Example Title Page

2. Table of Contents

The table of contents will address each of the following elements:

Introduction - optional.

A serial listing of all the elements for a laboratory QA plan.

A listing of any appendices which are required to augment the laboratory QA plan, it is suggested that all operational Standard Operating Procedures (SOPs) be included as appendices and organized in some manner that is convenient for the laboratory to distribute.

3. Quality Assurance Policy Statement

The policy statement in this section should describe the QA goals of the laboratory and describe, in general terms, the laboratory's commitment to ensure data are of known and documented quality.

The policy statement reflects management's commitment to QA throughout the data generating and processing operations. All reported data must be accompanied by a calculation of precision and accuracy. Where appropriate, a statement on the completeness, representativeness and comparability is to be included.

4. Corporate Ethics Policy on Waste, Fraud, and Abuse

A statement on/or the laboratory's policy on improper manipulation, falsification of data, or deviations from contractual requirements shall be included. The policy shall state how the laboratory will handle such activities and any punitive measures the lab will take towards employees engaging in such activities.

If data is generated for, or by, any department, agency, or entity of the federal government, then the appropriate department's Inspector General telephone numbers shall be included with instructions to report any allegations of fraud, waste or abuse occurring on government projects.

The laboratory shall post it's ethics policy in a prominent place and shall include its' policy in all Standard Operating Procedures.

5. Quality Assurance Management

The direct and ultimate responsibility for assuring data quality rests with the line manager (e.g., CEO, lab director, etc), not the quality assurance officer (QAO). In delegating QA responsibilities/authorities, line managers usually divide their delegations between their subordinate line managers. The QAO is there to provide technical support and to review and approve QA products.

This section should contain a description of the organizational entities involved in data collection activities. An organizational chart showing reporting lines should be provided and those specific groups responsible for data collection or for QA/QC activities should be identified and their inter-relationship defined. The responsibility/authority for carrying out the QA of each group should be described in a way which clarifies the nature of and

division of these delegations.

While it is typical for the laboratory analyst to provide the first level of data review in the laboratory, there should be an independent reporting channel for quality assurance/control of data. Thus if a problem arises, corrective action may be taken through normal administrative reporting channels. If the problem is not addressed, then an alternative channel for problem resolution exists outside of the normal administrative reporting/supervisory channels.

6. Administrative Organization

This section will cover the normal administrative reporting/ responsibilities of the laboratory. It will most likely be different than the QA Management reporting structure, but should show how and where QA management reports to the administrative management structure. QA management should be able to independently report to the administrative management.

This section will cover the duties and responsibilities of the key section heads in the lab and will include an organizational chart showing lines of authority and reporting responsibilities.

7. Personnel Qualifications

A brief listing of personnel should be included. This would include name, title, degree(s), years of experience and duties. This should be brief and detailed resumes are not expected but could be included at the labs option.

It is expected that personnel occupying certain positions would meet the minimal education and experience requirements stated in the Manual for the Certification of Laboratories Analyzing Drinking Water (3), EPA's Contract Laboratory Program Statements of Work for Inorganic or Organic Analyses (4,5), or in any applicable regulatory requirements for those positions.

Qualifications have been established for work performed under Agency contracts and Programs and are included in Appendix A of this guidance.

8. Facility Description and Capital Equipment

This section will have a brief description of the lab facility and layout. Key support services for proper lab operation should be identified, i.e., deionized water supply system, ventilation systems, working space, equipment and sample storage areas, etc.

A list of laboratory capital equipment at the site should be included. This would include such items as: GC/MS, GCs, AAs, ICP, etc. If the lab instruments have computer data systems then a listing should be included giving details on the software and revision being used for data acquisition or manipulation.

Information to be included is type of instruments (GC, GC/MS, AA, GFAA, etc.), manufacturer and model number, date of acquisition (year), and if applicable, software and revision used to control instrument or data acquisition and reduction. An example format for the capital instrument inventory is given in Figure 2.

Instrument Inventory

Make	Model	Type	Software /Revision	Identifier	Date Installed

Type = GC, GC/MS, ICP, GFAA, AA, etc.
Identifier = Lab specific instrument identifier where multiple instruments are involved.

Figure 2 - Example layout for an instrument inventory.

9. Preventive Maintenance

This section should include a schedule of specific routine maintenance to be performed on capital equipment and lab support systems. A list of critical spare parts should also be included.

10. Corrective Action

A corrective action program, which must have the capability to deal with errors or defects at any point in the generation of data, is an essential management tool for quality assurance/ quality control activities.

A plausible corrective action scheme must be designed to identify defects, tally defects, trace defects to their source, plan and implement measures to correct identified defects, maintain documentation of the results of the corrective process until each defect is eliminated. This may be accomplished through the use of corrective action forms.

This section should cover general corrective action procedures to be followed if lab QA/QC criteria are not met for an analysis or project.

11. Laboratory Evaluation and Audits

Management System Reviews (MSRs) are on-site audits of an organization used to verify the existence and to evaluate the adequacy of internal management systems and documents necessary for the implementation of a QA program. The primary purpose of a QA management audit is to determine the extent to which QA is being implemented within an organization and to recommend actions which are necessary to correct deficiencies.

Technical System Audits (TSAs) focus on the actual quality control and environmental data collection systems. A TSA entails an examination of calibration records, sampling and measurement procedures, general laboratory cleanliness, support systems, equipment and facilities, maintenance and repair records, control charts, etc. TSA auditors must be competent scientists who are familiar with the particular technology and quality control procedures.

A Performance Evaluation (PE) is the means of evaluating the performance of laboratory technicians and the instrumentation or analytical systems on which they work. A PE audit is accomplished by providing PE samples containing specific pollutants (in appropriate matrix) unknown to the technician in their concentration and/or identity.

Data Quality Audits (DQAs) are an evaluation of the documentation associated with data quality indicators of measurement data to verify that the data are of known quality. The primary purpose of this type of audit is to verify the availability of quantitative and qualitative indicators of data quality. Availability of data quality indicators depends upon the proper collection, interpretation, and reporting of information required to characterize the quality of data.

This section will detail the types and frequency of all performance and system audits to be performed in the laboratory on a routine basis. Certain projects may specify more frequent audits and if this occurs can be addressed on a project by project basis.

12. Quality Assurance Reports to Management

This section will discuss the periodic reports to be sent to management as a result of any audits or ongoing QC sample analysis. It should also discuss the mechanism used to follow up on any corrective actions needed as the result of an audit or continuing QC problems. This may be accomplished through periodic reports to management using an established schedule of reports.

It is recommended that the Laboratory QA Plan be reviewed and updated, if necessary, on an annual basis. This annual review may be accomplished through the use of a Management System Review.

13. Lab Documentation and Forms

This section should have copies of all the routinely used forms in the lab. Document control procedures should be discussed to explain how new forms are generated and documented and how new forms supersede older forms.

14. Sub-Contracting of Services

Because many labs will sub-contract out services they cannot perform on a large project, this section will discuss the general requirements for determining when and how such sub-contracting will be done. This should include selection of a sub-contractor, requirements to be imposed on the sub-contractor (such as having a QA plan), audit requirements, etc.

It should be noted that there are severe limitations on sub-contracting of services with EPA Contract Laboratory Program samples.

15. Standard Operating Procedures

Standard Operating Procedures (SOPs) are to be available for all routinely used sampling or analytical laboratory methods. The Laboratory must maintain a log of all SOPs in use and must maintain a file of all revisions of SOPs used in the past. A current list of all SOPs and revision number and date must be appended to the Laboratory QA Plan. All such methods shall be documented in detail. Generally, simply citing a published method is not adequate for a SOP. Published methods rarely have all the procedural details, and those that do generally have to be modified for the applications or facilities at hand. Suggested references for the format of SOPs are included in the reference section of this document (6, 8). These SOPs shall be prepared in document control format.

As a minimum the following items should be included:

* Title Page
* Scope and Applications
* Definitions
* Procedures
* QC Limits
* Corrective action Procedures, Including Procedures for Secondary Review of Information Being Generated
* Documentation Description and Example Forms
* Miscellaneous Notes and Precautions

* References

At times certain SOPs may not cover all the above elements, especially administrative type SOPs. In that case some other format and elements should be developed to properly address the purpose of documenting the procedure covered by the SOP. SOPs shall be located in an accessible place(s) and copies shall be available to all personnel needing them to perform their duties.

Once prepared, these SOPS would only have to be included in QA project plans by reference, after being subjected to prior review and approval.

This section will be quite flexible and will include all the lab's SOPs for all its' routine operating and analytical procedures. The following is a list of possible SOPs and should not be considered to be all inclusive:

1. Evidentiary SOPs

    1.1 Sample Identification
    1.2 Chain of Custody
    1.3 Sample Receiving
    1.4 Sample Tracking
    1.5 Laboratory Notebook Issuance and Correction Procedures (9)
    1.6 Document Numbering, Inventory and Storage

2. Sample Receipt and Storage

    2.1 Sample Custody Procedure
    2.2 Sample Identification Logbooks
    2.3 Refrigerator Temperature Logbooks
    2.4 Extract Storage Logbooks
    2.5 Security Precautions

3. Sample Preparation

    3.1 Reagent Purity Check Procedures and Documentation
    3.2 Extraction Procedure
    3.3 Extraction Bench Sheets
    3.4 Extraction Logbook Maintenance

4. Glassware Cleaning

    4.1 Organic Analysis Glassware Cleaning
    4.2 Inorganic Analysis Glassware Cleaning
    4.3 Sample Container Cleaning (if applicable)

5. Calibration (Balances)

    5.1 Procedures
    5.2 Frequency Requirements
    5.3 Acceptance Criteria and Corrective Actions
    5.4 Logbook Maintenance

6. Analytical Procedures (for each analytical System)

    6.1 Instrument Performance Specifications
    6.2 Instrumental Operating Conditions

- 6.3 Data Acquisition System Operation
- 6.4 Procedures When Automatic Quantitation Algorithms Are Overridden
- 6.5 QC Required Parameters
- 6.6 Analytical Run/Injection Logbooks
- 6.7 Instrumental Error Flag Descriptions and Resulting Corrective Actions

7. Maintenance Activities (for each Analytical System)

- 7.1 Preventive Maintenance Schedule and Procedures
- 7.2 Corrective Maintenance Determination and Procedures
- 7.3 Maintenance Authorization
- 7.4 Maintenance Procedures should be included for instrumentation and lab support systems, such as distilled water, hoods, gas supplies, etc.

8. Analytical Standards

- 8.1 Standard Coding/Identification and Inventory System
- 8.2 Standards Preparation Logbook(s)
- 8.3 Standards Preparation Procedures
- 8.4 Procedures for Equivalency and Traceability Analyses and Documentation
- 8.5 Purity Logbook (Primary Standards and Solvents)
- 8.6 Storage, Replacement, and Labeling Requirements
- 8.7 QC and Corrective Action Measures

9. Data Reduction Procedures

- 9.1 Data Processing Systems Operation
- 9.2 Outlier Identification Methods
- 9.3 Identification of Data Requiring Corrective Action
- 9.4 Reporting Format and/or Forms for Each Operation

10. Documentation Policy/Procedures

- 10.1 Laboratory/Analyst's Notebook Policy, including Review Policy
- 10.2 Organization and Storage Procedures for Raw Data and Reports
- 10.3 Data Inventory Procedures, including Review Policy

11. Data Validation/ Self Inspection Procedures

- 11.1 Data Flow and Chain of Command for Data Review
- 11.2 Procedures for Measuring Precision and Accuracy
- 11.3 Evaluation Parameters for Identifying Systematic Errors
- 11.4 Procedures to Assure that Hardcopy and Electronic Deliverables are Complete and Compliant with Client Requirements
- 11.5 Procedures to Assure that Hardcopy Deliverables are in Agreement With Electronic Deliverables
- 11.6 Demonstration of Internal QA Inspection Procedures (demonstrated by supervisory sign-off of personal notebooks, internal PE samples, etc.)
- 11.7 Frequency and types of internal audits (e.g., random,

quarterly, spot checks, perceived trouble areas)

11.8 Demonstration of problem identification-corrective actions and resumption of analytical processing, Sequence resulting from internal audit (i.e., QA feedback).

11.9 Documentation of audit reports (internal and external), audit responses, corrective actions, etc.

12. Data Management and Handling

12.1 Procedures for controlling and estimating data entry errors.

12.2 Procedures for reviewing changes for data and deliverables and ensuring traceability of updates.

12.3 Lifecycle management procedures for testing, modifying, and implementing changes to existing computing systems including hardware, software, and documentation or installing new systems.

12.4 Database security, backup, and archival procedures including recovery from system failure.

12.5 System maintenance procedures and response times.

12.6 Individual(s) responsible for system operation, maintenance, data integrity and security.

12.7 Specifications for staff training procedures.

13. Quality Assurance and Quality Control

13.1 Frequency and types of QC samples used in analysis methods.

13.2 Frequency and types of QC samples taken to determine performance of lab support facilities, i.e., deionized water supplies, etc.

13.3 Use of control charts or other data analysis procedures to evaluate analytical method quality control information.

13.4 Corrective action procedures to be taken when QC information indicates a problem or deviation.

16. Laboratory Personnel Training Record

The laboratory shall develop and document procedures for training each analyst in all methods that each analyst is conducting. The training method and period shall be documented in an SOP(s). Training records shall be maintained by the laboratory for each analyst. At a minimum, the records shall include the analyst's name, the method(s) and date(s) for which the analyst has completed training, the person(s) (supervisor) certifying completion of each training session, the date(s) recertification training is needed and the date(s) recertification was completed (if appropriate). Only analysts who have completed training may conduct analytical methods independently. An analyst in training must be directly supervised by an analyst who has completed training.

The training record may also include additional educational courses, professional seminars attended, in-house training courses, etc.

References

1. EPA-600/8-83-024, Guidelines and Specifications for Preparing Quality Assurance Program Plans, QAMS-004/80, EPA, June 1983.

2. Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans, QAMS-005/80, EPA, December 29, 1980.

3. EPA/570/9-90/008, Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance, 3rd Ed., EPA, April 1990.

4. U.S. EPA Contract Laboratory Program Statement of Work for Inorganic Analysis, Multi-Media Multi-Concentration, Document Number ILM01.0.

5. U.S. EPA Contract Laboratory Program Statement of Work for Organic Analysis, Multi-Media Multi-Concentration, Document Number OLM01.0.

6. Dux, James P., Handbook of Quality Assurance For The Analytical Chemistry Laboratory, Van Nostrand Reinhold Company (New York), 1986.

7. Taylor, John Keenan, Quality Assurance of Chemical Measurements, Lewis Publishers, 1987.

8. EPA-600/4-82-057, Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater, EPA, July 1982.

9. Kanare, Howard M., Writing the Laboratory Notebook, American Chemical Society, Washington, D.C., 1985.

Appendix A-Personnel Qualifications

The following qualifications have been established for work performed under Agency contracts or Programs and are recommended for equivalent positions and work.

Inorganic Laboratory Supervisor

Education: Minimum of a Bachelor's degree in chemistry or any scientific/engineering discipline.

Experience: Minimum of three years of laboratory experience, including at least one year in a supervisory position.

Quality Assurance Officer

Education: Minimum of a Bachelor's degree in chemistry or any scientific/engineering discipline.

Experience: Minimum of three years of laboratory experience, including at least one year of applied experience with QA principles and practices in an analytical laboratory.

Systems Manager

Education: Minimum of a Bachelor's degree with four or more intermediate courses in programming, information management, database management systems, or systems requirements analysis.

Experience: Minimum of three years of experience in data or systems management or programming including one year experience with software being utilized for data management and generation of deliverables.

Programmer Analyst

Education: Minimum of a Bachelor's degree with four or more intermediate courses in programming, information management, database management systems, or systems requirements analysis.

Experience: Minimum of two years of experience in systems or application programming including one year experience with software being utilized for data management and generation of deliverables.

ICP Spectroscopist

Education: Minimum of a Bachelor's degree in chemistry or any scientific/engineering discipline. Specialized training in ICP spectroscopy.

Experience: Minimum of two years of applied experience with ICP analysis of environmental samples.

ICP Operator

Education: Minimum of a Bachelor's degree in chemistry or any scientific/engineering discipline with one year of experience in operating or maintaining ICP instrumentation, or, in lieu of the

educational requirement, three additional years of experience in operating and maintaining ICP instrumentation.

Atomic Absorption Operator

Education: Minimum of a Bachelor's degree in chemistry or any scientific/engineering discipline with one year of experience in operating or maintaining AA instrumentation, or, in lieu of the educational requirement, three additional years of experience in operating and maintaining AA instrumentation, including graphite furnace, flame, and cold vapor techniques.

Inorganic Sample Preparation Specialist

Education: Minimum of a high school diploma and a college level course in general chemistry or equivalent.

Experience: Minimum of one year of experience in sample preparation in an analytical laboratory. If microwave digestions are performed an additional six months of experience with microwave digestions is required.

Classical Techniques Analysts

Education: Minimum of a Bachelor's degree in chemistry or any scientific/engineering discipline.

Experience: Minimum of one year experience with classical chemistry laboratory procedures, in conjunction with the educational qualifications; or, in lieu of educational requirement, two years of additional equivalent experience.

GC/MS Laboratory Supervisor

Education: Minimum of a Bachelor's degree in chemistry or any scientific/engineering discipline.

Experience: Minimum of three years of laboratory experience, including at least one year in a supervisory position.

GC/EC Laboratory Supervisor

Education: Minimum of a Bachelor's degree in chemistry or any scientific/engineering discipline.

Experience: Minimum of three years of laboratory experience, including at least one year in a supervisory position.

Sample Preparation Laboratory Supervisor

Education: Minimum of a Bachelor's degree in chemistry or any scientific/engineering discipline.

Experience: Minimum of three years of laboratory experience, including at least one year in a supervisory position.

GC/MS Operator

Education: Minimum of a Bachelor's degree in chemistry or any scientific/engineering discipline. Training courses in mass spectral interpretation.

Experience: Minimum of two years of experience in mass spectral interpretation.

GC/EC Operator

Education: Minimum of a Bachelor's degree in chemistry or any scientific/engineering discipline.

Experience: Minimum of one year of experience in operating and maintaining GC/EC with a Bachelor's degree or, in lieu of the Bachelor's degree, three years of experience in operating and maintaining the GC/EC and interpreting GC/EC data.

Pesticide Residue Analysis Expert

Education: Minimum of a Bachelor's degree in chemistry or any scientific/engineering discipline.

Experience: Minimum of two years of experience in operating and maintaining GC and interpreting GC chromatograms.

Extraction/Concentration Expert

Education: Minimum of a high school diploma and a college level course in general chemistry or equivalent.

Experience: Minimum of one year of experience in sample extraction/concentration.

Microbiology Supervisor

Education: Minimum of a Bachelor's degree in science.

Experience: Minimum of two weeks training from a Federal agency, state agency, or academic institution in microbiological analysis of drinking water.

Microbiology Analyst

Education: Minimum of a high school education. Training in microbiological analysis of drinking water, acceptable to the state (or EPA for nonprimacy states), plus a minimum of 30 days on-the-job training.

Experience: At least one year of bench experience in sanitary, water, milk, or food microbiology.

Radiochemistry Supervisor

Education: Minimum of a Bachelor's degree, or its equivalent.

Experience: Minimum of five years of experience.

Radiochemistry Analyst

Education: Minimum of a Bachelor's degree in chemistry, radiochemistry, radioisotope technology, or equivalent.

Experience: Minimum of one year of appropriate experience in radiation measurements and radiochemical procedures.

Radiochemistry Technician

Education: Minimum of a high school diploma or its equivalent, plus specialized training in standards and sample preparation, instrument calibration, calculations, and data handling.

Experience: Minimum of six months on-the-job.